

European Food Safety Authority



Peer Review Report on Chloropicrin (NAS)

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January 2020

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Comments on the draft assessment report on chloropicrin (NAS)

RMS UK
Co-RMS IT

End of commenting period: 22.04.2018 (MS; APPL; EFSA)

Date	Supplier	File
19.04.2018	PUBLIC French Chambers of Agriculture (AFCA)	01 chloropicrin_comments on DAR_PUBLIC (AFCA)_2018-04-19.pdf
19.04.2018	Germany	02 chloropicrin_comments on DAR_DE_2018-04-19.doc
19.04.2018	Ireland	03 chloropicrin_comments on DAR_IE_2018-04-19.doc
19.04.2018	The Netherlands	04 chloropicrin_comments on DAR_NL_2018-04-19.doc
20.04.2018	Austria	05 chloropicrin_comments on DAR_AT_2018-04-20.doc
20.04.2018	France	06 chloropicrin_comments on DAR_FR_2018-04-20.doc
20.04.2018	EFSA	07 chloropicrin_comments on DAR_EFSA_2018-04-20.doc
20.04.2018	APPLICANT European Chloropicrin Group c/o TSGE Ltd.	08 chloropicrin_comments on DAR_APPL_2018-04-25.doc
22.04.2018	Greece	09 chloropicrin_comments on DAR_EL_2018-04-22.doc

Comments of French Chambers of Agriculture (AFCA) on the draft/assessment report on chloropicrin (20.04.2018) 1/17

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

(1)			
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Identity (B.1, Annex C)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Physical and chemical properties of the active substance (B.2.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Further information (B.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume B Section 3.3 Details of Intended Use	We support the use on tree crops as reflected in the supported uses for chloropicrin. Apple replant disease is a particular concern for horticultural	

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Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Further information (B.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		cropping in France. This disease has limited the replanting of apple trees in many situations and is an important factor resulting in a decline in cropped area. The availability of chloropicrin, used under properly regulated conditions, would help to restore the competitiveness of French and, more generally, European horticulture. Use would be on limited areas and, as indicated by the applicant, no more than 1 year in 15 with consequent minimal impact on the environment.	
	B 3.5 Method of application	We support the conditions set out in this section to minimise human and environmental exposure. The use of specialist application equipment and trained operators is supported. We consider that this ensures that there a strong stewardship process in place which ensures compliance with any necessary measures to minimise exposure and risk resulting from chloropicrin use.	

Methods of analysis (B.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Effectiveness against target organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Effectiveness against target organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume B Section B.3.9 Effectiveness	We note that chloropicrin was widely authorised prior to 2011 and emergency authorisations have been granted since that time. Use against specific apple replant disease was effective and allowed successful replanting. The causes of replant disease are complex causes by a range of factors including a build-up of soil pathogenic organisms that can be effectively suppressed by chloropicrin. Effectiveness for replant disease can be demonstrated in support of product registrations. A single use can allow replanting without detrimental long-term effects as treatments are not repeated during the life of the crop. Currently there are no suitable effective alternatives.	

Occurrence of Resistance, Effects on quality/Processes/Yield/Phytotoxicity/Succeeding and Adjacent crops/Plants for propagation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1. Overall comment Level 3	We consider that in order to maintain competitiveness European horticulture access to a suitable range of soil fumigants is required. It is noted that by their very nature these substances will	

Comments of French Chambers of Agriculture (AFCA) on the draft/assessment report on chloropicrin (20.04.2018) 4/17

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>have effects on non-target organisms however as indicated in the overall summary these effects are limited in extent and duration. This is especially the case for the use for apple replant disease.</p> <p>Uncertainties identified can be resolved taking into account national conditions and use situations with if necessary additional information and national measures to minimise impacts on non-target organisms.</p>	

Comments of French Chambers of Agriculture (AFCA) on the draft/assessment report on chloropicrin (20.04.2018) 5/17

Section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Acute toxicity (B.6.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Short-term toxicity (B.6.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Genotoxicity (B.6.4)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Long-term toxicity and carcinogenicity (B.6.5)			

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Section 2 - Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Reproductive toxicity (B.6.6)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Neurotoxicity (B.6.7)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Other toxicological studies & Medical data (B.6.8-B.6.9)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 2 - Mammalian toxicology (B.6)

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.6.13	The conclusion indicates eye irritation is the most sensitive measure against which to consider applicator exposure and exposure to others. This appears a logical basis for the assessment to protect humans. We have commented on the assessment below.	

Toxicity of the product(s) (B.6.11)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Dermal absorption (B.6.12)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Toxicity of non-active substances (B.6.13)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 2 - Mammalian toxicology (B.6)

Exposure data (B.6.14)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.6.15	The assessment sets standards (PPE/RPE and other requirements) to protect users and these are supported. These are the responsibility of the specialised applicators and compliance can be expected. The exposure to others can be managed during the period of application and the necessary 50 m zone can be implemented in site specific considerations by the applicators supported by the farmer. Given the nature of the application with trained professionals we consider the proposed measures can be put in place on the farm to allow safe use.	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 3 - Residues (B.7)

3. Residues (B.7)

Storage Stability (B.7.0)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Metabolism in plants (B.7.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Metabolism in livestock (B.7.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Residue definition (B.7.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			

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Section 3 - Residues (B.7)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1 Section 2.7.4	We note that the residue trials result in no detectable residues being present in the horticultural crops for which studies have been conducted. For use on apples and other tree crops no trials have been submitted however we support the conclusion reached that, because of the duration of several years between planting and cropping, no residues will occur in apples and other similar tree crops by logical extrapolation from the results of the submitted trials. We seek confirmation that no specific residue trials will be necessary to support chloropicrin use on tree crops.	

Processing (B.7.7)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Livestock feeding (B.7.8)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Succeeding/Rotational crops (B.7.9)

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Section 3 - Residues (B.7)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.7.9 and 2.7.10	We agree with the conclusion that consumers will not be exposed to residues in apples from the proposed use and that there is no consumer risk. We support the conclusion that MRLs will not be exceeded from use in apples and other crops.	

Other comments

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 4 - Environmental fate and behaviour (B.8)

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Adsorption, desorption and mobility in soil (B.8.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

PEC in soil (B.8.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

PEC in surface water and ground water (B.8.6)			

Comments of French Chambers of Agriculture (AFCA) on the draft/assessment report on chloropicrin (20.04.2018) 13/17

Section 4 - Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.8.6.3 Groundwater	We are committed to the protection of groundwater and water courses from the use of pesticides. The pattern modelled for tree crops was 1 year in 3 however for these crops application is no more than 1 year in 15. Consideration should be given to this specific use pattern. We note that assessment questions whether the exposure values that have been calculated are reliable because of the volatility of chloropicrin. If this is the case then this should be specifically considered for chloropicrin so that a more reliable assessment can be conducted without overestimating exposure resulting from use. We expect this can also be further refined taking into account national situations for use in Member States.	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Definition of the residues (B.8.9)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 4 - Environmental fate and behaviour (B.8)

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Overall conclusion	The specific use on apples will be made to limited areas of the overall cropped area where there is a specific need to treat for replant disease. Use will not be on a large scale and limited to no more than 1 application in 15 years or longer. This is an important factor of the specific use which will minimise environmental exposure.	

Comments of French Chambers of Agriculture (AFCA) on the draft/assessment report on chloropicrin (20.04.2018) 15/17

Section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment	As mentioned previously, the specific use on apples will be made to limited areas of the overall cropped area where there is a specific need to treat for replant disease. Use will not be on a large scale and limited to no more than 1 application in 15 years or longer. Effects on birds and mammals are expected to be minimised by such use. Long term exposure is not expected in such situations and this is indicated by the measured values which do not support a significant duration of exposure.	

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to aquatic organisms	As mentioned above, the specific use on apples will be made to limited areas of the overall cropped area where there is a specific need to treat for replant disease. Use will not be on a large scale and limited to no more than 1 application in 15 years or longer. Long-term effects on aquatic are expected to be minimised by such use. Long term exposure is not expected in such situations.	

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Section 5 - Ecotoxicology (B.9)

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to bees	We acknowledge the importance of ensuring protection of bees. This is essential. The application is made to limited situations when no crop is present. We support the assessment conducted and note that the risk is considered acceptable. We note the possible need to remove bee hives during application and tarp removal. Bee hives are very unlikely to be present during this period however any necessary mitigation measures will be adhered to ensure safety to bees.	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to earthworms and other soil macro-organisms	We note there is a concern about earthworm populations recovering following treatment. It appears that the effects of treatment do not persist more than 100 days but more information is required to demonstrate full recovery. This is a factor for all soil fumigants which by their nature will reduce populations in treated areas. In line with other fumigants we consider this can be demonstrated with further data to support product registration. The treated areas are limited and as stated treatment to tree crops will not exceed 1 year in 15 – long-term effects are not expected and can be demonstrated	

Comments of French Chambers of Agriculture (AFCA) on the draft/assessment report on chloropicrin (20.04.2018) 17/17

Section 5 - Ecotoxicology (B.9)

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		with further information. It should also be noted that in some circumstances strip application in fields may be applied to treat the specific areas to be planted therefore providing in-field untreated areas which will aid recovery.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to non-target plants	We note it is concluded there is uncertainty about exposure of non-target plants. Chloropicrin has been used for many years in areas of intensive horticulture and our understanding is that damage to surrounding horticultural crops following treatment is not seen. Given the potential value of surrounding crops this would have been noted. We consider any concern can be addressed with additional information but there is no evidence from practical usage situations of damage or adverse effects on neighbouring plants.	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Comments of Germany on the draft assessment report on chloropicrin

(19.04.2018) 1/24

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Data on application and efficacy			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 – B.3, B.3.3, Details of intended use	DE: The indicated application rate per treatment for both products and for all proposed uses is specified as 188-376 kg as/ha. Please define when it is necessary to use the lower and the higher application rate.	
(2)	Vol. 3 – B.3, Appendix 1	DE: In the tabular summary of published efficacy trials only 2 references refer to nematodes as target pest. One of these references presents results of trials on pine nursery production. This cannot be extrapolated to the proposed uses.	
(3)	Vol. 3 – B.3, in general	DE: There are no details given to the nematode species to be controlled by chloropicrin. According to the study of Lopez-Aranda et al. (2009) there are differences in the susceptibility of different nematode species to chloropicrin. It seems to be less effective at controlling <i>Pratylenchus</i> spp.	

Further information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.4, packaging and procedures for cleaning application equipment	DE: Information for packaging and procedures for cleaning application equipment is missing.	

Comments of Germany on the draft assessment report on chloropicrin

(19.04.2018) 2/24

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.13.2 and list of end points	DE: The residue definitions for monitoring for the environmental matrices given in Vol. 1 differ from the information in the list of end points. Please align.	
(2)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: The analytical method for plant commodities with high water content is not acceptable. The LOQ of the primary method is not sufficiently low for the currently valid MRL of 0.005 mg/kg for commodities with high water content and the ILV is not acceptable due to significant modifications of the method. This is a data gap.	
(3)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: We support the data requirement for an analytical method for plant commodities with high fat content.	
(4)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: In the SANCO/825/00 rev. 8.1 guidance document it is stated that analytical methods for the 4 plant commodities should be submitted. An analytical method for dry crops is missing and should be provided. This is a data gap.	
(5)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: An ILV for the analytical method for drinking water is missing but required according to Regulation (EU) No. 283/2013. This is a data gap.	

Section 2 – Effects on human and animal health

2. Effects on human and animal health

Acute toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.2.1, Acute oral toxicity	<p>DE: On one hand, it is stated that no studies have been submitted. On the other hand, an LD₅₀ of 250 mg/kg bw is mentioned, referring to the "Pesticide manual". Is there any indication where this information might come from and how reliable it is? The proposed classification into category 3 is supported but only on condition that the basis is reliable.</p> <p>Otherwise, a firm conclusion on classification for acute oral toxicity cannot be drawn. Formally, a data gap should be set. However, since further animal testing with this very toxic substance should be avoided and because of its high volatility, acute toxicity should be assessed solely on the basis of the inhalation experiments.</p>	
(2)	Vol. 3, B.6.2.1, Acute oral toxicity	<p>DE: A high acute oral toxicity to rats is also likely when the death rate in the published 10-day study in SD rats with gavage application (see B.6.3.2.2) is taken into consideration even though the exact time of death was not reported. And what about using the micronucleus assay in mice (████████, 2003, See B.6.4.2.1) as an alternative source of information even though the post-observation period, of course, was too short? Is there any information on unscheduled deaths within the 24 or 48 hours in this study?</p>	

Comments of Germany on the draft assessment report on chloropicrin

(19.04.2018) 4/24

Section 2 – Effects on human and animal health

Acute toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol. 3, B.6.2.4, Skin irritation; B.6.2.5, Eye irritation	DE: Taking into account the brief justifications given to explain that, in the absence of specific studies, classification is needed, we do not understand why, in both cases, category 2 is assigned but not category 1. Please clarify!	
(4)	Vol. 3, B.6.2, Summary of acute toxicity, including irritancy and sensitisation, studies	DE: Is respiratory depression part of the likely mode of action resulting in the very high inhalative toxicity? If so, the proposal STOT-SE would mean a double classification for the same effect.	

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.4, Exposure data (maximum air concentrations)	DE: For shank application, the surface area treated in the available studies ranged from 7500 to 9200 m ² . Therefore, acceptable application should be restricted to less than 1 ha.	
(2)	Vol. 3, B.6.4, Exposure data (maximum air concentrations)	DE: Please, specify whether measured concentrations in the studies for operators and bystanders were weighted averages over one hour of exposure, maximum concentrations during exposure or total concentrations collected over the entire duration of the task and thus related to the duration of worker exposure.	In case peak or cumulative exposure is not reported, exposure estimation might not be conservative enough.

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.6.4, Exposure data (maximum air concentrations)	DE: The measured maximum air concentrations during shank application as depicted in Table 34 are not congruent with those listed in Section 8, Table B.8.8-1. Please, specify which values are correct.	
(4)	Vol. 3, B.6.4, Exposure data (operator)	DE: We do not consider it practicable to work with power-assisted RPE for several hours, especially when conducting labour-intensive tasks, such as cutting and sheeting removal.	As specified by the RMS, operators need to wear power-assisted RPE during all tasks for the entire working day to reduce exposure to an acceptable amount. Based on the low number of sampling stations and the high variability of the measured air concentrations at 1 and 50 m, any person within a range of 50 m should wear power-assisted RPE (ensuring the required reduction of exposure by 97.5 %).
(5)	Vol. 3, B.6.4, Exposure data (bystander)	DE: We share the RMS' concerns that substantial uncertainty remains with regard to the capturing of bystander peak concentrations and the potential underestimation of child exposure. With regard to the high acute toxicity of chloropicrin, the level of remaining uncertainty might be too high to conclude a safe use.	<p>It must be ensured that the cover remains intact throughout the entire time and that it cannot be impaired, for example by animals or harsh weather. This is especially important as a report of chloropicrin application in the US (see B.6.6, References relied on), where no cover was used, details the occurrence of chloropicrin poisoning at a four times lower application rate. The majority of the >300 reported health effect cases were non-occupational.</p> <p>Moreover, a safety zone of 50 m around treated surfaces is not likely to be feasible in Germany, as fields are often situated close to habited or recreational areas.</p> <p>Additionally, as discussed by the RMS, weather conditions and wind directions are critical to assess peak concentrations. The provided data is not sufficient to guarantee that the highest concentrations were detected by the available samplers, of which only one was situated at each distance for each direction.</p> <p>Finally, there is a high variability in the reported maximum air concentrations measured at 1 m and 50 m distance from the application site (see Table 34). Only two values were provided for determining that</p>

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
			<p>safe exposure can be guaranteed for residents and bystanders at 50 m from the application site. Of those two values, one is well within the range of reported values at 1 m distance.</p> <p>In conclusion, unconcerned persons may not be safe at a distance of only 50 m from the application site and power-assisted RPE should also be worn by any person within at least a 50 m range of the application site.</p>
(6)	Vol. 3, B.6.4, Exposure data (bystander)	DE: In the absence of appropriate data, the RMS modelled bystander short-term exposure by applying the CALMET/CALPUFF model with refined assessment factors adjusting for model uncertainty.	<p>With regard to the severe toxicity of the active ingredient and the known occurrence of adverse health effects, scenario specific data must be provided to proof the lack of risk for residents and bystanders, as no appropriate model is available.</p> <p>In the absence of data, the RMS provided a detailed expert review of the relevance and reliability of the CALMET/CALPUFF model to the situation to be assessed. The concluded additional scaling factors address the model shortcomings, but lead to AOEC exceedance.</p> <p>Therefore, a second refinement using power law estimation was conducted. The reliability of this refinement cannot be assessed, as the assumed relationship between short- and long-term concentrations has not been demonstrated for chloropicrin and the relevant scenario. We do not agree that safe use has been demonstrated based on the available data and refinements.</p>
(7)	Vol. 3, B.6.5, Exposure and risk assessment	DE: Please, include the specific requirements for operator and resident/bystander safe use in the LoEP. Details should be provided on the specification of the application vehicle, RPE, and buffer zone.	

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Section 2 – Effects on human and animal health

Other comments, incl comments on volume 4 (impurities, batches)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.8.6.3, Predicted environmental concentrations in groundwater	DE: Concerning the groundwater aspect only, approval of this substance should be granted only for application conditions under which no exceedance of the trigger value of 0.1 µg/L is predicted neither for chloropicrin nor for its metabolite DCNM. The latter must be considered a relevant metabolite. This should be clearly mentioned in the EFSA conclusion and MS should consider this issue very seriously when granting authorisations.	

Section 3 – Residue data

3. Residue data

Storage stability of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol.3, B.7.1	DE: We agree to the assessment of RMS. According to the data requirements, storage stability in strawberries is not addressed by a study, nor in water-dominant matrices except tomato, where the proposed compound of the residue definition is investigated. However, since the results show almost immediate instability, we agree to extrapolate this finding to the other water- and acid dominant matrices by default.	

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.1.1	DE: Given the high toxicity of chloropicrin, the lacking intermediate samplings, the inadequate extraction and identification of terminal harvest samples and the proven instability of parent and DCNM over much shorter storage intervals than applied in the metabolism study (4 days versus 290 days), we support the conclusion of the RMS to invalidate the metabolism study (but why is the data then considered reliable by RMS and no data requirement set in Vol. 1?). The EFSA conclusion of 2009 on not setting a data requirement for a new study is also not supported.	

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Section 3 – Residue data

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		The RMS conclusion that no residues are expected is not supported unless further data on plant metabolism are provided.	

Residue definition			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.7.3	DE: Residue definition should be considered as provisional due to the lack of reliable metabolism data.	

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, 7.6	DE: Suitability of trials for the representative uses may be given in case the residue definition "parent compound" (and probably DCNM) is supported by acceptable plant metabolism studies.	

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Section 3 – Residue data

Estimation of the potential and actual exposure through diet and other sources			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.7.9	DE: The compounds of dietary relevance are not known. RMS considers the plant metabolism as not addressed. While we agree to that, we do not support the conclusion without further proof, that no residues are expected and the risk for consumers is acceptable.	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7	DE: Some endpoints are not addressed (residues in pollen and honey, fish metabolism/feeding). Please add respective statements.	

Section 4 - Environmental fate and behaviour

4. Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B 8.1.1.1, study Vökel, 2004	DE: We believe that for an active substance as volatile as chloropicrin, an aerobic soil study without a total mass balance should not be considered acceptable. It is possible, that part of the active substance escaped from the system during incubation, besides, the amount of chloropicrin that vaporised from the soil into the headspace need to be considered before deriving DT ₅₀ endpoints. Otherwise, the derived DT ₅₀ endpoints are dissipation rates but not degradation rates.	
(2)	Vol. 3, B 8.1.1.1, study McLaughlin, 2013a	DE: We believe that the DT ₅₀ values for chloropicrin from this study should not be used. Chloropicrin is extremely volatile and with a total mass balance of only 30- 56 % at the end of the study it is likely that a high amount of chloropicrin escaped from the system or during the extraction. Thus the DT ₅₀ values represent dissipation rates and not degradation rates. The RMS states that the lost radioactivity is due to loss of a volatile metabolite but there is no evidence provided for this and even if some of the loss is due to a volatile metabolite, additional loss of chloropicrin cannot be ruled out.	

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Section 4 - Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol. 3, B 8.1.1.1, study McLaughlin, 2013b	DE: Also for the metabolite study with DCNM, we do not believe that the DT ₅₀ values from this study should be used. With a total mass balance of only 50-53 % at the end of the study it is likely that a high amount of DCNM escaped from the system or during extraction of the soil. Thus the derived DT ₅₀ values represent dissipation of DCNM and not degradation. Again, the RMS states that the lost radioactivity is due to loss of a volatile metabolite but there is no evidence provided for this and even if some of the loss is due to an additional volatile metabolite, additional loss of DCNM cannot be ruled out.	

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.3.3	DE: An OECD 309 study on aerobic mineralisation in surface water is missing.	
(2)	Vol. 3, B.8.3.3, McLaughlin, 2013c	DE: We believe that the DT ₅₀ values for chloropicrin and DCNM from this study should not be used. Chloropicrin is extremely volatile and with a total mass balance of only 62-63 % (with headspace) or 40 % (without headspace) at the end of the study it is likely that a high amount of chloropicrin escaped from the system or during the following extraction. Thus, the DT ₅₀ values represent dissipation rates and not degradation rates.	

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Section 4 - Environmental fate and behaviour

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol.3, B.8.3.5, Impact on water treatment procedures	DE: Since chloropicrin is very toxic and very prone to leaching into groundwater, the impact on water treatment procedures should really be addressed for this compound.	

PEC in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B 8.2	DE: No valid degradation DegT ₅₀ for chloropicrin or DCNM in soil are available (see our comments on aerobic soil degradation). Thus reliable PEC _{soil} values can only be derived immediately after one application.	

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B 8.6, PEC _{sw} and PEC _{gw}	DE: No valid DegT ₅₀ values of chloropicrin or DCNM in soil, water and sediment representing real degradation are available (see our comments above). The DT ₅₀ values used for PEC _{sw} and PEC _{gw} calculation represent dissipation rather than degradation and are not sufficient for surface water and groundwater modelling.	

Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(2)	Vol. 3, B 8.6, PEC _{sw}	DE: The most volatile compound investigated for the tool EVA was lindane with a vapour pressure of 0.04 Pa (20°C). It is not suitable to calculate the deposition fluxes of a compound as volatile as chloropicrin.	
(3)	Vol. 3, B 8.6, PEC _{sw}	DE: We believe that volatilisation and subsequent deposition of a compound as volatile as chloropicrin should be considered both in Step 3 (by running Step 4 with volatilisation and subsequent deposition but without risk mitigation measured) and Step 4.	
(4)	Vol. 3, B 8.6, PEC _{sw}	DE: Please check if the PEC _{sw} value for the R4 stream after application for olive tree planting is correct (Table B.8.6-21). It is very different to the PEC _{sw} of citrus trees although the application scenarios for both crops are very similar.	
(5)	Vol. 3, B.4.2, groundwater	DE: We believe that the application scenario used for groundwater modelling is not sufficient to reflect the real possible exposure of groundwater with chloropicrin or its metabolite DCNM in the intended uses. While no major water movement is likely to occur while the area is tarpred of, both compounds are highly volatile and will mainly remain in the gas phase of the soil. In the gas phase, both compounds can be distributed throughout the soil column via diffusion. The available field dissipation study Ivancovich, 1987 investigated the concentration profile of chloropicrin under tarp after injection of the active	

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Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		substance into the soil to depths of 15 to 20 cm and found elevated chloropicrin concentrations up to a depth of 121 cm in the sandy and the clay loam soil immediately after removing the tarp after only 2 days of incubation! Although the study was performed in California and the requirements of an OECD field dissipation study are not fulfilled, it cannot be ruled out that similar distribution of chloropicrin would occur in European soils. This would need to be reflected in an acceptable groundwater modelling for this substance.	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	General	DE: Please note that there is currently a complete ban of using PPPs containing chloropicrin in Germany.	
(2)	Vol. 3, B.8, General	DE: An open literature review on chloropicrin is missing.	

Section 5 - Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.2.2., refinement of chronic endpoint	<p>DE: In the text below Table 9.1.2-1 it is described that the long-term mammal endpoint comes from the 2-year rat study (████ 1995) and not from the 1-year dog study (████ 1994). The endpoint is not only based on decreased bodyweight but also on hyperplasia and hyperkeratosis which may in turn have led to the decreased food consumption and body weight. There is no two generation reproduction study with the active substance from oral exposure via feed.</p> <p>Reproduction has not been assessed in the study by █████ therefore it is not possible to draw a conclusion on whether or not the observed effects affect reproduction or not.</p>	In our opinion the chronic endpoint should not be set to 1 mg as/kg bw/d from the 1 year dog study. This is especially because in the rabbit inhalation study effects on foetal body weight were observed.
(2)	Vol. 3, B.9.1.2, overall conclusion	<p>DE: We disagree with the conclusion that no risk assessment is necessary for crops grown under permanent protection. This is due to the fact of the extreme volatility of chloropicrin. Permanent greenhouses or tunnels need to be aired sometime after application to allow personnel entering the greenhouse/tunnel. Since chloropicrin is a pulmonary agent, entering the greenhouse without protective clothing cannot take place before airing. Therefore, it is expected that once airing takes place high amounts of chloropicrin enter the surroundings and concentrations exiting the greenhouse/tunnel might even be higher than after lifting the VIF.</p>	This needs to be taken into account and addressed in the risk assessment. This statement is valid as well for the risk assessment for birds.

Section 5 - Ecotoxicology

Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.9.2.2, Report: IIA 8.2.4/01	DE: EC ₁₀ values should be calculated for the chronic fish study.	
(2)	Vol. 3, B.9.2.5, Report: IIA 8.3.2.1/01	DE: In our opinion the RMS should have requested the applicant to recalculate the mean measured concentrations based on the provisions given in the OECD GD 23 on difficult substances.	
(3)	Vol. 3, B.9.2.6, Report: IIA 8.4/01	<p>DE: The study needs to meet the validity criteria set out in the GD in force at time of application, since this reflects the current state of the art in science and technology. Please elaborate on this. It is scientifically not justifiable to reject one study because of non-compliance with the validity criteria set out whereas it has not been checked for the second study if the same validity criteria are met.</p> <p>Additionally, in our opinion the RMS should have requested the applicant to recalculate the mean measured concentrations based on the provisions given in the OECD GD 23 on difficult substances.</p>	
(4)	Vol. 3, B.9.2.6, Report: IIA 8.4/02	DE: Chloropicrin is to be notified as a herbicide. Therefore a valid study on a second taxonomic group is required according to the data requirements.	
(5)	Vol. 3, B.9.2.9, Table B.9.2.9-1	DE: Please also add NOEC values for all studies.	
(6)	Vol. 3, B.9.2.9, Risk assessment for algae	DE: The endpoint ErC ₅₀ is selected but there are some uncertainties regarding the level of	

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Section 5 - Ecotoxicology

Aquatic organisms			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: "... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future". Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended in the central zone to address this uncertainty at the level of each Member State.	
(7)	Vol. 3, B.9.2, general	DE: Since it is very likely that chloropicrin migrates to the groundwater in relevant concentrations the route of exposure of groundwater becoming surface water again needs to be considered.	

Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.3.2.1	DE: Since an exposure not only for ground dwelling arthropod species is possible (due to volatilisation and deposition), we consider studies with foliar dwelling species necessary. Since those are not provided this should be set as a data gap.	
(2)	Vol. 3, B.9.3.2.3, in field risk	DE: In our opinion the argumentation concerning the potential for recolonisation is insufficient. For the active substance 1,3-dichloropropene no effects on <i>Poecilus cupreus</i> , <i>Aleochara bilineata</i> , and	

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Section 5 - Ecotoxicology

Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<p><i>Pardosa spp.</i> were observed in an aged residue study. However, in the presented field studies no recovery could be concluded even after two years.</p> <p>Therefore in our opinion a full field study is needed in order to conclude on the recovery potential after chloropicrin application.</p>	

Earthworms and other non-target soil macro- and mesofauna			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.4.2, Report: IIA 8.9.2/01	DE: EC ₁₀ and EC ₂₀ values should have been reported. These values should be requested from the applicant.	
(2)	Vol. 3, B.9.4.2, Report: IIA 8.9.2/03	DE: EC ₁₀ and EC ₂₀ values should have been reported. These values should be requested from the applicant.	
(3)	Vol. 3, B.9.4.4, Risk assessment for earthworms	DE: The endpoints appear inappropriate for addressing the risk adequately due to the missing analytical verification/maintenance of active substance and initial exposure especially in the study by Paternaude (2013).	
(4)	Vol. 3, B.9.4.4, Risk assessment for earthworms	DE: In our opinion it is not appropriate comparing the results of the study by Paternaude (2013) with the results of the study by Rodgers (2009b). This is due to the fact, that the latter study has	

Section 5 - Ecotoxicology

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		been performed with aged natural soil residues instead of artificial soil and the application method and tarping is not documented.	
(5)	Vol. 3, B.9.4.4, Potential for recovery	<p>DE: The term "Potential for recovery" is misleading, since an application of chloropicrin at the rate applied for will lead to 100 % mortality – at 53 mg as/kg soil dw 100 % mortality occurred in the Paternaude 2013 study, the calculated PEC_{Soil} values for either application type are > 100 mg as/kg soil. Therefore, the term of recolonisation should rather be used.</p> <p>Additionally, we would like to point out that 100 % effect on non-target species like soil organisms is not acceptable. A recovery is not possible since no reproduction can take place when there are no earthworms left to reproduce.</p>	<p>The scientific opinion on in soil organisms (EFSA Journal 2017;15(2):4690) states, that for earthworms "the maximum initial magnitude of effect that might be tolerated in-field without impairing the general protection goal is suggested to be small effects less than 35 % up to months on the ecological entity 'populations of different earthworm species'. [...] This magnitude of effect is deemed to allow for internal recovery of earthworm populations so that biodiversity levels and the provision of the ecosystem-services in agricultural field soils is assured in relevant time frames (please refer to Section 3.2). For earthworm populations, medium effects higher than 65 % would not result in internal recovery in relevant time frames."</p> <p>The studies with the aged soils are of no additional informative value, because no earthworms will be present in field when the treated soil has aged.</p>
(6)	Vol. 3, B.9.4.4, Consideration of recovery from outside the treated area	DE: A relevant route of exposure for off field environments can also be run-off. This should be considered, too due to the high application rate and the high toxicity of chloropicrin.	
(7)	Vol. 3, B.9.4.4, RA for other soil macro-organisms, potential for recovery	DE: Due to the nature of the active substance it is expected that at the application rate of the representative use 100 % effects on mortality will be observed. Therefore the same applies as for earthworms.	The scientific opinion on in soil organisms (EFSA Journal 2017;15(2):4690) states the following for enchytraeids: "The maximum initial magnitude of effect that might be tolerated in-field without impairing the general protection goal is suggested to be small effects less than 35 % for months on the ecological entity 'populations of different enchytraeid species' or medium effects less than 65 % for weeks. These magnitudes of effects are deemed to allow for internal recovery of enchytraeids populations (see Section 3.2), so that biodiversity levels and

Section 5 - Ecotoxicology

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
			<p>the provision of ecosystem services in agricultural field soils is assured in relevant time frames.”</p> <p>And for macroarthropods: “The maximum initial magnitude of effect that might be tolerated in-field without impairing the general protection goal are suggested to be medium effects less than 65 % for weeks on the ecological entity ‘populations of different macroarthropod species’ or small effects less than 35 % for months. These magnitude of effects will allow for internal recovery and recolonisation by macroarthropod species (see Section 3.2), so that biodiversity levels and the provision of ecosystem services in agricultural field soils is assured in relevant time frames.”</p> <p>The studies with the aged soils are of no additional informative value, because no collembolan will be present in field when the treated soil has aged.</p>
(8)	Vol. 3, B.9.4, Risk assessment for soil organisms in general	DE: Resulting from the intended use of chloropicrin as nematicide against harmful organisms in soil, effects of the pesticide on soil organisms, especially beneficial nematodes, should be assessed at higher tier level in order to ensure a sufficient protection level for these organisms.	

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Section 5 - Ecotoxicology

Soil nitrogen transformation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.9.5, Report: IIA 8.10.1/03	DE: It appears questionable how an application of chloropicrin can be "commercial" as stated in the study title, when this active substance is not approved in the EU. This seems illegal.	

Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.9.6.2, Risk to non-target terrestrial plants from representative uses of chloropicrin	DE: A relevant route of exposure for off field environments can also be run-off. This should be considered, too, and is not covered by the adjusted exposure study presented. Since chloropicrin is applied for as a herbicide, also seedling emergence should be tested according to the respective OECD GD with concentrations to be expected from run-off.	
(2)	Vol. 3, B.9.6.2, Risk to non-target terrestrial plants from representative uses of chloropicrin	DE: Please present the risk assessment in a tabular manner for better clarity.	

Section 5 - Ecotoxicology

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.9.11, Literature review	DE: Please elaborate on why chloropicrin has not been searched for in the RTECS database. This appears to be a relevant data base for literature on toxic effects.	
(2)	Vol. 3, B.9.11, Literature review – summary of search results	DE: Why are the 13 studies that were not excluded for relevance not further discussed to have a transparent reasoning for the non-inclusion in the risk assessment?	
(3)	Vol. 3, Appendix 3: UK Pesticide Usage Survey	DE: How can chloropicrin have been used in UK as a soil sterilant when this substance was not approved in the EU neither under Directive 91/414/EEC nor under Regulation (EC) No 1107/2009? This seems rather illegal.	
(4)	Vol. 1, Level 2, 2.10. C&L	DE: The proposal for aquatic environment (4.1) appears to be missing. Please add.	
(5)	Vol. 1, Level 3, 3.1.1.1	DE: We disagree that approval is possible as the risks could be refined with further data at MS level. The purpose of a common active substance assessment is that safe uses have been demonstrated for the intended use. As this is not the case the risk should be first refined at EU level i.e. in the active substance assessment.	
(6)	Vol. 1, Level 3, 3.1.4.9	DE: We are of the opinion that further studies need to be generated in order to refine the risk (e.g. earthworm and arthropod field studies).	

Section 5 - Ecotoxicology

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(7)	Vol. 1, Level 3, 3.1.5	DE: Additional issues that could not be finalised are in our opinion: risk to earthworms, risk to non-target arthropods, risk to beneficial nematodes, and risk to aquatic organisms due to the simultaneous exposure via run-off/drainage and volatilisation/deposition. Alternatively, these issues could also be added to Section 3.1.6 "Critical areas of concern".	
(8)	Vol. 1, Level 3, 3.2	DE: We disagree with the RMS' conclusion that chloropicrin can be approved under Regulation (EC) No 1107/2009.	
(9)	General	DE: We would like to point out that no uses of chloropicrin in Germany are allowed since 1980, due to its high toxicity to warm-blooded species and for the protection of groundwater.	

Section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3 – B.9.2.5, p. 139	IE: Section 2 describes the preparation of stock solution. This paragraph reads as 5.93 µg was dissolved in 1L to make a 10mg/L stock solution. Please change the unit µg to µL .	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 5 - Ecotoxicology (B.9)

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other comments			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.10, Classification and Labelling	IE: Please include Aquatic Acute 1 (M 1000) and Aquatic Chronic 1 (M 100) in the proposed classifications in section 4.1 Hazardous to the aquatic environment.	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 4, C. Confidential information and, where relevant, details of any task force formed for the purposes of generating tests and studies submitted p. 4.	NL: It is stated that there is no task force and only a single applicant, however in Vol. 1 under 1.2 applicant information it is stated that an EECG consists of two companies/applicants and under 1.2.3 it is stated that an task force of companies collectively known as ECG, please explain.	
(2)	Vol. 4, C.1.2.3 Analytical profile of batches p.9.	NL: It seems that the proposed and supported minimum purity of the active substance (990 g/kg) is not fully supported by the mean – 3xSD value ([REDACTED]), and thus by the 5 batch analysis. Please clarify why this value was proposed by applicant/RMS. Additionally, Please state the LOQ/LOD of the individual impurities in the 5-batch analysis, for completeness purposes. The absence of a reference standard for the determination/quantification and identification of impurity D ([REDACTED]) is (highly) questionable, especially when proposed in the reference specification. This however can be found acceptable for impurities not included in the proposed specification. Additional information (e.g. QC-data) should be provided for this impurity with an validated method (including an reference standard, which is now available) to support the proposed specification.	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the active substance and the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.2.1.2 Boiling temperature p. 5.	NL: Is the method used for the boiling point similar/equal to the EC A.2 method. <i>This also applies to B.2.1.3 (EC A.3), B.2.1.12 (EC A.6), B.2.1.13 (EC A.8), B.2.1.15/16 (EC C.7)</i>	
(2)	Vol. 3, B.2.1.10 Spectra p.7-8.	NL: Is it possible to include the spectra of the UV/VIS, IR, NMR and MS into the results column for completeness.	

Data on application and efficacy			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Further information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
-	-	NL: No comments.	

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.5.2. ANALYTICAL METHODS	NL: 'Fit for purpose' is not a characterisation which is appropriate and acceptable for post-registration	

Comments of The Netherlands on the assessment report on chloropicrin

(19.04.2018) 3/19

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	(RESIDUE) FOR TREATED PLANTS, PLANT PRODUCTS, FOODSTUFFS OF PLANT AND ANIMAL ORIGIN AND FEEDING STUFFS p. 9-10	<p>methods used for monitoring/enforcement purposes. Please indicate if the reviewer accepts or does not accept this analytical method (for monitoring/enforcement purposes) in light of the SANCO/825/00 rev. 8.1 guidance. Additional data is therefore required and should be provided, to prove the analytical method is satisfactory validated according to SANCO/825/00 rev. 8.1.</p> <p><i>This also applies to the ILV studies provided on p. 11-16, primary method study on p. 17-18, ILV study on p. 21-22, primary method study soil p. 23-24, primary method study water p. 25-27, primary method study air p.28-30 and primary method studies body fluids and tissues p. 31-35.</i></p> <p>NL: The conclusion stated on p. 36 is therefore not correct and incomplete and additional data gap's should be stated. This is unless it can be sufficiently substantiated that is not needed in light of possible residues in the plant/animal matrices, environmental matrices and human fluids and tissues.</p>	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
-	-	NL: No comments.	

Section 2 – Effects on human and animal health

2. Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		NL: No comments	

Acute toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.2	NL: Since the information is based on public literature, it would be informative to have the information on these publications with a (short) summary.	
(2)	Vol. 3, B.6.2.6	NL: As it is currently written down here, it indicates that chloropicrin is a sensitiser ("Since, chloropicrin is a skin irritant and sensitiser"). From Vol. 1, and the current harmonised classification it can be concluded that chloropicrin is not a skin sensitiser. Please adjust the wording in Vol. 3, B.6.2.6.	

Short-term toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		NL: No comments	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 2 – Effects on human and animal health

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.4.1.1	NL: The AMES test does not include E. coli WP2 uvrA or TA 102, therefore, no strain was included that can detect cross-linking mutagens.	

Long-term toxicity and carcinogenicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Reproductive toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Neurotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.7	NL: A waiver is included indicating that no effects indicative of neurotoxicity were observed in the database. However, in some of the short-term studies effects were mentioned that might be related to neurotoxicity (e.g. decreased activity and tremor in the 8-week dog study; impaired limb function in the 90-day rat study).	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 2 – Effects on human and animal health

Further toxicological studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Medical data and information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Toxicological end points: ADI, ARfD, AOEL			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.6.13	NL: The RMS proposes a new AOEL value based on a human volunteer study, contrary to the previous evaluation where the AOEL was based on animal studies. The setting of the AOEL should be discussed in an expert meeting	

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Other comments, incl comments on volume 4 (impurities, batches) and proposals for classification			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		NL: No comments	

Section 3 – Residue data

3. Residue data

Storage stability of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.7.2, Strawberry	NL: Stability of dichloronitromethane in strawberry is demonstrated for 4 days instead of the concluded 7 days.	
(2)	Vol. 1, 2.7.1, Summary of storage stability of residues	NL: Since storage stability is a problem for both chloropicrin and its metabolite dichloronitromethane, storage stability studies for both analytes in high acid as well as high water content commodities are required, instead of extrapolating between the crop groups.	

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.1.1, Metabolism, distribution and expression of the residue in primary crops	NL: In the metabolism study, already two days after treatment, the plastic covering was removed, and 14 days after treatment the crops were planted. This is in contrast with the representative uses, where the soil is covered with a film for at least 21 days after treatment, with an additional 7-14 days before planting. Please provide argumentation whether the metabolism study can be considered acceptable to cover the representative uses.	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 3 – Residue data

Metabolism, distribution and expression of residues in poultry, lactating ruminants, pigs and fish			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.2	NL: No comments.	

Residue definition			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.7.3	NL: No comments.	

Residue trials in plants and identification of critical GAP			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.6.1, Tomato	NL: Minor comment regarding study S12-003523: as is mentioned in the text, <i>in one trial (S12-03523-01) the time between harvest and analysis for DCNM was 24 days, therefore this result hasn't been considered further, as stability data does not support this length of storage.</i> The corresponding result in table B.7.6.1-1 should not be underlined.	
(2)	Vol. 3, B.7.6.1, Tomato	NL: Trial S24/2014-01 and trial S24/2014-03 seem to be not independent, since the application took place at the same day and location. Similar observations are made for trial S26/2015-01 and trial S26/2015-06, and trial S26/2015-14 and trial S26/2015-15.	
(3)	Vol. 3, B.7.6.2, Pepper	NL: Whether or not trials are independent should also be checked for the pepper trials of report S26/2015, since it seems that the application was	

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Section 3 – Residue data

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		conducted at the same day and at the same location.	
(4)	Vol. 3, B.7.6.3, Strawberry	NL: See also previous comments: can strawberry trials from the reports S12-03522, S24/2014 and S26/2015 be considered independent?	
(5)	Vol. 3, B.7.6.5, Courgette	NL: Please also check independency of courgette trials from report S26/2015.	
(6)	Vol. 3, B.7.6.6, Melon	NL: In line with previous comments, the independency of the melon trials of report S26/2015 should be checked.	

Feeding studies in poultry, ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.9	NL: No comments.	

Effects of processing			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.8	NL: No comments.	

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Section 3 – Residue data

Residues in rotational crops			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.10	NL: No comments.	

Summary of other studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7	NL: No comments.	

Estimation of the potential and actual exposure through diet and other sources			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.7.9	NL: No comments.	

Proposed MRLs and compliance with existing MRLs			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.7.10	NL: No comments.	

Proposed import tolerances and compliance with existing import tolerances			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.7.11	NL: No comments.	

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Section 3 – Residue data

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1/3	NL: No comments.	

Section 4 - Environmental fate and behaviour

4. Environmental fate and behaviour

Route and rate of degradation in soil			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3.B.8. Study McLaughlin 2013B	NL: The NL has the opinion that this study is not acceptable because the mass balance are not sufficient. Since the mass balance are not correct the DT50 derived from this study are also not acceptable a part of the mass is missing, this can be DCNM that is not degraded and this will have an effect on the DT50 value that has been estimated.	
(2)	Vol. 3.B.8.1.1 Table B8.1-37	NL: Typo at an A after McLaughlin (2013)	
(3)	Vol. 3.B.8.1.1 Table B8.1-39	NL: Could the RMS explain why are the values in this table different for Brierlow and Speyer 2.2 than the values in table B8.1-38	
(4)	Vol. 3.B.8.1.1 conclusion page 23	NL: doesn't agree with the RMS that on basis of the microbial biomass the DT50 of Speyer 2.3 soil is an outlier. The biomass is within the range given in the OECD307 guidance and therefore should not be considered as an outlier. Also the refinements with the shorter DT50 without this soil DT50 should be taken out of the dossier.	
(5)	Vol. 3B.8.1.1 Table B.1-12 and B8.1-17	NL: the percentage of biomass at the end of the study seems unrealistic high	

Adsorption, desorption and mobility in soil			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1 and 3.B.8	NL: is not familiar with the SSLRC classification	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 4 - Environmental fate and behaviour

Adsorption, desorption and mobility in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	B.8.1.2.4.	system, please included an reference where these can be found classification can be found	

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3.B.8.3.3.3	NL: the mass balances in the study, especially towards the end, are not acceptable. This has been observed after 7-14 days however no discussion and explanation was given. NL doubts if this study is acceptable. Is it possible that volatiles are formed from the metabolite DCNM that are not are not trappable ?	

Fate and behaviour in air			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3.B.8.3.4 and 3.B.8.3.2 Aquous photolysis	NL: Quantum yield of 0.5699 and 0.87 are reported in the DAR, please explain the difference	
(2)	Vol. 3.B.8.7	NL: According to the Atkinson calculations the active substance has the potential for long range transport. The photolytic half-life is much shorter. Can this be used instead?	

Section 4 - Environmental fate and behaviour

PEC in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments	

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	PECsw and PECgw calculations	<p>NL: has doubts to use the load of chloropicrin and metabolite after 21 days of the VIF with the geometric mean DT50 of 4.2 days. Since these first 21 not only degradation but also sorption, horizontal and vertical transfer will occur.</p> <p>Additionally the drip application will also result in further movement of the active. Groundwater flow might also have an influence on the active substance distribution. As a conservative and realistic worst case approach the initial load should be used input for the models. As higher tier the worst case DT50 of the Speyer 2.3 soil can be used since this is also applied for the PECsoil calculations instead of the geometric mean DT50 value.</p>	

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Section 4 - Environmental fate and behaviour

PEC from airborne transport and other routes of exposure			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: No comments	

Definition of the residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: No comments	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: No comments	

Section 5 - Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

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Section 5 - Ecotoxicology

Soil nitrogen transformation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Other non-target terrestrial organisms (flora and fauna)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Biological methods for sewage treatment			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Comments of The Netherlands on the assessment report on chloropicrin

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Section 5 - Ecotoxicology

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	NL: no comments.	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

AT: not considered

Section 2 – Effects on human and animal health

2. Effects on human and animal health

Acute toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6, general	AT: RMS has stated that no acute toxicity studies have been provided but that the applicant has referred to harmonised C&L. AT is of the opinion that applicant should show access to data and that the acute toxicity studies should be evaluated in the DAR. If applicant has no physical access to these studies, the data owner can provide them, upon agreement with the applicant, to RMS for inclusion in the DAR.	
(2)	Vol 3, B.6.2.2.	AT: Acute dermal toxicity is a data requirement according to Regulation 283/2013 ("The acute dermal toxicity of the active substance shall be reported unless waiving is scientifically justified (for example where oral LD 50 is greater than 2 000 mg/kg). Both local and systemic effects shall be investigated"). We do not consider the acute inhalation study as sufficient to address dermal toxicity, since the study design of dermal toxicity study is different. Since chloropicrin is liquid, dermal toxicity study is technically feasible. However, in order not to promote animal testing we would propose either to apply for dermal toxicity the same hazard as for oral toxicity, as a worst case assumption or to justify more in detail why no acute dermal toxicity is expected. The sentence in the DAR that chloropicrin is not	

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Section 2 – Effects on human and animal health

Acute toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		classified for acute dermal toxicity according to CLP is not substantiated by data, since it appears that no appropriate data (study) on dermal toxicity is available.	

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.4.1.1	AT. We agree that AMES test can be considered as positive. However, we miss an appropriate follow-up test for gene mutation. Indeed, there is no single assay deemed sufficient to mitigate concerns with an AMES positive finding. However, one in vivo option is transgenic gene mutation assay. RMS/applicant is kindly asked to add justification for no follow up test for positive AMES assay. Please note that neither MN assay in vivo nor UDS assay are appropriate or sufficient follow up for genotoxicity in bacterial cells.	
(2)	Vol. 3, B.6.4.1.3	AT: RMS is kindly asked to add information on positive controls, which are not mentioned in the study summary. Positive controls are needed to demonstrate the ability of the laboratory to identify mutagens. The validity of results without positive controls is questionable. RMS is also kindly asked to add the exposure time, as well as to check the units for mutant frequency.	

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Section 2 – Effects on human and animal health

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		RMS is kindly asked to extend the description of this study, and also add deficiency of the study comparing to current OECD Guideline.	
(3)	In vivo MN assay	AT: in MN assay in vivo only 2000 erythrocytes were examined per animal for micronuclei instead of 4000. This appears to be somehow acceptable in cases where only negative vitro results were observed but is questionable for follow up of positive in vitro results.	

Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.8.1.1 Groundwater metabolites	AT: It appears that no studies on DCNM were provided, but publicly available data summarised in the position paper. AT is of the opinion that if public data are provided to support substance/metabolite evaluation than these data have to be considered for their relevance and reliability and in case that these two criteria are fulfilled than the data have to be summarised in a robust study summary. Nothing like this could be found in the DAR. Therefore, the data are presented are not considered as sufficient to conclude on toxicity of DCNM.	

Section 3 – Residue data

3. Residue data

AT: not considered

Section 4 - Environmental fate and behaviour

4. Environmental fate and behaviour

AT: not considered

Section 5 - Ecotoxicology

5. Ecotoxicology

Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.9, Bees	AT: The risk to honey bees should have been assessed based on the EFSA GD on honey bees (2013).	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.9	AT: The studies were evaluated by the RMS taking into account the test guidelines used at the time of testing. However, for the validation of the studies the current valid test guidelines should have been considered.	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4, C.1.1.2, Starting materials and reagents	FR: For each starting material or reagent, the minimum purity and the mention "commercially available" are sufficient. The supplier name should not be clarified when it is a common chemical, as it can change.	
(2)	Vol. 4, C.1.1.2, Starting material and reagents	FR: MSDS in compliance with Annex II of the Regulation (EC) No 1907/2006 (REACH) and the ECHA related guidance document "Guidance on the compilation of safety data sheets", should be provided for each starting material used for the manufacture of the active substance. Moreover, if one of the starting material has toxicological or eco toxicological properties or if it contains any relevant impurity, this relevant starting material/impurity should be determined in the batch analysis or it should be demonstrated that this relevant starting material/impurity cannot be present at unacceptable level in the technical substance. If MSDS are not available, it should be demonstrated that starting materials have no toxicological relevance at contents lower than 1 g/kg (example: harmonized classification according to the Regulation (EC) No 1272/2008...).	
(3)	Vol.4, C.1.2.3, impurities, p10-13	FR: A rationale should be provided to explain the presence of each impurity found in the technical material (solvent, by-product, impurity in a starting material, ...)	
(4)	Vol.4, Table C.1.3-2	FR: CAS number of [REDACTED] is erroneous	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		and should be corrected. Moreover, the MSDS of this coformulant should be provided.	
(5)	Vol.4, C.1.4.1.1., §3	FR: Please correct the typo [REDACTED] [REDACTED].	
(6)	Vol.4, C.1.2.2., significant impurities	FR: Applicant proposed a specification of ≤1 g/kg for [REDACTED] as a significant impurity. [REDACTED] was shown to be unstable at room temperature and to decompose into [REDACTED]. Moreover, [REDACTED] was shown to be almost completely degraded into [REDACTED] when analyzed by GC (Vol.4, p50). Therefore, because [REDACTED] coelutes and lead to a single analyte, the specification of ≤1 g/kg should apply to the sum of [REDACTED] [REDACTED].	
(7)	Vol.4, C.1.2.2., significant impurity D	FR: As [REDACTED] decomposes into [REDACTED] upon analysis, we consider that the identity of Impurity D remains unclear. A standard of [REDACTED] or an additional analytical technique may help to get this point clear.	
(8)	Vol. 3CA-CP, B1.2.3	FR: Please correct the typo "vapour releasing" instead of "vapour realising"	

Physical and chemical properties of the active substance

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the active substance			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, Table B2.1-1, point B2.1.5	FR: According to OECD 104, vapour pressure should be measured at least at 2 temperatures in the 0-50 °C range. This is particularly important in this dossier, considering the intended use.	
(2)	Vol. 3CA-CP, Table B2.1-1, point B2.1.6	FR: It should be notified that Henry's law constant has been estimated from the vapour pressure measured at 25 °C and density measured at 20 °C.	
(3)	Vol. 3CA-CP, Table B2.1-1, point B2.1.11	FR: According to OECD 105, pH of the solution should be reported.	
(4)	Vol. 3CA-CP, Table B2.1-1, point B2.1.22	FR: As the technical substance contains some explosive impurities ([REDACTED] [REDACTED]), the representativeness of the batch used for the test compared to the specifications should be argued.	

Physical and chemical properties of the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, Table B2.2-1, point B2.2.12	FR: It should be clarified that it is <i>kinematic</i> viscosity. Moreover, the shear rate at which the measure was performed should be specified according to OECD 114.	
(2)	Vol. 3CA-CP, Table B2.2-1, point B2.2.15	FR: Please make sure that there is no typo in the unit of the reported corrosion rate.	
(3)	Vol. 3CA-CP, Table B2.2-1, point B2.2.15	FR: Considering the reported corrosion rate, a test of corrosion to metal according to UN RTDG Manual of tests and criteria ST/SG/AC.10/11/Rev. 6 Part III Section 37.4 should be required.	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(4)	Vol. 3CA-CP, Table B2.2-2, point B2.2.11	FR: The coformulant included in this preparation being a surfactant, the result on the substance alone cannot be extrapolated and the surface tension test should be required.	
(5)	Vol. 3CA-CP, Table B2.2-2, point B2.2.12	FR: It should be clarified that it is <i>kinematic</i> viscosity. Moreover, the shear rates at which the measures were performed should be specified according to OECD 114.	
(6)	Vol. 3CA-CP, Table B2.2-2, point B2.2.15	FR: We agree that further data are needed to demonstrate a 24 months shelf-life. Moreover, emulsifiability and emulsion stability of the aged product should be provided (preferably according to CIPAC MT 36.3).	
(7)	Vol. 3CA-CP, Table B2.2-2, conclusion	FR: Considering the lack of information concerning "Chloropicrin EC" formulation, both on physical and chemical properties (no surface tension test, no stability study), analysis (no analytical method to determine a.i. in the formulation) and identity (no MSDS nor CAS number of the co-formulant), it should be made clear that some additional data will be required for this preparation to be authorized.	

Data on application and efficacy			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, CA-CP B.3.3., Details of intended use (Chloropicrin EC, p.12 to	FR: Please explain or correct the unit used in the column 12 about the water volume: mm/ha.	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Data on application and efficacy			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
20)	Vol. 1, 1.5., Detailed uses of the plant protection product (Chloropicrin EC, p.17 to 26)		

Further information			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3CA-CP, B4.1., storage and handling	FR: Temperature storage should be made explicit in this section.	

Methods of analysis			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3CA-CP, Table B.5.1.3-4	FR: Please correct the typo $R^2=1$ instead of $R^2>1$	
(2)	Vol. 3CA-CP, Tables B.5.2-6, B.5.2-10, B.5.2-14, B.5.3.2-3 and B.5.3.3-2	FR: The linear range should not be said appropriate, as it does not fulfil SANCO/825/00 rev.8.1. However, we agree with the RMS evaluation of the validity of the analytical methods.	
(3)	Vol. 3CA-CP, B.5.2. Residues in plant products	FR: Only analytical methods in high water content (tomato) and acidic (strawberry) matrices are discussed in this section. Dry matrices or matrices with high oil content are not described and are	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		lacking. Whatever the claimed uses, analytical methods validated according to SANCO/825/00 rev 8.1 for determining residues in plant products are required for each type of plant matrix.	
(4)	Vol. 3CA-CP, B.5.2. Residues in plant products	FR: Extraction efficiency has not been evaluated in all types of matrices. It should be clearly indicated that these data will be required if a preparation including chloropicrin claims some uses where extraction efficiency data are lacking.	
(5)	Vol. 3CA-CP, B.5.3.2. Residues in water	FR: An ILV is required for the analytical method for the determination of residues of chloropicrin in water, and it is lacking.	

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Section 2 – Effects on human and animal health

2. Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		FR: No comment.	

Acute toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.6, B.6.2.1 Acute toxicity by oral route and table B.6.2-2	FR: According to US EPA data*, a LD50 of 37.5 mg/kg bw is available by oral route. In the absence of acute oral toxicity study in the renewal dossier, this value would support a more severe classification proposal (Acute oral tox. 2). * US EPA - Chloropicrin. Human health assessment scoping document in support of registration review, Sept 2013. https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0153-0003	
(2)	Vol. 3 B.6, B.6.2.3 Acute toxicity by inhalation route and table B.6.2-2	FR: supports the newly proposed classification Acute tox. 1 H330.	
(3)	Vol. 3 B.6, B.6.2.5 Acute toxicity, Eye irritation and table B.6.2-1 and 2	FR: Further available data (human data see section B.6.9 and US EPA data) indicate that a corrosive classification could be relevant for chloropicrin. Furthermore, as no skin/eye irritation studies are available, a corrosive effect cannot be excluded on this basis. Could you please discuss this point?	

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Section 2 – Effects on human and animal health

Acute toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		If classification as corrosive is not considered appropriate, it has to be taken into account that the harmonized CLP classification is a translation from the former directive. For eye irritation, the classification criteria of CLP are less permissive. Without the results of the study/data used to classify H319 (R36), it cannot be certain that chloropicrin is not more dangerous for this endpoint. Furthermore, H318 is supported by the effects observed in human.	

Short-term toxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		FR: No comment.	

Genotoxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 B.6, B.6.4.1 <i>In vitro</i> studies Ames test	FR: Could you please provide the whole tabulated data for every strains of every assay with and without S9? FR agrees that the Ames test is positive on several strains as concluded by the RMS. It can also be added that strain TA100 shows borderline results,	

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Section 2 – Effects on human and animal health

Genotoxicity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<p>i.e. reproducible dose-related increases with a maximum value just below the threshold of 2-fold increase. In the first assay with S9 mix, the increase for this strain is 1.7-fold. Without S9, no results were provided for this strain. In the confirmatory assay with and without S9 mix, the increase of revertants is dose-related and represents a 1.8- and 1.7-fold increase respectively.</p> <p>Moreover, a strain able to detect cross-linking mutagens (<i>Salmonella typhimurium</i> strain TA102 or <i>E. coli</i> strain WP2 or WP2 (pKM101)), as required by OECD Guidance Document 471, was not used in this assay.</p>	
(2)	Vol. 3 B.6, B.6.4.1.2 <i>In vitro</i> genotoxicity testing-test for clastogenicity in mammalian cells, Puttman and Morris, 1990 Vol. 3 B.6.4.2.1 <i>In vivo</i> genotoxicity testing (somatic cells)- micronucleus test in rodents, [REDACTED], 2003a	FR: FR agrees that the test is positive at cytotoxic concentrations. However, as a negative <i>in vivo</i> test on the same endpoint is available (micronucleus test), with proof of the bone marrow exposure (supported by the data in ADME), chloropicrin can be considered non-clastogenic <i>in vivo</i> .	
(3)	Vol. 3 B.6, B.6.4.1.3 <i>In vitro</i> genotoxicity testing-Test for gene mutation in	FR: Please indicate the meaning of "V.C." in the tables of this study. Could you please also provide the positive control data and detail the deviations	

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Section 2 – Effects on human and animal health

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	mammalian cells, RHC and Sigler, 1990	of this study. Based on these additional data, the reliability of the negative result of the study should be discussed.	
(4)	Vol. 3 B.6.4 Summary of genotoxicity studies	<p>FR: Chloropicrin was positive in several strains of <i>Salmonella typhimurium</i> in the Ames test available and in the literature review. Moreover, a strain able to detect cross-linking mutagens was not used in this assay.</p> <p>It is acknowledged that the <i>in vitro</i> gene mutation study was considered negative (pending clarifications on the reliability of the result, see above comment). Nevertheless, the UDS test is not considered as sufficiently sensitive. Therefore, it is considered that there is an uncertainty on the mutagenic potential of chloropicrin.</p>	

Long-term toxicity and carcinogenicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 B.6.5.3, Long-term toxicity and carcinogenesis, Chloropicrin: Vapor inhalation oncogenicity study in CD-1 mice, [REDACTED], 1995b	<p>FR: Increased incidence of lung adenomas was observed in males and females. Please provide relevant HCD for this finding.</p> <p>Could you please provide the tabulated results for organ weights and non-neoplastic lesions observed in the respiratory tract?</p> <p>Regarding the incidence of non-neoplastic findings, statistically significant and dose-related increased</p>	

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Section 2 – Effects on human and animal health

Long-term toxicity and carcinogenicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>incidence of lung peribronchial lymphocyte infiltration was observed from 0.1 ppm for both males and females (percent incidences for the control, 0.1 ppm, 0.5 ppm and 1.0 ppm groups: 2.8%, 22%, 27%, 29% and 12%, 26%, 45%, 72% in males and females respectively).</p> <p>Moreover, this finding was associated with bronchiectasis from the low dose level (3 in males and 4 in females versus 0 in controls). These findings are therefore considered relevant and could be used to set a LOAEC of 0.1 ppm for the long-term mouse study.</p>	

Reproductive toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 B.6.6.1 Reproductive toxicity, generational studies, [REDACTED], 1994	FR: Considering the observed mortality in several other studies, the deaths observed at the high dose in this 2-generation study should be considered as treatment-related. Nevertheless, there is no impact on the set NOAEC.	
(2)	Vol. 3 B.6.6.2.2 Reproductive toxicity, Developmental toxicity studies, Inhalation development toxicity study in New Zealand white rabbits, [REDACTED], 1993	<p>FR: Please provide the tabulated results for pulmonary pathology (necropsy findings) mentioned in the conclusion of the study.</p> <p>Abortions can be considered related to developmental toxicity. Therefore, it is proposed to set the developmental NOAEC at 0.4 ppm.</p>	

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Section 2 – Effects on human and animal health

Neurotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment.	

Further toxicological studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 B.6.8.2.1 Supplementary studies on the active substance, [REDACTED], 2004	FR: Considering the summary provided, it is not clear whether the concentration of 75 ppb could be considered as a NOAEC. Indeed, in the "Phase 2" results, effects were noted at 75 ppb.	
(2)	Vol. 3 B.6.8.2.2 Supplementary studies on the active substance, [REDACTED], 2007	FR: Could you please detail how the BMCL10 was derived (e.g. software used...)?	

Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1 2.11 Relevance of metabolites in groundwater 2.11.3.2 STEP 3, Stage 2: screening for genotoxicity	FR: It is stated that DCNM was "found at levels of approximately 20% of the parent compound". Please detail how this value was derived.	
(2)	Vol. 1 2.11 Relevance of metabolites in groundwater 2.11.3.3	FR: DCNM should be considered relevant considering the uncertainties on the genotoxicity profile of chloropicrin and the lack of data for acute oral	

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Section 2 – Effects on human and animal health

Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	STEP 3, Stage 3: screening for toxicity	and inhalation toxicity.	
Medical data and information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)		FR: No comment.	
Toxicological end points: ADI, ARfD, AOEL			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1 Level 2 2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI	FR: Agreed. It is noted that the proposed value covered the results of the 2-year rat study by inhalation.	
(2)	Vol. 1 Level 2 2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)	FR: Agreed. The setting of an ARfD is supported by the results of the rat and rabbit developmental studies by inhalation where body weight loss was observed in the dams at the beginning of the treatment.	
(3)	Vol. 1 Level 2 2.6.13. Toxicological end point for assessment of occupational, bystander	FR: FR agrees with the use of an AOEC instead of an AOEL, given the toxicological profile of chloropicrin. It is noted that clarifications/details on the derivation	

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Section 2 – Effects on human and animal health

Toxicological end points: ADI, ARfD, AOEL			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	and residents risks – AOEL chloropicrin	of BMCL10, and on the study used to derive this value (see above comment), are needed to conclude on the reliability and relevance of this value as the point of departure to determine the AOEC.	
(4)	Vol. 1 2.6.14 Toxicological endpoint for assessment of occupational, bystander, and residents risks -- AOEL phosgen	FR: FR supports the use of SCOEL information. However, could you please detail the rationale used for choosing the 15-min STEL value of 2 mg/m ³ (0.5 ppm) instead of the 8h-TWA value (0.4 mg/m ³ or 0.1 ppm)?	

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 B.6.10 Acute toxicity of plant protection products	FR: Please update the product classification according to chloropicrin classification.	
(2)	Vol. 1-Level 2, 2.6.15, Summary of product exposure and risk assessment	FR: The respective operator and worker activities need to be clearly differentiated. Indeed, it seems that activities allocated to workers (theoretically dedicated to re-entry tasks) in part 2.6.13 have been allocated to operators (theoretically dedicated to application tasks) in part 2.6.15.	
(3)	Vol. 1-Level 3, 3.1.1.3. Restrictions on approval	FR: RMS stated that, as a restriction to approval, « Professional users only (Chloropicrin 99 is supplied directly from the manufacturer to professional applicators)" should be involved.	

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		The tasks allocated to the professional users need to be specified for a better understanding of the targeted mitigation measures related to each of the personnel involved.	
(4)	Vol. 1-Level 3, 3.1.1.3. Restrictions on approval	FR: As for Chloropicrin 99, could you please specify that the representative preparation Chloropicrin EC is also supplied directly from the manufacturer to professional applicators?	
(5)	Vol. 1-Level 1, 1.5.1. Details of representative uses	FR: Could you please define the unit given for the water supply in the drip irrigation system for Chloropicrin EC (mm/Ha)?	
(6)	Vol. 3 – B.6.4. Exposure data	FR: A summary table with the number of monitored individuals by task (ie fumigation tasks, VIF cutting, VIF removal and transplanting) and the number of monitoring points (for the estimation of bystander/resident exposure) would be of value by type of application (shank injection vs drip irrigation; field vs greenhouse, large vs small areas treated), by study and by analysed substance (chloropicrin and phosgene). This will allow a better visibility on the number of data available for each of the exposure categories in each experimental condition.	
(7)	Vol 3 – B.6.4.1.1. Chloropicrin 99 – shank injection. Table 2. Summary of shank application studies	FR: Could you please confirm that, based on the description of the sampling phase for bystander, we should read in table 2, 16 chloropicrin stations (instead of 20) and 12 phosgene stations (instead of 12) for bystander data of study 08/2012?	
(8)	Vol 3 – B.6.4.1.1.	FR: It should be noted that in the case of shank	

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Chloropicrin 99 – shank injection. Table 2. Summary of shank application studies	injection, data from a single study (study 08/2012) are available to assess the bystander/resident exposure to phosgene. A more robust argument needs to be added in order to support the conclusion related to the bystander/resident exposure to phosgene for this type of application.	
(9)	Vol. 3 – B.6.4. Exposure data	FR: No data were generated for the child bystander (no measurements taken below 1.50 meters height) while it appears to be necessary to have some measurements at least at a reasonable infant height since the density of chloropicrin and phosgene is higher than that of air resulting in a higher concentration of both chloropicrin and phosgene at this height.	
(10)	Vol. 3 – B.6.4. Exposure data	FR: It appears that there is far less analytical data collected for phosgene than for chloropicrin. Information is lacking on kinetic and rate conversion from chloropicrin to phosgene in air. This information is needed for a more objective interpretation of these data and to ensure that the experimental conditions reflect the optimal conditions for this conversion process.	
(11)	Vol. 3 – B.6.4. Exposure data	FR: For operators and workers, the given maximum air concentrations are said "time weighted averages over the duration of exposure". Could you please clarify whether these values represent actual quantified data (over the actual time of exposure), or a weighting of the raw values? The same question applies to bystanders/residents	

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		("concentrations reported are time weighted averages over approx. 8h »).	
(12)	Vol. 3 – B.6.4. Exposure data	FR: Since the volatilization rate of gas from soil is highly dependent on soil type, could you please clarify the representativeness of the experimental grounds compared to the type of soil on which the claimed plants usually grow?	
(13)	Vol. 3 – B.6.4. Exposure data	FR: Many studies were performed outside the indicated period in the GAPs (June to September): study 14/2013 (shank injection), studies 12/2012, 13/2012 and CEMS-5732 (drip irrigation). The influences of these differences on the results need to be addressed.	
(14)	Vol 3 – B.6.4.1.2. Chloropicrin EC –drip irrigation. Table 30. Summary of samples collected.	FR: Could you please confirm that in table 30, for operator chloropicrin samples corresponding to the studies 12/2012, 13/2012 and 15/20013, we should read the value 13 instead of 26 (in accordance with the content of table 24)?	
(15)	Vol 3 – B.6.4.1.1. Chloropicrin 99 – shank injection/ B.6.4.1.2. Chloropicrin EC –drip irrigation.	FR: There is a lack of night time sampling of phosgene after DAT0. An argument needs to be added to address this point.	
(16)	Vol 3 – B.6.5. Exposure and risk assessment	FR: Since a buffer zone of 50m has been proposed as a mitigation measure for bystander/resident, until all concentrations of chloropicrin are below the AOEC, could you please clarify for how long this buffer zone should be maintained? The same comment applies to phosgene.	

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Section 2 – Effects on human and animal health

Other comments, incl comments on volume 4 (impurities, batches)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1 Level 2 Summary of available studies and 3 B.6 Tabulated summary and Overall summary Toxicology and metabolism data – RMS inhalation concentration conversion	FR: Agreed with the equation provided to convert external dose in ppm to mg/l. However, it seems that the correction for the exposed days per week was not considered by the RMS.	
(2)	Vol. 1 Level 2 and 3 B.6 general	FR: Please report in the summary tables, when necessary, both the local and the systemic NOAEL/C and LOAEL/C.	
(3)	Vol. 1 Level 2 Summary of available studies	FR: Please correct the LOAEC value of the mouse inhalation 90-day study from 0.54 to 0.96 mg/kg bw/d. To be noted also that these values would be lower when taking into account the correction for exposed days per week (see comment above).	
(4)	Vol.1 Level 2 2.10 classification and labelling	FR: Mortality was observed in several toxicity studies by inhalation at doses leading to STOT RE 1 H372. Therefore, this classification could be considered for chloropicrin.	

Section 3 – Residue data

3. Residue data

Storage stability of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.7.1. Tomato	FR: The storage stability of chloropicrin in tomato is not clear, sometimes 3 days and sometimes 4 days. Please clarify	

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Metabolism, distribution and expression of residues in poultry, lactating ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Residue definition			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Comments of France on the assessment report on Chloropicrin

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Section 3 – Residue data

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Feeding studies in poultry, ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Effects of processing			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Residues in rotational crops			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Summary of other studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

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Section 3 – Residue data

Estimation of the potential and actual exposure through diet and other sources			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.7.9. Estimation of the potential and actual exposure through diet and other sources	FR: Contrary to TMDI calculation, IESTI calculation had to be performed only for the intended uses.	
(2)	Vol. 1, 2.7.9. Estimation of the potential and actual exposure through diet and other sources	FR: Concerning exceedance of ARfD for orange, knowing that a no residue situation is expected, should it be preferable to use the LOQ at 0.005 mg/kg?	

Proposed MRLs and compliance with existing MRLs			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Proposed import tolerances and compliance with existing import tolerances			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. LoEP, Metabolism in	FR: Since the metabolism study on plants is not fully	

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Section 3 – Residue data

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	plants	validated, should it be mentioned in the LoEP?	

Section 4 - Environmental fate and behaviour

4. Environmental fate and behaviour

General comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8	FR (April, 2018): RMS should distinguish its own conclusions and opinions from the study summary and from notifier's conclusions for each study.	
(2)	Vol. 3, B.8, Appendix 2, Literature review	FR (April, 2018): Only 2 databases were consulted for the literature review proposed for chloropicrin and its metabolite DNCM. This seems low compared to current literature reviews provided.	

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol. 3, B.8.1.1, Route and rate of degradation	FR (April, 2018): Agrees that current European Guidelines may not fit the very specific characteristics of chloropicrin and in particular its very high volatility. Studies and endpoint determinations could be assessed using a consistent approach and weight of evidence.	
(4)	Vol. 3, B.8.1.1.1, McLaughlin, 2013a	FR (April, 2018): As reported for the active substance, the visual fits for the kinetic assessment performed for metabolite DNCM should be reported.	
(5)	Vol. 3, B.8.1.1.2, Photolysis in soil	FR (April, 2018): Agrees with RMS that a soil photolysis study may not be considered as required in the case of the very specific application method of chloropicrin. Weight of	

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Section 4 - Environmental fate and behaviour

Route and rate of degradation in soil				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
		evidence may apply.		
(6)	Vol. 3, B.8.1.1.3, Field studies	FR (April, 2018): No storage stability data for chloropicrin are available for field dissipation studies. RMS should mention this point.		

Adsorption, desorption and mobility in soil				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
(7)	Vol. 3, B.8.1.2.1, Adsorption in soil	FR (April, 2018): RMS should indicate for each adsorption study if a potential correlation between adsorption and soil characteristics is observed.		
(8)	Vol. 3, B.8.1.2.1, Penketh, 2008	FR (April, 2018): As stated by RMS, only 4 soils are considered acceptable in order to determine chloropicrin adsorption behaviour. Based on these 4 soils, a potential correlation of Kfoc and soil pH has been pointed out by RMS. However, all soil pH values (in water) are not exceeding 6.9 according to table B8.2-2. Additional alkaline soils should be provided by applicant in order to clarify the possible pH dependence for Kfoc of the active substance.		

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
(9)	Vol. 3, B.8.3.3, General	FR (April, 2018): Agrees with RMS considering that		

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Section 4 - Environmental fate and behaviour

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	comment on water/sediment studies	the data are sufficiently robust, considered the volatility of chloropicrin, in order to characterize the AS behaviour in water-sediment systems despite low mass balances. Weight of evidence may apply.	

PEC in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(10)	Vol. 3, B.8.2, PECsoil calculations	FR (April, 2018): Agrees with the approach proposed. It could be noticed that PECsoil values from deposition from the air can be considered negligible compared to PECsoil values from application to soil either by shank injection or drip irrigation.	

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(11)	Vol. 3, B.8.4.1, PECsw and PECsed calculations	FR (April, 2018): Different vapour pressure values are given for chloropicrin between sections. For PECsw and PECsed calculations in Step 3 (p.99), a vapour pressure of 4226 Pa is reported whereas a value of 2666 Pa (at 20°C) in section B.8.6.1 (p. 139). RMS should harmonize the values reported in the different sections.	
(12)	Vol. 3, B.8.4.1, PECsw	FR (April, 2018): Although the EVA tool is not very	

Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	and calculations PECsed	suitable for fumigant as explained in FOCUS guidance document AIR (2008), Tier 1 calculations should have been performed with EVA in order to address the potential surface water contamination from atmospheric deposition with a common and harmonized EU tool (like GW simulations were proposed with FOCUS tools). Experimental data could be used as a Tier 2 if refined PECsw calculations are required.	
(13)	Vol. 3, B.8.4.1, PECsw and PECsed calculations	FR (April, 2018): Agrees with RMS approach concerning the use of the experimental data for PECsw calculations.	
(14)	Vol. 3, B.8.4.2, PECgw calculations	FR (April, 2018): Agrees with RMS approach and comments. Although the suitability of both FOCUS models PEARL 4.4.4 and PELMO 5.5.3 for fumigants can be questioned, they are the only European models available for now in order to fulfil the EU requirement for groundwater risk assessment.	

Section 5 - Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol.3 B9. pp.4	FR: Could you please further define the term "Virtually Impermeable Plastic"? Is this meaning that the plastic is almost impermeable?	
(1)	Vol.3 B9.1.1 pp.72-74	FR: The applicant proposal to use Haber's law would be an interesting approach but we agree with RMS that no enough data are available to support it and reminds that the reliability of Haber's law has been criticised in literature. Thus FR agrees also to not consider this approach in the risk assessment. Moreover, a dilution factor could have been derived with at least one or two more sampling point at different distance. FR agrees with the RMS conclusion regarding the impossibility to conclude for the long term risk of inhalation exposure for birds.	
(1)	Vol.3 B9.1.2 pp.98	FR: FR agrees with the data gap proposed by RMS based on the lack of information regarding the toxicity for chronic exposure to inhalation pathway in the context of VIP removal and persistence of the active substance.	

Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Section 5 - Ecotoxicology

Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol.3 B9.3.1 pp.231-232	FR: The inhalation toxicity study is a reliable option for bees in the case of chloropicrin, especially regarding the persistence in air of the active substance after the VIF removal (as observed in operator study). The available endpoint covered the acute risk for inhalation for bees. It is FR opinion that without other data with longer exposure or with other development stage of bees, it would not be possible to have a robust conclusion of the effects of chloropicrin on bee colonies.	
(1)	Vol.3 B9.3.1 pp.231-232	FR: FR agrees with the conclusion of RMS regarding the non-target arthropods assessment. It is FR opinion that the off-field assessment exclusively performed for soil arthropods is not complete and addresses an acceptable risk only for bare soil off-field. FR suggests that further data or justifications should be provided to support that the existing data package would be sufficient to support a robust conclusion also for vegetated off-field considering also that no toxicity data are available for the representative species (<i>Typhlodromus pyri</i> and <i>Aphidius rhopalosiphii</i>).	

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Section 5 - Ecotoxicology

Earthworms and other non-target soil macro- and mesofauna			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3 B9.4.4 pp. 326	FR: Regarding the acute toxicity study on earthworms, FR agrees with conclusion of RMS.	
(1)	Vol.3 B9.4.4 pp. 327	FR: A criticism could be made regarding the airtightness of "food grade transparent film" used in Patnaude (2013). Indeed, this type of plastic film could be permeable to gas and this would explain the lack of recovery of chloropicrin at the beginning of the test. Could please RMS precise the grade of transparent film used in the study and if the food grade film used in this test can be considered impermeable to gas? Is it similar to those uses in field, with a similar impermeability? This should be considered before using the Patnaude (2013) study in the risk assessment	
(1)	Vol.3 B9.4.4 pp. 327	FR: FR agrees with the endpoint value based on initial mean measured concentration and the RMS conclusion regarding the absence of knowledge regarding the potential recovery of the earthworm, especially depending of the extent of treated area and the proposal of data gap for field uses.	

Soil nitrogen transformation			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		FR: No comment	

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Section 5 - Ecotoxicology

Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

Other non-target terrestrial organisms (flora and fauna)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol.3 B9.6.2 pp. 381	FR: FR agrees the RMS conclusion regarding the non-target plant risk assessment. Based on the specific behaviour and exposure pattern (chronic exposure in field) to non-target plants (NTP) to this substance, the provided study would not cover the exposure of NTP to this gas. Moreover, an explanation on the different opinions of RMS regarding the exposure of tested organisms via the air would be welcome. Indeed, it is not clear why the 1h inhalation exposure of bees is considered sufficient whereas the 2 x 6h exposure pattern for NTP is not.	

Biological methods for sewage treatment			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		FR: No comment	

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Section 5 - Ecotoxicology

Other comments incl. available monitoring data			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		FR: No comment	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 4, C.1.4.1.1. Introduction	EFSA: a small editorial, it is written: "Chloropicrin is formulated ...or an 'EC' formulation (96% chloropicrin TGAI)" it should be 94%	
(2)	Vol. 4, C.1.4.1.2. Residues Trials	EFSA: Please clarify LOQ for the chloropicrin and correct if it is needed 0.005 g/kg or 0.01 g/kg	
(3)	Vol. 4, C.1.4.1.2. Residues Trials, Magnitude of residues of chloropicrin, [REDACTED] [REDACTED] impurities in strawberries, zucchini, melon, tomatoes and pepper grown in protected fields following professional drip application in Italy in 2015, 2015	EFSA: Please check the levels of chloropicrin and DCNM. In the table are reported as <0.01 g/kg, however it seems that the methods have been validated with LOQs 0.005 g/kg as it is stated in <i>Discussion and conclusions</i> (p.49)	

Physical and chemical properties of the active substance			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 CA-CP, B.2.1.10 (IIA 2.5) Spectra	EFSA: Here it is reported: " $\lambda_{max} = 274.0 \text{ nm}$ $\epsilon = 321 \text{ mol}^{-1} \text{ cm}^{-1}$ "	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the active substance			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	(UV/VIS)	In LoEP is: "λ _{max} ,: 203.7 nm (ε1648), 274.0 nm (ε32)" Please check and correct where it is needed	

Physical and chemical properties of the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 CA-CP, 'Chloropicrin 99', B.2.2.14 (IIIA 2.7), Accelerated Storage Stability	EFSA agrees with RMS additional data is needed in relation with the accelerated storage stability of "Chloropicrin 99"	
(2)	Vol. 3 CA-CP, 'Chloropicrin EC', B.2.2.11 (IIIA 2.5) Surface tension	EFSA: Surface tension was determined using the technical material. Additional justification on the acceptability of the submitted study is required.	
(3)	Vol. 3 CA-CP, 'Chloropicrin EC', B.2.2.14 (IIIA 2.7), Accelerated Storage Stability	EFSA agrees with RMS data on the accelerated storage stability for "Chloropicrin EC" is required	
(4)	Vol. 3 CA-CP, 'Chloropicrin EC', B.2.2.14 (IIIA 2.7), Shelf life	EFSA: The final report on the 2 years shelf life study to be submitted including determination of the technical characteristics relevant for EC before and after storage	

Comments of EFSA on the assessment report on Chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 CA-CP, B.5.2. Analytical methods (residue) for treated plants, plant products, foodstuffs of plant and animal origin and feeding stuffs (IIA 4.2.1, IIIA 5.2)	EFSA: The methods presented could be considered as validated for high water and high acid content matrix groups, providing that the deficiencies pointed out by RMS are addressed.	
(2)	Vol. 3 CA-CP, B.5.2. Analytical methods (residue) for treated plants, plant products, foodstuffs of plant and animal origin and feeding stuffs (IIA 4.2.1, IIIA 5.2)	EFSA agrees with RMS a validated monitoring method for determination of residue definition in high oil content matrix is needed.	
(2)	Vol. 3 CA-CP, B.5.2. Analytical methods (residue) for treated plants, plant products, foodstuffs of plant and animal origin and feeding stuffs (IIA 4.2.1, IIIA 5.2), Method SXC0033	EFSA: Please clarify the reason of reporting method SXC0033. The method has deficiencies: no confirmatory method is present, matrix effects are not investigated. It is stated that the intention is the method to be an ILV of the LN96-A, however better validated method (S13-03747) is reported as an ILV for LN96-A.	
(3)	Vol. 3 CA-CP, B.5.3.1. Residues in soil (IIA 4.2.2) B.5.3.2. Residues in water (IIA 4.2.3) B.5.3.3. Residues in air (IIA 4.2.4)	EFSA: Level of the matrix effects needs to be addressed.	

Comments of EFSA on the assessment report on Chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	B.5.4. Analytical methods (residue) in human and animal tissues and fluids (IIA 4.2.5, IIIA 5.2)		
(4)	Vol. 3 CA-CP, B.5.5. Evaluation and assessment	EFSA: Thank you for the summary table. A few editorials: Please check LOQ for the method in water. Please express LOQ for the method in air in µg/m ³ Residue in body fluids could be determined by GC-ECD also (Airs, D 2009)	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.13.2. Definition of residues for monitoring, LoEP Residue definition for monitoring purposes p. 23 and p.97	EFSA: Please check and correct where it is needed the components of the residue definition in the environmental compartments. They are reported differently at different parts of DAR	

Section 2 – Mammalian toxicology

2. Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.1.1.1, ADME in rats by oral route, p.9	EFSA: It should appear in one of the tables how the oral absorption was estimated to be higher than 80% (based on table B.6.1.1-2, it could be considered to be only 75%, but it seems the tissue residues are missing).	
(2)	Vol. 3, B.6.1.1.2, Metabolism in mice, p.11	EFSA: In the available metabolism studies, chloropicrin is described as metabolised into dichlorodinitromethane and chloronitromethane. It seems that these metabolites were identified but not precisely quantified and therefore cannot be concluded as major metabolites of chloropicrin.	

Acute toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol. 1, 2.6.2, Summary of acute toxicity, p.34	EFSA: In the list of end points, for acute toxicity, a line should be added to report the result triggering the classification STOT SE Cat. 3.	
(4)	Vol. 3, B.6.2.1, Acute oral toxicity, p.16	EFSA: In the absence of a detailed acute oral toxicity study in the dossier, the more severe proposal for classification (Toxic if swallowed) is difficult to support. It is also noted that in the micronucleus test, the maximum dose administered is 250 mg/kg bw	

Section 2 – Mammalian toxicology

Acute toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		and is considered that maximum tolerated dose.	

Short-term toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(5)	Vol. 3, B.6.3, Summary of short term toxicity, p.71	<p>EFSA: For the 90-day rat/mouse inhalation study, the RMS concludes that the lowest dose of 0.3 ppm is the NOAEC (equivalent to 0.54 mg/kg bw per day for rats and 0.96 mg/kg bw per day for mice). The conversion from ppm to mg/kg bw per day should be further checked because it seems that the normalisation from 5 to 7 days per week was not done.</p> <p>Furthermore it should be kept in mind that a local LOAEC of 0.3 ppm was also identified in this study based on inflammatory lesions in lungs and nasal cavities.</p>	

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(6)	Vol. 3, B.6.4.2.1, In vivo micronucleus test, p.83	EFSA: Considering the results of the chromosome aberration test in CHO cells, it is important to demonstrate that the results of the in vivo micronucleus test can be relied upon. Based on the ADME data, the exposure of the bone marrow	

Section 2 – Mammalian toxicology

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		after oral administration of a single dose has been demonstrated (up to 47-48 ppm).	
Long-term toxicity and carcinogenicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(7)	Vol. 3, B.6.5.2, 2-yr inhalation rat study, p.99	<p>EFSA: For the changes in body weight gain during the first weeks of the study at 0.5 ppm, it is noted that in females (based on Table B.6.5.2-6), the change at 0.5 ppm is higher than 10% when compared to the control group and therefore should still be considered as adverse.</p> <p>It is acknowledged that the conclusion of the previous peer-review is maintained.</p>	
(8)	Vol. 3, B.6.5.3, 78-wk inhalation mouse study, p.114	<p>EFSA: The peribronchial lymphocytic infiltration at the low dose and the lung tumours at all doses are not considered adverse. Considering that the respiratory tract is a target organ for the toxicity of chloropicrin (including for humans), the relevance of the lung tumours should be further considered.</p> <p>It is noted that for the conversion from ppm to mg/kg bw per day, there will also be the need for normalisation for 5 days of exposure per week (to 7 days).</p>	

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Reproductive toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(9)	Vol. 3, B.6.6.1, 2-generation study, p.125	EFSA: During the first peer review, based on the tables B.6.6.1-3 and B.6.6.1-5, the increased incidences at the high dose of animals who died or were euthanised in extremis was considered potentially treatment-related.	
(10)	Vol. 3, B.6.6.2.1, Rat developmental toxicity study, p.139	EFSA: The calculation used for conversion of the inhalation levels (in ppm) to the systemic levels (in mg/kg bw per day) should also be briefly mentioned in this chapter.	
Further toxicological studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(11)	Vol. 3, B.6.8.3, Studies on endocrine disruption, p.167	EFSA: Has chloropicrin been screened with ToxCast for potential ED properties ?	
Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(12)	Vol. 3, B.6.8.1.1, Groundwater metabolites, p.160	EFSA: For the metabolite DCNM, it should be clarified what are the data (in the DAR) supporting that it was found at levels of approximately 20% of the parent. The considerations given in this chapter on the	

Comments of EFSA on the assessment report on Chloropicrin

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Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		toxicological profile of DCNM should be supported by more robust data in order to allow the conclusion that it is less toxic than chloropicrin.	

Toxicological end points: ADI, ARfD, AOEL, AAOEL			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(13)	Vol. 1, 2.6.13, AOEL for chloropicrin, p.41	EFSA: Consideration should have been given to the derivation of an AAOEL as well.	
(14)	Vol.1, Level 3, 3.1.1.4, Criteria for the approval, p.85, Impact on human health	EFSA: Considering the derivation of the AOEL, the limited uncertainty factor of 3 applied to a human study might not ensure an appropriate safety margin of at least 100.	

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(15)	Vol. 3, CP, B.6.4.1.1, Chloropicrin 99 – shank injection, p.4	EFSA: We support the idea that the 2 modifications introduced with the years should not be considered standard for all applicators and maximum reported values without these modifications should still be taken into account. It is noted that phosgene was not monitored in all studies, and the levels were reported at or below the LOQ. A worst case approach could be to	

Section 2 – Mammalian toxicology

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		consider phosgene as always present at the LOQ. With regard to possible standardisation of parameters, it could be appropriate to consider a workday with a duration of 6 or 8 hours.	
(16)	Vol. 3, CP, B.6.4.1.1, Chloropicrin 99 – shank injection, p.4	EFSA: It is noted that phosgene was not monitored in all studies, and the levels were reported at or below the LOQ. A worst case approach could be to consider phosgene as always present at the LOQ.	
(17)	Vol. 3, CP, B.6.4.1.2, Chloropicrin EC – drip irrigation, p.19	EFSA: The duration of the worker exposure might have been extended to 6 or 8 hours per day.	
(18)	Vol. 3, CP, B.6.4.1.2, Chloropicrin EC – drip irrigation, p.19	EFSA: Considering the Table 32, it might be realistic to sum up the exposures measured for the different activities, knowing that in some countries, the same worker might perform all activities.	
(19)	Vol. 3, CP, B.6.4.1	EFSA: It should be clarified why the previously submitted field studies (eg by Trevisan) have been discarded from the exposure assessment.	
(20)	Vol. 3, CP, B.6.4.2, Bystander and resident exposure, p.34	EFSA: It is noted that the measured values during the field studies could potentially underestimate the exposure of children since they were not done below 1.5 m height. How has this been taken into account for the bystander/resident exposure assessment ?	

Section 2 – Mammalian toxicology

Other comments, incl comments on volume 4 (impurities, batches) and proposals for classification			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(21)	Vol. 4, C.1.2.2, Identity of impurities, p.7; and C.1.2.5, Proposed specification, p.25; and C.1.4, Information on the batches used for the mammalian toxicity tests, p.26	EFSA: Pending confirmation of the acceptability of the technical specification at the end of the commenting period, further consideration might need to be given to the toxicological relevance of the potential impurities and to the representativeness of the batches used in the toxicity studies.	
(22)	Vol. 3, B.6.11, References relied on, p.181	EFSA: It is briefly mentioned that a literature review has been done. A more detailed assessment of this literature review should be provided in a revised DAR, demonstrating that it has been performed in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). A clear description should be given for the search terms, the selection criteria (to identify relevant articles) and the reliability criteria that have been applied to each selected article, in order to determine a weight of evidence for comparison with regulatory studies.	

Section 3 – Residue data

3. Residue data

Storage stability of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.7.2, Storage stability in strawberries	EFSA: According to SANCO guideline 7032/VI/95 rev.5 individual results should not be corrected to 100 % yield. The procedural recoveries for the corresponding days are all in the range of 79 to 83 % indicating sufficient performance of the analytical method. However, the recovery rates in strawberries indicate that the stability of dichloronitromethane in this matrix is limited to only 1 day as the recovery at day 2 is already below 70 % (68%).	

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.1, Metabolisms, Distribution and expression of the residues in plants	EFSA: possible metabolism of chloropicrin including possible metabolites should be discussed.	

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.6.1-6,	EFSA: Although the field trials are very detailed	

Section 3 – Residue data

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	Residues arising from supervised trials	described information is requested on the location of the trials. Currently only the region is given and thus it cannot be concluded whether the trials can be considered as independent. Pls report – also for the greenhouse and protected (polytunnel) trials the exact location.	
(2)	Vol. 3, B.7.6.3, Residues arising from supervised trials, strawberries	<p>EFSA: It is reported that in one trial with strawberries chloropicrin was detected at an estimated level of 0.2 ug/kg thus a 'zero' residue situation is not given as this would imply that "no detectable residues occur in studies with exaggerated application rates compared to the envisaged ones."</p> <p>Is information available to verify that the observed signal in the chromatogram is the active substance, e.g. analysis with GC-MS?</p>	
(3)	Vol. 3, B.7.6.1, Residues arising from supervised trials, tomato	EFSA: In the report LN95 of the field trials with tomato it is stated that samples arrived in the lab at 9/3 and 30/3 and were analysed for chloropicrin and dichloronitromethane at 17/3; 26/3 and 1/4 resulting in storage periods > 3 days. This seems to be in contrast to the information given in the DRAR in table B.7.6.1-1 (page 25). Pls clarify.	
(4)	Vol. 3, B.7.6.8, Summary	EFSA: It is noted that trials for all proposed crop	

Section 3 – Residue data

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	of residues arising from supervised trials	commodities grown in glasshouses and in "existing protected structure greenhouse/walkin tunnel" are performed only Sicily and Liguria. It is debatable whether these trials restricted to 2 locations in one country of the SEU can be regarded as representative for all European areas as e.g. outside temperature in this region might not represent the most critical conditions for SEU and NEU given the relatively high volatility of the active substance.	
(5)	Vol. 3, B.7.6.8, Summary of residues arising from supervised trials	EFSA: It is noted that critical GAP compliant trials are not provided for open field applications (both SEU and NEU) for any of the proposed crop commodities with the exception of the two trials for tomatoes which cannot be considered independent as they were performed in the same location.	
(6)	Vol. 3, B.7.6.8, Summary of residues arising from supervised trials	EFSA: It is noted that in all trials for all proposed crop commodities are performed as drip application tarpred except for one trial where the active substance was applied to tomato via Shank injection, tarpred. However, this trial is not according to the critical GAP Evidence should be provided that both application forms lead either to the same residue situation or that the drip application can be regarded as more critical.	

Section 3 – Residue data

Residues in rotational crops			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.2, Metabolims, Distribution and expression of the residues in rotational crops	EFSA: A study of metabolism in rotational crops might be necessary depending on the outcome of discussion on the residue field trials.	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.19. References relied on	EFSA: A the justification for choosing the databases for the literature search should be provided together with information on the main focus of the searched database.	
(2)	Vol.4, C. 1.4.1, consideration of residues of impurities from the TGAI in food commodities	EFSA: Are the analytical methods used to determine the impurities B, C, D and F in tomato and strawberries validated for all impurities and matrices. If so what are the performance characteristics of the analytical method?	
(3)	Vol.4, C. 1.4.1, consideration of residues of impurities from the TGAI in food commodities	EFSA: Are stability data of the eight impurities in food available?	

Section 4 – Environmental fate and behaviour

4. Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation 1).Craine, E.M. 1985	EFSA: It is agreed that results of study Craine, E.M. 1985 cannot be used to derive assessment end points, mainly due to the difficulty to guarantee that no losses occurred taking into account that no radiolabelled material is used and volatility of the substance and its potential metabolites.	
(2)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation. Hatton C, shepler K., Ruzo L. 1995.	EFSA: The determination of DegT50 in this study is a reasonably realistic worst case and usually the accepted method for DegT50 determined from laboratory studies in the case of volatile substances. Excluding the amount of chloropicrin in the volatile trap (foam plug) will result on a DissT50 not a DegT50. This study gives supporting indications that nitromethane and chloronitromethanol are likely to be metabolites down in the route of degradation of chloropicrin.	
(3)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation. Voekel, W. 2004.	EFSA: The aerobic degradation study in soil (Voekel, W. 2004) was already considered in the previous assessment of chloropicrin. It is noted that a slight different end point than the previous agreed is proposed for the soil IV Senozan (silty clay loam) probably due to the use of non-linear fitting vs previously derived values by linear regression. Also it is noted that for the exposure assessment the	

Section 4 – Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>soil with longest DT50 (soil II) has been discarded as an outlier. However, the reason does not seem to be fully justified in the evaluation of the study. In a more modern study (McLaughlin, S. 2013a, see comments below), important losses of volatiles (either parent or metabolites) are observed not being possible to close an acceptable mass balance. Since in this study material balance was not accounted, it cannot be excluded that a significant fraction of the losses observed are actually volatilization instead of degradation. Therefore, it is doubtful the DT50 can be considered to represent pure degradation.</p>	
(4)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation 4). McLaughlin, S. 2013a.	<p>EFSA: In chloropicrin aerobic degradation study (McLaughlin, S. 2013a), recoveries significantly below of 90 % are the symptom of a failure on the experimental methodology. Without an adequate explanation of the losses the study should be discarded and not used for deriving kinetic end points. The presumed volatile metabolite would need to be identified.</p> <p>Despite to the losses metabolite DCNM can be confirmed as a major soil metabolite by the data in these experiments considering the amounts quantified should be taken as lower values in the actual range.</p>	
(5)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of	EFSA: In metabolite DCNM aerobic degradation study (McLaughlin, S. 2013b), recoveries	

Section 4 – Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	degradation in soil. Aerobic degradation. Metabolite DCNM McLaughlin, S. 2013b.	significantly below of 90 % are the symptom of a failure on the experimental methodology. Without an adequate explanation of the losses the study should be discarded and not used for deriving kinetic end points. The presumed volatile metabolite would need to be identified.	

Adsorption, desorption and mobility in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(6)	Vol. 3, B.8.1.2 Adsorption, desorption and mobility in soil (IIA 7.1.3, IIA 7.1.4). Metabolite DCNM. Kang, S., 2013	EFSA: In the summary of study Kang, S., 2013 on the adsorption desorption of DCNM in soil it is stated that the tested substance was stable under the tests conditions. However, no evidence seems to have been provided. Evidences on the stability of the test substance under the test condition should be required to the applicant and summarized in the RAR.	

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(7)	Vol. 3, B.8.3.5. Impact on water treatment procedures.	EFSA: Regulation (EC) No 1107/2009 requires in its approval criteria that 'it shall have no immediate or delayed harmful effects on human health,	

Section 4 – Environmental fate and behaviour

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		including that of vulnerable groups, or animal health,through drinking water (taking into account substances resulting from water treatment). Further data, or a more elaborate and detailed case, is needed on the impact of water treatment procedures may have on residues of chloropicrin.	

PEC in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(8)	Vol.3. B.8.2 PEC soil.	EFSA: The DT50 of 8.8 d has been used to refine PEC soil arguing the worst case in Voelkel (2004) of 26.9 d was an outlier (due to low microbial activity). Independently of other issues identified with this study (as lack of mass balance determination) it does not seem that authors of the study found soil II had to be discarded. In addition, since there is serious doubts on the acceptability of the values derived from study McLaughlin, S. 2013a, the exclusion of soil II in Voelkel (2004) may result on reducing the data set for the active substance to only three soils and the identification of a data gap (and the need to use DT50 = 8.8 d for the rest of the exposure assessment instead of the geometric mean).	

Section 4 – Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(9)	Vol. 3, B.8.4.1 PEC SW	EFSA: The results of the PEC SW calculations are very dependent on the DT50 soil, since only the amounts remaining after the covered period contribute to the loads to surface water. Therefore, PEC SW may need to be recalculated once the issues identified during the peer review, with respect to the studies of degradation in soil, are clarified. Specially, in relation to the STEP 4 calculations for which the longest DT50 is proposed to be removed from the set used for geometric mean calculation as an outlier.	
(10)	Vol. 3, B.8.4.1 PEC SW Step 4. VBS	EFSA: 20 m vegetated buffer zones have been assumed in the Step 4 calculations. It should be noted that according FOCUS SW, efficacy of such risk mitigation measures is not demonstrated for substances with mobile as chloropicrin.	
(11)	Vol. 3, B.8.4.1 PEC SW Atmospheric deposition.	EFSA: Atmospheric deposition has been calculated on basis of data from operators and bystanders exposure on air concentration at 1m and 50 m. However, to be used for the environmental assessment values at other distances (eg. 10 m and 20 m) would be needed to be in line with possible mitigation buffer zones. Values obtained would need to be added to the loads by drainage and run off.	
(12)	Vol. 3, B.8.4.2 PEC GW	EFSA: the presumption that there is not significant leaching or downwards movement of chloropicrin during the time the soil is covered is not realistic. By its nature chloropicrin may distribute to over	

Section 4 – Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		the upper soil horizons even in the absence of leaching water. In addition the water entering laterally to the field can increase this effect and cannot be precluded without further data. For the drip irrigation applications, according GAP table, water is added in high amounts at the precise moment of application.	
(13)	Vol. 3, B.8.4.2 PEC GW	EFSA: The results of the PEC GW calculations are very dependent on the DT50 soil, since only the amounts remaining after the covered period contribute to the leaching to ground water. Therefore, PEC GW may need to be recalculated once the issues identified during the peer review, with respect to the studies of degradation in soil, are clarified.	
(14)	Vol. 3, B.8.4.2 PEC GW. Drip application. Refinement of injection depth to 5 cm	EFSA: For the reasons given in a comment above, assuming the application depth as 0 cm is not realistic even for the drip application. Movement of chloropicrin through the upper soil horizons during the time soil is covered cannot be excluded. Actually, it seems is necessary in order the treatment is efficacious. For the same reasons the “refinement” by reducing the injection depth to 5 cm seems also not realistic, since even if the injection is produced at this depth chloropicrin will move deeper during the time the soil is covered.	
(15)	Vol. 3, B.8.4.2 PEC GW.	EFSA: considerations by the RMS in relation to the reliability or representativeness of the values	

Section 4 – Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		obtained by FOCUS GW model for a substance of the characteristics of chloropicrin are agreed. Whether the values calculated can be considered representative worst cases for the respective scenarios may be subject to discussion.	
(16)	Vol. 3, B.8.4.2 PEC GW.	EFSA: Study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004. (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions.) presented in the ecotox section needs to be summarized in fate chapter and be considered with respect to its implications for the soil and ground water assessment.	
(17)	Vol 4, PEC GW of relevant impurity [REDACTED]	EFSA: Most of the comments relevant to the PEC GW calculations for the parent and soil metabolite are also applicable to the calculations produced for main relevant impurity [REDACTED]. In addition, the fact that input parameters are modelled, add extra uncertainty to the results. As shown by the RMS, an increase in the DT50 will result on a number of scenarios exceeding 0.1 µg/L. the same is likely to happen if the Koc is reduced (for example by using the one of [REDACTED]).	
(18)	Vol 4, PEC GW Impurities.	EFSA: It seems other impurities identified besides [REDACTED] may be considered toxicologically	

Section 4 – Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		relevant and need to be assessed for groundwater exposure.	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(19)	Vol. 3, B.8 Appendix 2. Literature search.	EFSA: Surface water metabolites chloronitromethane, nitromethane, iminodimethanethiol thiocianic acid are not covered by the literature search.	
(20)	Vol. 3, B.8 Appendix 2. Literature search.	EFSA: The five papers found relevant for the fate section, would need to be summarised and assessed in the RAR. Otherwise, there is no transparent support to the claim that the data in these studies does not supersede other experimental data in the dossier.	

Section 5 - Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
5(1)	Vol. 3, B.9, B9.1.1 p11	EFSA: No negative control is used in study [REDACTED] (2009a), please note that this is not in line with the test guideline OECD 223. While it is acknowledged that no mortality was seen for the lowest six doses (when combining stage 1, 2, and 3), this still represents a significant deviation from the guideline. Hence the use of the endpoints from this study for RA should be further discussed.	
5(2)	Vol. 3, B.9, B9.1.1 p11	EFSA: Only males were tested in study [REDACTED] (2009a). The RMS indicated equal sensitivity of sexes based on [REDACTED] (2009b). However, this is based on one dose only (for both formulation) and a rather restricted number of organisms (5x2 for each sex). As such, the hypothesis of equal sensitivity might be challenged.	
5(3)	Vol.3, B9.1.1, study IIA 8.16.2./01 (Bartolomè, 2009)	EFSA: the RMS has stated that the application rate in the study (272 L/ha) exceeds the maximum proposed rate of 227 L/ha (equivalent to 376 kg a.s./ha). However, we were not able to find anywhere the proposed application rate in terms of L/ha. It would be more transparent to include how this value was obtained.	
5(4)	Vol. 3, B.9.1.1.1. Acute bird risk assessment, risk	EFSA: In the acute risk assessment for inhalation, the RMS chose to use the LC50 value from	

Section 5 - Ecotoxicology

Birds and other terrestrial vertebrates			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	via inhalation	████████ (2008). While this seems logical, in lack of a specific risk assessment scheme for inhalation, further discussion on this approach might be needed. Please note that this comment is also applicable to mammals.	
5(5)	Vol. 3, B9.1.1, Summary of avian toxicity data	EFSA: In table 9.1.1-28, the RMS used a conversion from ppm to mg a.s./m ³ for the endpoint from █████ (2008). Please explain the conversion factor.	
5(6)	Vol. 3, B.9, B9.1.1	EFSA: It was noted that the draft OECD Test Guideline for Avian Reproductive Toxicity Test in the Japanese Quail or Northern Bobwhite (2000) was used. It needs to be considered that this Guideline is not among those listed in the Commission Communication related to the data requirements. As the exposure in this guideline is considerably shorter than the more commonly used OECD 206 (6 vs. 20 weeks), its relevance for the present risk assessment needs to be further discussed.	
5(7)	Vol. 3, B.9, Table B9.1.1-10	EFSA: LC50 value under Table 9.1.1-10 should be reported as a 'greater than' value (i.e. > 562 ppm a.s.)	
5(8)	Vol. 3, B.9, Table 9.1.2-1	EFSA: NOAEC from study █████ (1993a) is < 0.3ppm (from B6) not =0.3ppm (in the table in part B9)	
5(9)	Vol. 3, B.9	EFSA: Inhalation studies for birds and mammals are generally not required. This substance has clearly peculiar characteristics, so the inhalation data and	

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Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		a risk assessment are appreciated. However, as no standard methods exist, the whole appropriateness of the approach needs to be discussed.	
5(10)	Vol. 3, B.9, Table 9.1.2-1	EFSA: We have noted that the dataset does not include any 2-generation test for oral toxicity. As this is normally the most relevant study type for setting the reproductive dietary endpoint, the current setting of the endpoint can be challenged.	
5(11)	Vol. 3, B.9, B.9.1.2.	EFSA: It is noted, that Bartolome (2009) study was used for refinement in RA. Considering the specificity of the substance and its application techniques, we agree that it is appropriate to use specific residue data in the risk assessment. Nevertheless, the choice of the values to be used in both the acute and chronic dietary risk assessment should be further discussed.	
5(12)	Vol. 3, B.9,	EFSA: For drip irrigation, why were the two studies by Gao et al. (2004, 2008) only included in the appendix of the RAR? If these are providing relevant information, complete study summaries and RMS evaluations should be included in the main text. Also, please note that these studies were not presented in the environmental fate part. Only when this information is appropriately peer reviewed, there could be an agreement about the extrapolation of the Bartolome (2009) study for the drip irrigation uses.	
5(13)	Vol. 3, B.9, B9.1.1. drinking water risk	EFSA: For the puddle scenario (risk via contaminated drinking water) where contamination was	

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Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	assessment	assumed via deposition, we believe that the performed calculations should be further justified. For example, why was deposition only calculated from protected uses? Why only over 24 hours? Please note that this comment is also relevant for mammals.	
5(14)	Vol. 3, B.9.1.2.1, Toxicity to mammals, table 9.1.2-1	EFSA: The unit for the acute endpoint (from Pesticide Manual) is not correct (should be mg a.s./kg bw).	
5(15)	Vol. 3, B.9.1.2.1, Acute mammal risk assessment	EFSA: In general, refining the DT ₅₀ of residues on food items is considered appropriate. We also consider appropriate to fit only the decrease part of the available dataset. However, we believe that when doing this operation, it is better to re-calculate time by fixing t=0 when the maximum residue was measured. It is acknowledged that this would not result in major inconsistencies when SFO is used (the largest difference is still very small in this case - for barley seeds we have calculated a DT ₅₀ of 1.27 days instead of 1.07 days), but it might be more relevant when the dissipation follows 2nd order kinetics.	
5(16)	Vol. 3, B.9.1.2.1, Acute mammal risk assessment	EFSA: We disagree with the setting of different endpoints for different tiers of the assessment. Please note that during the ecotox general meeting (Pesticide Peer Review Meeting 133), it was decided that a unique ecotoxicologically relevant endpoint should be chosen and used consistently in the risk assessment. In addition, we are not fully convinced about the choice of the	

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Birds and other terrestrial vertebrates			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		RMS to increase the previously agreed endpoint by one order of magnitude. This may need further discussion.	

Aquatic organisms			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(17)	Vol. 3, B.9, B.9.2.5	EFSA: in the chronic study with daphnids (Jenkins , 2009) geometric mean measured concentrations were calculated to estimate the exposure. There was, as expected, a clear issue with the concentration maintenance. In addition, only few measurements in time were performed, often resulting below the detection limit. On the other hand, for the concentration representing the NOEC the analysis were always resulting in a quantifiable level of the substance.	
5(18)	Vol. 3, B.9, Table B.9.2.9-1	EFSA: Jenkins study is from 2009	
5(19)	Vol.3, B.9.2.6. Effects on algal growth, study IIA 8.4/01 (Flatman, 2004d)	EFSA: It is not clear whether all validity criteria listed in the new version of OECD 201(2011) guideline were respected in the study. In the study summary only reference to the criteria of the previous version of the guideline (1984) are mentioned.	
5(20)	Vol.3, B.9.2.6. Effects on algal growth, study IIA 8.4/01 (Flatman, 2004d)	EFSA: Analytical measurements are too scattered for a reliable definition of the actual concentrations tested. Nevertheless, we don't believe that using	

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Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		nominal concentrations is by any means better in this situation. The actual suitability of this study for risk assessment purposes should be questioned.	
5(21)	Vol.3, B.9.2.7. Effects on aquatic macrophytes, study IIA 8.6/01 (Wilby 2009b).	EFSA: Analytical measurements are scattered and often below the LOD. The reliability of the calculated geometric mean measured concentrations for establishing the experiment endpoint should be further considered.	
5(22)	Vol. 3, B.9, B.9.2.10.5	EFSA: Pending on the discussion in the environmental fate section, some refinement of PEC values in FOCUS Step 4 with buffer strip may not be considered appropriate.	
5(23)	Vol. 3, B.9, B.9.2.9	<p>EFSA: Some of the endpoint estimation for some metabolites are based on extremely small dataset, for which a proper regression is either very unreliable (e.g. DCNM toxicity to algae, based on a halonitrite dataset of 2 points) or even impossible (toxicity of isothiocyanic acid to daphnids and algae, based on a imides dataset consisting of one data point?).</p> <p>Furthermore, the EFSA (2013) guidance recommends to follow a scheme for the application of QSAR estimation which encompasses several steps, including an analysis of the validity of the model (e.g. predictive capacity), whether the modelled substance is within the domain of the model, etc.</p> <p>In this case, the QSAR were used in a kind of weight of evidence approach, which is also foreseen in</p>	

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Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		the EFSA guidance document. Nevertheless, in such case, the guidance recommends to provide estimations from different models. Use of other models to confirm the prediction obtained with ECOSAR would increase the confidence of the present estimations, particularly for those based on very small data sets.	
5(24)	Vol. 3, B.9, p 207	EFSA: for some scenarios/crop combinations, a high risk is still predicted despite the application of mitigation measures.	

Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
5(25)	Vol. 3, B.9.3.1. Effects on bees, study IIA 8.7/01 (Porch, 2009)	EFSA: Vapour exposure studies are generally not requested. This substance is highly volatile, so the vapour exposure study is appreciated. However, as no standard methods exist, the setup of the study and its use in the risk assessment need to be further discussed.	
5(26)	Vol. 3, B.9.3.1. Effects on bees, study IIA 8.7.1/01 (Patnaude, 2010)	EFSA: This study presents several shortcomings. First of all, the solvent control showed high mortality, more than the allowed 10%. This might be due to an amount of acetone larger than the recommended. The positive control also showed a higher effect than expected. This means that validity criteria were not entirely met. However, the biggest issue is that the exposure to	

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Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<p>the test item was not confirmed. Due to the volatility of the a.s., it is not clear whether the authors took sufficient measures to ensure that the bees were actually exposed to the nominal doses. The lack of visible effect at all concentration tested is odd, when considering the toxicity shown by this chemical to other invertebrates (e.g. other NTAs, aquatic invertebrates, etc.).</p> <p>The final assessment of this study from the RMS is not clear: in vol.3 B9 it was stated that "the reliability of this study is considered to be limited". However, the study endpoint does not appear in the LoEP. If the RMS considers the study to be invalid, this should be clearly mentioned in the assessment.</p>	
5(27)	Vol. 3, B.9.3.1, Acute oral toxicity, Table 9.3.1-4.	EFSA: In the Patnaude (2010) study, there are inconsistencies between the replicates and the average mortality after 24 and 48h exposure to 50 µg a.s./bee. Please align.	
5(28)	Vol. 3, B.9.3.1. Effects on bees, study IIA 8.7.2/01 (Patnaude, 2011)	<p>EFSA: This study presents several shortcomings. First of all, the solvent control showed high mortality, more than the allowed 10%. This might be due to an amount of acetone larger than the recommended. The positive control also showed a higher effect than expected. This means that validity criteria were not entirely met.</p> <p>It should be pointed out that this test might not be fully relevant for highly volatile substances, as the</p>	

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Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		test item is likely to dissipate before being taken up by the bees.	
5(29)	Vol. 3, B.9.3.1. Effects on bees, Risk via oral consumption and contact exposure	EFSA: The calculated HQ for acute contact is above the trigger value, indicating a potential risk. Although the conclusion of the RMS that 'an acceptable risk to bees via contact exposure can be concluded based on minimal exposure' seems reasonable, there might be the need to discuss this further. Note that the same comment applies to the risk assessment for oral exposure.	
5(30)	Vol. 3, B.9.3.1. Effects on bees, p. 231	EFSA: It is unclear how the conversion factor of 24.45 to convert ppm concentrations to mg/m ³ was derived. Please provide explanation	
5(31)	Vol. 3, B.9.3.2. Effects on non-target arthropods	EFSA: No standard tests for tier 1 testing with <i>Aphidius rhopalosiphi</i> and <i>Typhlodromus pyri</i> are performed, HQ calculation for tier 1 tests is therefore not possible.	
5(32)	Vol. 3, B.9.3.2. Effects on non-target arthropods	EFSA: Application of chloropicrin is non-standard as it is injected in bare soil. It is noted that the application methods for the reference materials used in all NTA studies are not comparable to the application method for chloropicrin. The study design and use of reference material should therefore be further discussed. This comment applies to all NTA studies performed.	
5(33)	Vol. 3, B.9.3.2. Effects on non-target arthropods, IIA 8.8.1.3/04 (Gray, 2004a)	EFSA: There is inconsistency in the reporting of the reference item. Both dimethoate and decis (deltamethrin) are mentioned in different parts of the study summary.	

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Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5(34)	Vol. 3, B.9.3.2. Effects on non-target arthropods, IIA 8.8.2.3/01 (Sharples, 2004b)	EFSA: It is noted that in the Sharples 2004b study spiders were used that were collected in autumn. Based on the application time of chloropicrin (june-september) over-wintered spiders should be used, as described in ESCORT2. As over-wintered species are more sensitive, endpoints used in RA may underestimate risks. The use of this endpoint should be further discussed.	
5(35)	Vol. 3, B.9.3.2. Effects on non-target arthropods, IIA 8.8.2.3/01 (Sharples, 2004b) and IIA 8.8.2.3/02 (Gray, 2004b)	EFSA: It is noted that data on reproduction effects is missing in the aged residue studies from Sharples (2004b) and Gray (2004b). The ESCORT2 guidance states that reproduction assessments should be included in aged residue studies. Please provide the missing data.	
5(36)	Vol. 3, B.9.3.2.2, Effects on non-target terrestrial arthropods in extended laboratory/semi –field tests	EFSA: For all the three available aged residue studies, it is not clear when the animals were inserted in the test system. Was that when the tarp was removed?	
5(37)	LoEP, bees risk assessment	EFSA: the final risk assessment for oral and contact exposure is not included in the LoEP, while being qualitatively presented in vol. 3 B9. This should be aligned.	
5(38)	LoEP, bees risk assessment	EFSA: the final conclusion of the risk assessment for inhalation should be briefly reported in the LoEP.	
5(39)	LoEP, NTAs risk assessment	EFSA: The outcome of the risk assessment considering the aged residue tests is not clear in the LoEP. It might be useful to add a short	

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Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		conclusion also there.	

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
5(40)	Vol. 3, B.9.4.1 Earthworm – acute effects, study IIA 8.9.1/01, Rogers (2004)	EFSA: In table 9.4.1-2, header of columns "Percentage (%)" and "Number of mortalities" seem to be swapped.	
5(41)	Vol. 3, B.9.4.2 Earthworm – acute effects, study IIA 8.9.2/01, Patnaude (2013)	<p>EFSA: The setting on the NOEC at 11 mg a.s./kg is questionable, as the number of surviving offspring was considerably reduced at all concentrations (even if not significantly in statistical terms at 11 mg a.s./kg).</p> <p>When assessing this, it should also be considered that the lack of dose-response for the three lowest nominal concentrations might be driven by an overlap in terms of actual exposure. Indeed, at those levels, all measured soil concentrations were either below or slightly above the LOQ at the beginning of the exposure phase. Particularly, at 3.6 mg a.s./kg, all analytical verifications resulted in concentrations below the LOQ and at 11 mg a.s./kg, values below the LOQ were recorded for two out of three samples. In the RAR, averages concentrations were calculated using LOQ/2, when values were below the LOQ. In principle, this approach is considered correct,</p>	

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Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>nevertheless, the observed lack of dose-response should be carefully considered in this case, as there are serious limitations to a reliable quantification of the exposure.</p> <p>We suggest that no reliable NOEC (nor ECx) could be derived from the present study.</p>	
5(42)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other soil macro-organisms	EFSA: It is not clear why the RMS has decided not to apply the correction factor of 2 despite the LogP of chloropicrin being higher than 2.	
5(43)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other soil macro-organisms	<p>EFSA: The approach presented in the RAR to demonstrate the potential for recovery of earthworms is not agreed upon. First of all, there are serious concerns about the selection of the NOEC from the Patnaude (2015) study, which was not corrected despite the LogP of the substance, and was then compared to the foreseen PEC until 100 days after the application.</p> <p>In addition, as already highlighted by the RMS, such comparison would anyway be not sufficient to demonstrate a recovery potential, as earthworms are characterised by extremely slow movements, and as there are also still uncertainty regarding possible contaminations (particularly due to lateral movements) of areas surrounding the treated field.</p> <p>Without more appropriate data, we don't believe that a low risk is demonstrated.</p>	
5(44)	Vol. 3 B.9.4.4. Risk	EFSA: The approach presented in the RAR to	

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Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	assessment for earthworms and other soil macro-organisms	<p>demonstrate the potential for recovery of other soil organisms is not agreed upon. No NOEC is available for Hypoaspis, and it is noted that the endpoint for Folsomia was not corrected despite the LogP of the substance.</p> <p>Most importantly, the available studies can only be used to derive a suitable (with some uncertainty) time frame to determine when a potential recovery can start. This is not equivalent to demonstrate a recovery. With the available data, we don't believe that a low risk to other soil organisms has been demonstrated.</p>	
5(45)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other soil macro-organisms	EFSA: As a high risk is concluded for the parent, the risk assessment for chloropicrin cannot "cover" for the metabolite DCNM	
5(46)	LoEP	EFSA: the time scale for all earthworm chronic studies is reported to be 28 days, while it should be 56 days.	
5(47)	LoEP	EFSA: the endpoints reported for the third line of the table have a wrong unit (676 kg a.s./kg should be 676 mg a.s./kg)	

Soil nitrogen transformation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
5(48)	Vol. 3, B.9.5, Risk	EFSA: We agree with the conclusion of the RMS that	

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Soil nitrogen transformation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	assessment for soil micro-organisms	<p>the study from Carter (2009) is not sufficient to demonstrate a low risk for soil micro-organisms. In addition to the uncertainties already discussed by the RMS in the RAR, it should be noted that the soil aged in the field has been strongly manipulated (sieved) before the start of the lab test. This has the potential to have a significant effect on the residues in the soil.</p> <p>Furthermore, the test itself can be considered a laboratory one, as only the treatment and the aging was performed in the field, while the quantification of C and N transformation was done under controlled conditions, and after 3-6 days of acclimatisation. As such, we don't see particular justification for the variability observed among control replicates.</p>	
5(49)	Vol. 3, B.9.5, Risk assessment for soil micro-organisms	EFSA: As a high risk is concluded for the parent, the risk assessment for chloropicrin cannot "cover" for the metabolite DCNM	

Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
5(50)	Vol. 3, B.9.6, Risk to non-target terrestrial plants from representative uses of chloropicrin	EFSA: we agree with the conclusion of the RMS that the available data are not sufficient to demonstrate a low risk to NTTPs from the intended uses of chloropicrin, particularly	

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Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		concerning the mismatch between the length of the exposure used in the effect study and the potential length of the exposure in the field.	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
5(51)	Vol. 4, C.1.4.2. Consideration of Impurities in the active substance material	EFSA: As the RMS specified in the RAR: "The high application rate of chloropicrin means that impurities in the active substance material may be applied to the soil in significant amounts". Indeed, at least 4 impurities were found to be applied in several grams per hectare (up to >300 g/ha - see table C.1.5.1.3-2). Why this issue was not considered for the environmental risk assessment?	

Comments of applicant on the assessment report on chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Physical and chemical properties of the active substance			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Physical and chemical properties of the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.2.2.14 (IIIA 2.7), Storage stability, 'Chloropicrin 99'	Applicant: It is appreciated the cited study was not run for the advised length - 2 weeks at 54 °C - to emulate storage at ambient temperature for two years, but this reflects the age of the study. The accelerated study, run for 7 days at 54 °C (C. M. Sparacino, 1994), found the test item to be stable after storage: the study found a (relatively small) 1.5% reduction in chloropicrin content, and the test item was also stable in other endpoints measured. If this study was extended for a further 7 days, it would be expected that the formulation would remain within acceptable limits, assuming a linear rate of degradation. Additionally, existing data confirms this	

Comments of applicant on the assessment report on chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		formulation is stable for up to 35 months at ambient temperature, and the 2011 EFSA conclusion set no requirement for an additional study to be conducted to address the elevated temperature storage endpoint. It is therefore considered that a new accelerated study for 14 days is not necessary since existing data demonstrates the formulation to be stable at elevated temperatures.	
(2)	Vol. 3, B.2.2.15 (IIIA 2.7), Storage stability, 'Chloropicrin EC'	Applicant: Chloropicrin 99 data confirms this formulation is stable for up to 35 months at ambient temperature (Chloropicrin 99, B.2.2.15), and the difference in composition between both representative formulations is slight: Chloropicrin EC contains an additional 60 g/kg surfactant only. It is therefore considered that Chloropicrin 99 storage data can be used to support the registration of Chloropicrin EC, endorsing the stability of Chloropicrin EC for two years at ambient temperature, so it can be concluded that Chloropicrin EC is stable at ambient temperature for two years when stored in commercial containers. An accelerated storage stability study on the Chloropicrin EC is available (Paulson, 2011), confirming the formulation is stable when stored at 40 °C for 8 weeks, and can be provided upon request. Additionally, Chloropicrin EC is expected to be stable at elevated temperatures in line with the Chloropicrin 99 formulation. However, if the requirements are confirmed in the peer review, accelerated and ambient temperature storage studies on Chloropicrin EC	

Comments of applicant on the assessment report on chloropicrin

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the plant protection product			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		will be conducted for submission at Member State level to support product authorisations.	

Data on application and efficacy			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>		

Further information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>		

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 5, B.5.5, Evaluation and assessment	Applicant: Within the evaluation and assessment of the methods section B5, it is stated that Todd, 2007a (B.6.1.2.2) is not considered acceptable as an independent laboratory validation (ILV) of method LN78-01 because a different method was used. The extraction method is the same as used in the original validation study, it was only the	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		chromatographic conditions that were changed. Different instruments (in this case GC-ECD) often require different conditions in order to optimise the performance, however the acceptable recovery and precision data demonstrated that the method was sufficiently independently validated and could be used for monitoring purposes. Although the ILV was only conducted down to an LOQ of 0.01 mg/kg, compared with an LOQ of 0.005 mg/kg for the method validation itself, this was considered acceptable for monitoring purposes.	
(2)	Vol. 5, B.5.5, Evaluation and assessment	Applicant: Within the evaluation and assessment of the methods section B5, it is stated that a monitoring method is required for high oil commodities. This comment is noted and suitable data will be provided on request.	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>>	<<description>>	

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Section 2 – Effects on human and animal health

2. Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.1.3: comparative <i>in vitro</i> metabolism	Applicant: The study of Cinelli <i>et al.</i> , 2004 (B.6.1.2.2) demonstrates that investigation of the <i>in vitro</i> metabolism of chloropicrin is associated with significant technical difficulties due to its reactivity and volatility. Furthermore the metabolism of chloropicrin is shown to be mediated via its direct (chemical) reaction with glutathione and is therefore unlikely to be influenced by microsomal enzyme activity.	

Acute toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Short-term toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.3.3.1: 90-day inhalation study (████████, 1993)	Applicant: the proposed LOAEC of 0.3 ppm for local effects in rats in this study appears to be driven by the increased incidence of goblet cell hyperplasia in female rats at the lowest exposure concentration. Although significantly elevated	

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Section 2 – Effects on human and animal health

Short-term toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		compared to controls, this finding lacks a dose-response relationship and the incidence in females is lower than seen in all groups of males (including controls). This relationship of this finding to chloropicrin is therefore questionable; and the finding itself is not considered to be of clear toxicological significance in isolation. It is also notable that this finding was not reported on the 2-year rat inhalation study at exposure concentrations of up to 1 ppm. A local NOAEC of 0.3 ppm is therefore proposed for rats in this study.	

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.4: Summary of genotoxicity	Applicant: We agree with the RMS and co-RMS conclusion that chloropicrin is not genotoxic <i>in vivo</i> , based on the negative results in the bone marrow micronucleus and UDS assays. This is consistent with the conclusion presented in the EFSA Conclusion ¹ on the pesticide peer review for chloropicrin published in 2011 which concludes that chloropicrin is weakly genotoxic <i>in vitro</i> and non-genotoxic <i>in vivo</i> . The overall conclusion being that chloropicrin has no	As the current application for approval of chloropicrin was submitted in December 2013 the applicable active substance data requirements are those set out in Commission Regulation 544/2011. According to those requirements, the unscheduled DNA synthesis (UDS) assay is the suitable and required follow-up to the positive result for gene mutation reported in the Ames test. In addition, the mouse micronucleus assay is specified as a suitable follow-up to the positive result for cytogenicity reported in the study <i>in vitro</i> . Recently, since the submission of the chloropicrin dossier, the

¹ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance chloropicrin. EFSA Journal 2011;9(3):2084. [58 pp.]. doi:10.2903/j.efsa.2011.2084

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Section 2 – Effects on human and animal health

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		genotoxic potential relevant to humans.	<p>applicability of the UDS assay has been reconsidered by EFSA. The recent EFSA Scientific Opinion (published in December 2017) proposes that the UDS assay should no longer be recommended for 'future assessments'. The Opinion recommends for 're-assessments' that existing UDS studies may be considered adequate to assess genotoxic potential if the results are positive but that the reliability and significance of negative results will need to be considered carefully in a weight of evidence approach (taking into account all available information on mode of action, metabolism, toxicokinetics etc.) before a decision is taken on the need for more sensitive tests.</p> <p>In the current application, both the RMS (UK) and co-RMS (Italy) are in agreement that the existing data are sufficient to show that chloropicrin is not genotoxic <i>in vivo</i>. This conclusion was reached with both the RMS and co-RMS being aware of the discussions surrounding the applicability of the UDS assay. Therefore, given that the submission meets the applicable data requirements, it is proposed that the results of the UDS assay are carefully considered by Member States, in line with the weight of evidence approach proposed for re-submissions, in order to avoid unnecessary animal testing. Following that consideration should a requirement be identified for further <i>in vivo</i> testing such a requirement should be considered as being confirmatory given that, in line with Article 6 (f) of Regulation 1107/2009, this would clearly represent a situation where "<i>new requirements are established during the evaluation process or as a result of new scientific and technical knowledge.</i>"</p> <p>EFSA Guidance notes that genotoxicity 'is an endpoint <i>per se</i>' and missing or inadequate genotoxicity cannot be substituted with negative carcinogenicity toxicity data. For chloropicrin, however, it is clear that the relevant route of exposure is inhalation and that concerns relate to exposure at the site of contact. In this context it is notable that</p>

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Section 2 – Effects on human and animal health

Genotoxicity				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
		carcinogenicity using inhalation exposure do not show any evidence of respiratory tract carcinogenicity.		

Long-term toxicity and carcinogenicity				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>			

Reproductive toxicity				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>			

Neurotoxicity				
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations	
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>			

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Section 2 – Effects on human and animal health

Further toxicological studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Medical data and information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Toxicological end points: ADI, ARfD, AOEL			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, Section 2.6.3: Toxicological endpoints for assessment of occupational, bystander and residents risks	Applicant: we support the UK RMS' position on the use of human data for derivation of the chloropicrin AOEC as this is based on the most sensitive endpoint of relevance to chloropicrin exposure (i.e. sensory irritation). The application of an assessment factor of 3 (to cover potential	It should be noted that the human volunteer study (████, 2007) was not specifically conducted to set an AOEL/AOEC for use in a regulatory risk assessment to support the registration of chloropicrin in plant protection products. Chloropicrin is used in low concentrations as an alerting/warning agent with other fumigants. The aim of the study was to determine levels at which humans could detect the presence of

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Section 2 – Effects on human and animal health

Toxicological end points: ADI, ARfD, AOEL			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		intraspecies variation) to the BMCL10 represents a conservative and protective position.	chloropicrin (odour threshold), at levels below irritation became apparent.
Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B6opex, B.6.4.1.1. Table 2 page 7	Applicant: The fifth column of this table is incorrectly headed Area (ha) this should be headed Area (m ²).	
(2)	Vol. 3, B6opex, B.6.4.1.3, Disconnection study 1 st para. P8	Applicant: The RMS considers the fan system (which results in much reduced air concentrations for the tractor driver) used in some trials to minimise exposure to the tractor driver to be "somewhat rudimentary". It is considered that this modification (which is simple rather than 'rudimentary') has potential for use to minimise operator exposure. The California Department of Pesticide Regulation determined that the fan system was very effective in reducing driver exposure to methyl bromide. As a result, CDPR included the requirement for this fan system in the California Code of Regulations, Title 3, Division 6, 6447.3. Further information on this system and evidence supporting its adoption as a suitable engineering control (as an alternative to the recommended closed cab/RPE) can be provided in the context of application for product authorisations at Member State level.	

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Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol. 3, B6opex, B.6.4.1.3, Disconnection study 2nd para. p33	Applicant: The RMS speculates that the " <i>reduced application rate could be the reason why the measured values are significantly less in the drip disconnection trial compared to the original drip trials.</i> " It should be noted that disconnection exposure is due to release of chloropicrin from the application equipment and not related to the application rate. The release during disconnection is independent of whether the rate of application is high or low.	
(4)	Vol. 3, B6opex, B.6.4.1.3, Disconnection study 2 nd para. p33	Applicant: In relation to the two methods for minimising exposure during disconnection (long handled wrench and partial loosening with operator standing away from the cylinder for 5 minutes) the RMS states " <i>Whilst these methods certainly do not eliminate the need for RPE they do represent further measures that can be undertaken by the operator to further reduce the risk of exposure</i> " It should be noted that the ECG has incorporated these methods into the standard operating procedures for chloropicrin application. Evidence of the inclusion in the operating procedures can be provided on request if necessary.	
(5)	Vol. 3, B6opex, B.6.4.2, Bystander and Resident exposure	Applicant: Although it is a possibility that released gas may not pass directly through the measurement locations, it should be recognised that each study included measurements at multiple locations. In view of this and the large	

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Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		number of monitoring studies (including hundreds of individual measurements), it is considered unlikely that the released gas would have not passed directly through the measurement locations in all studies.	
(6)	Vol. 3, B6opex, B.6.4.2, Bystander and Resident exposure	Applicant: In view of the theoretical possibility that concentrations of chloropicrin may be higher at heights below 1.5 m, an additional monitoring study has been performed. This study includes directly comparable measurements at sampling heights of 1.5 and 1 m, in order to address concerns raised by the RMS in relation to the exposure of child residents. The study included measurements using different sampling heights and at distances of 15, 25 and 50 meters from the site of application. The study indicates that airborne concentrations at a sampling height of 1m are (on average) marginally (1.04 times) higher than those at 1.5m, but do not exceed the proposed AOEC. The study is available for submission.	
(7)	Vol. 3, B6opex, B.6.4.2.3, CALMET/CALPUFF air dispersion modelling; p39	Applicant: The use of additional 'assessment factors' to take into account the potential for peak chloropicrin exposures over shorter periods of 15 minutes and 1 hour is not supported. In many cases, the use of this approach results in airborne concentrations of chloropicrin in excess of the maximum theoretically possible.	

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Section 2 – Effects on human and animal health

Other comments, incl comments on volume 4 (impurities, batches) and proposals for classification			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 3 – Residue data

3. Residue data

Storage stability of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Metabolism, distribution and expression of residues in poultry, lactating ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Residue definition			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Residue trials in plants and identification of critical GAP			
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Section 3 – Residue data

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 B.7., B.7.6.8. Summary of residues resulting from supervised trials p73-75	Applicant: we agree with the RMS assessment that in all of the submitted trials residues of chloropicrin and its metabolite dichloromethane (DCNM) were below the LOQ and, with the exception of one crop, no residues detected in the crops. [The exception was a single trial on strawberries where the submitted chromatograms indicated levels of 0.2 µg/kg (i.e. ~4% of the LOQ of 0.005 mg/kg).] We agree with the assessment that the chromatograms submitted to support the studies show no peaks were present in the treated samples which were not also present in the control samples for the same commodity (with the exception of the strawberry sample cited above) and agree this supports the conclusion that, in addition to the absence of chloropicrin and DCMN, other potential metabolites and impurities of chloropicrin were not present in the samples (further supported by the specific data on impurities provided in Volume 4). It should be noted that a further 22 supervised residue trials were conducted in 2016 (two trials (one drip and one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons, strawberries and lettuce) and these are available for submission in response to a request from EFSA. These additional trials provide further confirmation of the 'no residues' situation.	
(2)	Vol. 3 B.7., B.7.6.8. Summary of residues	Applicant: we agree with the RMS conclusion that, given the 'non-residues' situation demonstrated	

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Section 3 – Residue data

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	resulting from supervised trials - first full para. p75	from five crops (from three crop groups) where harvest of the edible part of the commodity is within a year of treatment, that no residues will be expected in tree crops taking into account the much longer time between treatment and first crop harvest. As mentioned in applicant comment 1 in this section, further supervised residue trials are available for submission on request from EFSA which confirm the 'no residues' situation. Therefore, the applicant considers that no supervised residues trials will be required on tree crops (to support use on pome fruit, stone fruit, citrus fruit and olives) at Member State level.	

Feeding studies in poultry, ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>><<description>>		

Effects of processing			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>><<description>>		

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Section 3 – Residue data

Residues in rotational crops			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	
Summary of other studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	
Estimation of the potential and actual exposure through diet and other sources			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1 Section 2.7.9, Estimation of the potential and actual exposure through diet and other sources	Applicant: We agree with the overall conclusion that all of the submitted data support a 'no residues' situation and that there is no dietary risk to consumers from the use of chloropicrin in line with the supported GAP. It should be noted that to provide further confirmation of 'no-residues' a further 22 supervised residue trials were conducted in 2016 (two trials (one drip and one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons, strawberries and lettuce). These studies are available for submission in response to a request from EFSA.	

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Section 3 – Residue data

Proposed MRLs and compliance with existing MRLs			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Proposed import tolerances and compliance with existing import tolerances			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Section 4 - Environmental fate and behaviour

4. Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.1.1.4, Summary & assessment – Soil studies, Page 49	Applicant: Under "Aerobic soil (rate of degradation of DCNM)" in the first line McClaughlin should be amended to McLaughlin	

Adsorption, desorption and mobility in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Fate and behaviour in air			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 4 - Environmental fate and behaviour

PEC in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>		

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.4.1. Surface water and sediment	<p>Applicant: It is our position that the FOCUS models do not reliably estimate exposure for highly volatile substances and will overestimate predicted surface water (and groundwater) exposure. The RMS recognises in the DAR that the models are "particularly sensitive to the vapour pressure value and associated temperature" and states that the use of the FOCUS models may not be appropriate for predicting exposures for highly volatile substances. The limitations are clearly illustrated by the need to enter a lower vapour pressure in order to get the models to run. This has been recognised for other similar volatile fumigants, and flux data from the air monitoring studies indicate a far more rapid decline than is being assumed in the models. It is considered that the peer review should specifically consider whether the model outputs can be relied on for estimating surface water and groundwater concentrations for highly volatile substances. The applicant can</p>	<p>It is recognised that, despite the contention that the models do not reliably estimate exposure for highly volatile substances, acceptable risk to aquatic life is identified for a majority of FOCUS surface water scenarios (in some cases with mitigation at FOCUS Step 4) allowing 'safe use' to be demonstrated. However, for some scenarios, the potential overestimation is a significant factor for the aquatic risk assessment and will be of particular importance at MS level where all uses may be required to pass hence making this a more critical issue. The lack of an appropriate accepted validated tool to assess the exposure for highly volatile compounds therefore should dictate a more pragmatic approach. The product is applied under an impermeable tarp and in the DAR the applicant contends that the evidence of a raised temperature under the impermeable tarp can be used to refine the degradation assumed under the tarp (one of the purposes of such a tarp is to increase soil temperature). The RMS is reluctant to accept this having concerns that the elevated soil temperature may lead to elevated levels in the gas phase, thus affecting the degradation rate. The sole data in the Dossier relating to the possible effect of temperature on degradation is from the study of Volk (2004) where degradation rates in a single soil were 9.8 and 3.9 days at 10 and 20°C respectively. Although it is recognised that in this study the headspace was kept to a minimum and there will be</p>

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Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<p>submit additional information making the case that the models overestimate exposure including consideration of the influence of raised temperatures under the VIF ('tarp') using daily soil temperature data from the monitoring trials (in covered and uncovered plots). This can be submitted as additional information on request from EFSA.</p>	<p>fewer air spaces in a sieved soil compared to a structured field soil, these values give no indication of any retardation of degradation due to increased levels in the gas phase at the higher temperature. Daily soil temperature data are available from two of the sites from the monitoring studies, one in EU CZ and one in EU SZ. At both sites the average difference between covered and uncovered plots was ca 6°C. Application of such an adjustment to the soil temperature over the 21 day covered period results in a significant reduction in the residue available after removal of the membrane to <10% of that assumed in the DAR. This has the potential to significantly reduce run-off losses, for example for Step 3 for R3 for drip irrigation to pome fruit the PECsw for chloropicrin is reduced from 24.525 µg/L to <0.6 µg/L. Additional information can be submitted in support of this contention and a more detailed case made in relation to the overestimation of exposure for highly volatile substances by the accepted models.. It is noted that this is an area where there is a clear potential for refine PECsw estimates with the generation of further data to support refinement if necessary.</p>
(2)	Vol. 3, B.8.4.2. Groundwater	<p>Applicant: It is our position that the FOCUS models do not reliably estimate exposure for highly volatile substances and will overestimate predicted groundwater (and surface water) exposure. The RMS recognises in the DAR that the models are "particularly sensitive to the vapour pressure value and associated temperature" and states that the use of the FOCUS models may not be appropriate for predicting exposures for highly volatile substances. This has been recognised for other similar volatile fumigants, and flux data from the air monitoring studies indicate a far more rapid</p>	<p>It is recognised that, despite the contention that the models do not reliably estimate exposure for highly volatile substances, acceptable risk to groundwater is identified for half of the FOCUS groundwater scenarios modelled allowing 'safe use' to be demonstrated. However, for several scenarios, the potential overestimation is a significant factor making this an important concern. The lack of an appropriate accepted validated tool to assess the exposure for such compounds therefore should dictate a more pragmatic approach. For example in the DAR the applicant proposed that the evidence of a raised temperature under the impermeable tarp could be used to refine the degradation assumed under the tarp (one of the purposes of such a tarp is to increase soil temperature). The RMS are reluctant to accept this having concerns that the elevated soil temperature may lead to elevated levels in the gas</p>

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Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>decline than is being assumed in the models. It is considered that the peer review should specifically consider whether the model outputs can be relied on for estimating surface water and groundwater concentrations for highly volatile substances. The applicant can submit additional information making the case that the models overestimate exposure including consideration of the influence of raised temperatures under the VIF ('tarp') using daily soil temperature data from the monitoring trials (in covered and uncovered plots). This is can be submitted as additional information on request from EFSA.</p>	<p>phase, thus affecting the degradation rate. The sole data in the Dossier relating to the possible effect of temperature on degradation is from the study of Volk (2004) where degradation rates in a single soil were 9.8 and 3.9 days at 10 and 20°C respectively. Although it is recognised that in this study the headspace was kept to a minimum and there will be fewer air spaces in a sieved soil compared to a structured field soil, these values give no indication of any retardation of degradation due to increased levels in the gas phase at the higher temperature. Daily soil temperature data are available from two sites, one in EU CZ and one in EU SZ. At both sites the average difference between covered and uncovered plots was ca 6°C. Application of such an adjustment to the soil temperature over the 21 day covered period results in a significant reduction in the residue available after removal of the membrane to <10% of that assumed in the DAR, with consequent improvements for the PECgw. Additional information can be submitted in support of this contention and a more detailed case made in relation to the overestimation of exposure for highly volatile substances by the accepted models. It is noted that this is an area where there is a clear potential for refine PECgw estimates with the generation of further data to support refinement if necessary.</p>

PEC from airborne transport and other routes of exposure			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.6.1. Chloropicrin, Table B8.8-1	Applicant: The values in this table differ to those given in B8.6-34 and 35, should they differ?	

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Section 4 - Environmental fate and behaviour

Definition of the residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Section 5 - Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, B.9, B.9.1.1.2, reproductive bird risk assessment, Risk via inhalation p72	<p>Applicant: The RMS has proposed that a data gap be set to consider the reproductive risk to birds via the inhalation exposure. The assessment proposed by the RMS is highly conservative given that long term exposure to chloropicrin will not occur following a single application.</p> <p>Overall the opportunities for inhalation exposure of birds from a single application are considered to be very limited, both in terms of concentration, duration and geographical scale, and are therefore unlikely to invoke long-term reprotoxic effects in birds. It is considered that inhalation exposure presents a low reproductive risk to populations of birds from a single application of chloropicrin. The applicant proposes to make a submission of additional information to address this uncertainty identified by the RMS. This will include information on the duration of exposure from the existing monitoring studies and the new monitoring study which is available for submission (see section 2 comment 6) and information on the scale of exposure. The additional information will also include, as proposed by the RMS, a consideration of the results from the avian dietary studies in the reproductive risk assessment for the inhalation exposure route (see applicant comment 3 below in this section). This additional information can be provided in response to a request from EFSA.</p>	<p>Application of chloropicrin to any given site would only be once per year. In some use scenarios there is a longer interval between applications (for tree crops application is no more than 1 year in 15) and the areas treated are typically small, but within areas of intensive horticultural production (as set out in the example information on usage provided in the RMS evaluation in Appendix 3 of Volume 3CA-CP B.9).</p> <p>During preparation (clearance of vegetation, fine soil tillage and formation of planting beds) and during application there would be intense human and machine activity. The disturbance during application and loss of cover giving protection against predation may be expected to discourage either birds or mammals from foraging on or near the treated and tarpred soil before and during the application period. The VIF is laid immediately behind the applicator vehicle, primarily to minimise volatilisation loss of chloropicrin to the atmosphere, but it also presents a physical barrier to ground-foraging birds and mammals while it remains in place.</p> <p>Further disturbance occurs during crop-planting, with the VIF still in place. Once the VIF is lifted there remains little likelihood of mammals actively foraging in the treated area until such time has passed to allow the restoration of protective ground cover vegetation and food sources. Similarly, when the VIF is removed human activity would again discourage foraging. As acknowledged in the assessment concentrations in air following chloropicrin application are not maintained at the same peak concentration for a prolonged period of time and decline rapidly after application. The RMS used the peak concentrations in their initial assessment of long-term inhalational exposure for mammals whereas it is evident from the operator exposure studies that time weighted average</p>

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Section 5 - Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
			values would be markedly lower than the maximum air concentrations. It is therefore proposed to provide additional information for consideration in the peer review taking into account the above factors and to include information from the new monitoring study (which provides information on atmospheric monitoring at intermediate distances of 15 and 25m) and also to consider, for the avian assessment, use of the dietary studies in the reproductive risk assessment for the inhalation exposure route as suggested by the RMS in the DAR.
(2)	Vol. 3CA-CP, B.9, B.9.1.2.2. Reproductive mammal risk assessment - Risk via inhalation p97	Applicant: The RMS has proposed that a data gap be set to consider the reproductive risk to mammals via the inhalation exposure. The assessment proposed by the RMS is highly conservative given that long term exposure to chloropicrin will not occur following a single application. Overall the opportunities for inhalation exposure of mammals from a single application are considered to be very limited, both in terms of concentration, duration and geographical scale, and are therefore unlikely to invoke long-term reprotoxic effects in mammals. It is considered that inhalation exposure presents a low reproductive risk to populations of mammals from a single application of chloropicrin. The applicant therefore proposes to make a submission of additional information to address this uncertainty identified by the RMS. This will include information on the duration of exposure from the existing monitoring studies and the new monitoring study which is available for submission (see section 2 comment 6) and information on the scale of	Further explanation as for applicant comment 1 above in this section.

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Section 5 - Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		exposure taking into account the results of the available inhalation studies. This additional information can be provided in response to a request from EFSA.	
(3)	Vol. 3CA-CP, B.9, B.9.1.1.2, reproductive bird risk assessment, Risk via inhalation (pp. 72-74)	Applicant: We acknowledge the helpful suggestion offered by the RMS that it may be possible to consider results from dietary studies in the reproductive risk assessment for the inhalation exposure route. The RMS notes that this would require chloropicrin concentrations in air to be converted to equivalent internal doses and preferably such an approach would need to account for ADME processes. The applicant will prepare such an assessment as part of the overall additional information to address the uncertainty identified by the RMS about the risk posed by long-term inhalational exposure to birds (see application comment 1 above in this section). This additional information can be provided in response to a request from EFSA.	

Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, B.9, B.9.2, Conclusion on the aquatic risk assessment	Applicant: The RMS has noted that the risk assessment for aquatic organisms, driven by toxicity to algae and based on FOCUS Step 4	

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Section 5 - Ecotoxicology

Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>exposure estimates, is unresolved for a limited number of scenarios.</p> <p>It is recognised in the DAR, and in the evaluations of a number of other fumigants, that the use of the FOCUS models may not be appropriate for volatile substances such as fumigants and are likely to overestimate exposure. The limitations are further illustrated by the need to enter a lower vapour pressure to get the models to run, which will further overestimate the PECsw.</p> <p>Further information on this aspect is provided in the Applicant's comment (1) in response to Vol. 3, B.8.4.1; Surface water and sediment.</p>	

Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>		

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, B.9, B.9.4	Applicant: The RMS has identified a data gap for	

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Section 5 - Ecotoxicology

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>further consideration of the risk to earthworms on the basis that recovery of earthworm populations within the treated area has not been fully demonstrated within an acceptable period. The RMS noted that the size of the overall area treated and the presence of any untreated areas within the field would be important factors in recolonisation. Chloropicrin is a high-cost treatment and is generally only applied on limited areas e.g. under strawberry or tomato cultivation, and in some situations at intervals of many years, for example on land bearing tree crops (e.g. citrus, top fruit, olives), where applications are made no more than on 1 year in 15 (as specified in the GAP). In some circumstances strip applications are made thus providing reservoirs for recolonisation. It should also be noted that populations of earthworms in fields that are suitable for chloropicrin treatment are likely to be low – irrespective of chloropicrin exposure - due to other unfavourable factors e.g. the characteristics of the soil (typically sandy with low organic matter content) and agronomic practices that entail removal of surface cover vegetation, causing the upper soil horizon to remain predominantly inhospitably dry – especially in S-EU MS. It is intended that further information to address the uncertainty about earthworm population recovery and recolonization can be provided as additional information in the peer review process. This will include information from</p>	

Section 5 - Ecotoxicology

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		the public domain and other sources and will take into account agronomic information. This can be provided in response to a request from EFSA for consideration in the peer review.	

Soil nitrogen transformation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, B.9, B.9.5	Applicant: The RMS considers that recovery of soil microflora within the treated area has not been fully demonstrated within an acceptable period. Chloropicrin is a high-cost treatment and is generally only applied on limited areas e.g. under strawberry or tomato cultivation, and in some situations at intervals of many years, for example on land bearing tree crops (<i>e.g.</i> citrus, top fruit, olives), where applications are made no more than on 1 year in 15 (as specified in the GAP). Further information drawn from the public literature to address the uncertainty about soil microorganisms can be provided as additional information in the peer review process in response to a request from EFSA.	

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Section 5 - Ecotoxicology

Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3CA-CP, B.9, B.9.6 Effect on non-target terrestrial higher plants Risk to non-target terrestrial plants from representative uses of chloropicrin p381	<p>It is noted that the RMS assessment used the maximum air concentration determined at 1 m from the treated area in the monitoring trials (0.2937 mg a.s./m³) which results in a TER of 22.9 when compared to the ≤ 50% effects concentration. (6.72 mg a.s./m³). This is in excess of the conventional SANCO/10329/2002 risk assessment trigger value of 5 and indicates safe use. The RMS indicates uncertainty in relation to longer term risk as the [REDACTED] (2009) study on which the effect concentration was based was limited to 2 daily periods of 6 h, which the RMS considers may underestimate the duration of exposure of non-target plants in the field. The RMS acknowledges that concentrations in air following application are not maintained at the same peak concentration for a prolonged period of time and decline relatively rapidly. It should also be noted that chloropicrin is used in areas of intensive horticulture and in many years of usage there is no evidence of unacceptable effects on surrounding commercial crops. The applicant can submit additional information taking into account information on the concentration and duration of exposure from the existing monitoring data and the new monitoring study as well agronomic information to address this point. This additional information can be provided on request from EFSA for consideration in the peer review.</p>	

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Section 5 - Ecotoxicology

Other non-target terrestrial organisms (flora and fauna)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Biological methods for sewage treatment			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Physical and chemical properties of the active substance			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Physical and chemical properties of the plant protection product			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Data on application and efficacy			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Further information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Methods of analysis			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Section 2 – Effects on human and animal health

2. Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Acute toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.1. Oral	EL: A more specific reference to the source of the study would be useful (<i>i.e.</i> type of study). Since the LD ₅₀ of 250 mg/kg bw/day has been agreed, classification as Acute Tox. 3 – H301 is supported. Please, correct the classification reported in the summary Table B.6.2-1.	
(2)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.3 Inhalation	EL: Classification as Acute Tox. 1 – H330 is supported. Please, include the classification related to acute inhalation toxicity in the summary Table B.6.2-1.	
(3)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.4 Skin Irritation	EL: A reference and if possible a summary of the available information/data for classification as Skin Irrit. 2 – H315 should be provided.	
(4)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.5 Eye Irritation	EL: A reference and if possible a summary of the available information/data for classification as Eye Irrit. 2 – H319 should be provided.	

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Section 2 – Effects on human and animal health

Short-term toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Genotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Long-term toxicity and carcinogenicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Reproductive toxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 2 – Effects on human and animal health

Neurotoxicity			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Further toxicological studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Toxicological data on metabolites			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Medical data and information			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 2 – Effects on human and animal health

Toxicological end points: ADI, ARfD, AOEL			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.6.11 ADI	EL: The ADI proposed by the RMS, i.e. the value already agreed by the previous EU review, is supported.	
(2)	Vol. 1, 2.6.12 ARfD	EL: The ARfD proposed by the RMS, i.e. the value already agreed by the previous EU review, is supported.	
(3)	Vol. 1, 2.6.13 AOEL/AOEC	EL: The proposed AOEC/AOEL value is significantly higher than the AOEL agreed by the previous EU review. Considering the systemic toxicity of chloropicrin the basis of the AOEC derivation, i.e. the BMCL10 of 0.073 ppm for ocular symptoms in a human volunteer sensory irritation study, should be discussed in a meeting of experts.	

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.10 Acute toxicity of plant protection products, B.6.10.1 Oral toxicity	EL: The proposed classification of chloropicrin is Acute Tox. 3 – H301 and therefore, based on the calculation method (Regulation (EC) No. 1272/2008), the product should be also classified as Acute Tox. 3 – H301.	
(2)	Vol. 3 Bystander/resident exposure assessment	EL: The exposure assessment has been performed considering that bystanders/residents would not be present at 1m from the edge of the treatment area, i.e. not present at 50m from the treated area. The acceptance/applicability of a 50 m	

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Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		buffer zone restriction should be further discussed.	

Other comments, incl comments on volume 4 (impurities, batches) and proposals for classification			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<MS/EFSA/applicant>>: <<comment>> <<description>>		

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Section 3 – Residue data

3. Residue data

Storage stability of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Metabolism, distribution and expression of residues in plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Metabolism, distribution and expression of residues in poultry, lactating ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Residue definition			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 3 – Residue data

Residue trials in plants and identification of critical GAP			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Feeding studies in poultry, ruminants, pigs and fish			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Effects of processing			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Residues in rotational crops			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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Section 3 – Residue data

Summary of other studies			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>; <<comment>>	

Estimation of the potential and actual exposure through diet and other sources			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>; <<comment>>	

Proposed MRLs and compliance with existing MRLs			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>; <<comment>>	

Proposed import tolerances and compliance with existing import tolerances			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>; <<comment>>	

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Section 3 – Residue data

Other comments			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Comments of EL on the assessment report on chloropicrin

(22.04.2018) 12/18

Section 4 - Environmental fate and behaviour

4. Environmental fate and behaviour

Route and rate of degradation in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Adsorption, desorption and mobility in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Fate and behaviour in air			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Comments of EL on the assessment report on chloropicrin

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Section 4 - Environmental fate and behaviour

PEC in soil			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.2, PECsoil	EL: Please clarify if redeposition from volatilisation has been considered in the PECsoil calculations presented.	

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.4, PEC in groundwater and surface water	<p>EL: The available models are not designed to model such volatile substances, as well as do not take into consideration the application methods and practices used for chloropicrin. This can be also understood from the comparison of the PEARL and PELMO model results for shank application; as it is apparent that one of the two models over- or under- estimates the actual concentrations.</p> <p>Thus, from our point of view, the results of PECgw and PECsw calculations shall be taken into account with caution since the FOCUS models are not validated for volatile substances thus are also not appropriate for such calculations.</p>	
(2)	Vol. 3, B.8.4, PEC in groundwater	EL: For consistency reasons, we would propose to include in the non confidential part of the RAR (Volume 3) PECgw calculations for impurities, without though noting their names, structures, or any other confidential characteristic.	
(3)	B.8.3.5	EL: Even if it is unlikely that the a.s. will occur in	

Comments of EL on the assessment report on chloropicrin

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Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	Impact on WTP	such facilities it is proposed to present the possible fate of chloropicrin in WTP, after a scientifically based theoretical assessment.	

PEC from airborne transport and other routes of exposure			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.5, Redeposition via air	EL: A more recent EVA model is available and should have been used for the estimation of volatilisation and redeposition.	

Definition of the residues			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3 Monitoring studies data	EL: RMS to consider taking into account the available monitoring results from the US, after the appropriate evaluation of their representativeness in the geoclimatic conditions of the EU. Relevant	

Comments of EL on the assessment report on chloropicrin

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Section 4 - Environmental fate and behaviour

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		approach has been followed for TFD studies from the US for several other active ingredients in the near past.	

Section 5 - Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Aquatic organisms			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Bees and non-target arthropods			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Earthworms and other non-target soil macro- and mesofauna			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Comments of EL on the assessment report on chloropicrin

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Section 5 - Ecotoxicology

Soil nitrogen transformation			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Terrestrial non-target higher plants			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Other non-target terrestrial organisms (flora and fauna)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Biological methods for sewage treatment			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

Comments of EL on the assessment report on chloropicrin

(22.04.2018) 18/18

Section 5 - Ecotoxicology

Other comments incl. available monitoring data			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/EFSA/applicant>>: <<comment>>	

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06	Comments on the draft EFSA conclusion

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 4, C.1.1.2, Starting materials and reagents	FR: For each starting material or reagent, the minimum purity and the mention "commercially available" are sufficient. The supplier name should not be clarified when it is a common chemical, as it can change.	Applicant: Comment noted RMS: Noted, the fact these are commercially available can be added to the DAR. Inclusion of a specific manufacturer is to demonstrate that the chemical is commercially available. Addressed	Addressed
1(2)	Vol. 4, C.1.1.2, Starting material and reagents	FR: MSDS in compliance with Annex II of the Regulation (EC) No 1907/2006 (REACH) and the ECHA related guidance document "Guidance on the compilation of safety data sheets", should be provided for each starting material used for the manufacture of the active substance. Moreover, if one of the starting material has toxicological or eco toxicological properties or if it contains any relevant impurity, this relevant starting material/impurity should be determined in the batch analysis or it should be demonstrated that this relevant starting material/impurity cannot be present at unacceptable level in the technical substance. If MSDS are not available, it should be demonstrated that	Applicant: SDSs for the starting materials can be provided as additional information if requested. RMS: MSDSs are not required in accordance with Reg (EU) 544/2011. Any impurities of toxicological relevance in the starting materials are stated, and analysed for in the 5-batch study if applicable. However, if MSDSs are provided by the applicant they can be added to the DAR. Addressed	Addressed

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		starting materials have no toxicological relevance at contents lower than 1 g/kg (example: harmonized classification according to the Regulation (EC) No 1272/2008...).		
1(3)	Vol.4, C.1.2.3, impurities, p10-13	FR: A rationale should be provided to explain the presence of each impurity found in the technical material (solvent, by-product, impurity in a starting material, ...)	Applicant: Additional information can be provided on the proposed origin of the species identified in the technical active substance if requested. RMS: The assessment is to Reg. (EU) 544/2011. Therefore details of the formation of the impurities are not required. Addressed	Addressed According to Regulation (EU) 544/2011 details of the formation of the impurities are not required.
1(4)	Vol.4, Table C.1.3-2	FR: CAS number of [REDACTED] is erroneous and should be corrected. Moreover, the MSDS of this coformulant should be provided.	Applicant: The CAS number provided is incorrect and should be removed. A CAS number is not relevant to this co-formulant since it is a commercial blend of emulsifiers. An SDS for this co-formulant is included within Appendix 1. RMS: This can be updated in the DAR Addressed	Addressed RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
1(5)	Vol.4, C.1.4.1.1., §3	FR: Please correct the typo " [REDACTED] ".	Applicant: RMS to amend DAR.	Addressed RMS to correct in an amended DAR,

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			RMS: This can be updated in the DAR Addressed	this action is needed according to SANCO/10180/2013-rev.1.
1(6)	Vol.4, C.1.2.2., significant impurities	FR: Applicant proposed a specification of ≤1 g/kg for [REDACTED] as a significant impurity. [REDACTED] was shown to be unstable at room temperature and to decompose into [REDACTED]. Moreover, [REDACTED] was shown to be almost completely degraded into [REDACTED] when analyzed by GC (Vol.4, p50). Therefore, because [REDACTED] and [REDACTED] coelutes and lead to a single analyte, the specification of ≤1 g/kg should apply to the sum of [REDACTED] and [REDACTED]	Applicant: [REDACTED] was not identified as part of the five batch analysis (KIIA 1.11.1/01) therefore it is considered unnecessary for it to be included within the specification. RMS: Based on further consideration of the available data for impurity D, it does not appear that Impurity D can be conclusively identified as [REDACTED] and [REDACTED], as the spectra were not compared with a reference standard, and the ions observed in the MS could potentially be attributed to either [REDACTED] as the parent ion for [REDACTED] is not observed. Based on the findings of the subsequent study, [REDACTED] is unstable and rapidly degrades to [REDACTED], therefore even if [REDACTED] was present in the five batches it is likely to degrade to [REDACTED] during analysis. On this basis, analysis of reference standards of [REDACTED] would potentially provide	Addressed EFSA agrees with the proposal of FR and RMS to specify the impurity as the sum of [REDACTED] with max level of 1g/kg. See also 1(7), 1(11) See data requirement in 2(101).

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>further evidence of this degradation during analysis, but because of this are unlikely to be sufficient to conclusively determine the identity of the impurity.</p> <p>In the absence of the ability to distinguish between these two components analytically, FRs proposal to specify the impurity as the sum of [REDACTED] is considered an acceptable approach if these impurities are considered significant.</p> <p>However, due to a lack of available toxicological data on these metabolites, it has been considered during the peer review that there is insufficient information to conclude on the toxicological relevance of [REDACTED].</p> <p>Therefore the RMS considers that the toxicological assessment should be finalised with respect to the relevance of these impurities prior to confirmation of the specification, and hence depending on this outcome, further consideration of identity and specification of Impurity D may be required.</p>	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
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			Open point	
1(7)	Vol.4, C.1.2.2., significant impurity D	FR: As [REDACTED] decomposes into [REDACTED] upon analysis, we consider that the identity of Impurity D remains unclear. A standard of [REDACTED] or an additional analytical technique may help to get this point clear.	Applicant: As [REDACTED] is unstable, it is considered that sufficient data has been provided to quantify impurity D. Applicant: It has been found in a later study (26/2015) that [REDACTED] was unstable at room temperature and that the degradation was enhanced at elevated temperatures. GC-FID analysis was conducted at elevated temperatures during which [REDACTED] was completely degraded producing dichloronitromethane. Therefore, the availability of a [REDACTED] standard would not have significantly added to the findings of this study. RMS: See RMS response to 1(6)	See comment in 1(6)
1(8)	Vol. 3CA-CP, B1.2.3	FR: Please correct the typo "vapour releasing" instead of "vapour realising"	Applicant: RMS to amend DAR. RMS: This can be updated in the DAR Addressed	Addressed RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
1(9)	Vol. 4, C.1.4.1.1. Introduction	EFSA: a small editorial, it is written:	Applicant: Agreed, 94% is correct	Addressed

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
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		"Chloropicrin is formulated ...or an 'EC' formulation (96% chloropicrin TGAI)" it should be 94%	RMS: This can be updated in the DAR Addressed	RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
1(10)	Vol. 4, C. Confidential information and, where relevant, details of any task force formed for the purposes of generating tests and studies submitted p. 4.	NL: It is stated that there is no task force and only a single applicant, however in Vol. 1 under 1.2 applicant information it is stated that an EECG consists of two companies/applicants and under 1.2.3 it is stated that an task force of companies collectively known as ECG, please explain.	Applicant: The European Chloropicrin Group (ECG) is a taskforce consisting of two companies: Trinity Manufacturing Inc. and Nikolor Chemical Co. Inc. RMS: The DAR Vol 4 can be updated to reflect details of the taskforce. Addressed	Addressed RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
1(11)	Vol. 4, C.1.2.3 Analytical profile of batches p.9.	NL: It seems that the proposed and supported minimum purity of the active substance (990 g/kg) is not fully supported by the mean – 3xSD value (██████████), and thus by the 5 batch analysis. Please clarify why this value was proposed by applicant/RMS. Additionally, Please state the LOQ/LOD of the individual impurities in the 5-batch analysis, for completeness purposes. The absence of a reference standard for the determination/quantification and identification of impurity D	Applicant: 990 g/kg was the previously proposed specification (IT, 2009), though the cited five batch analysis provides a minimum purity of █████. Applicant: The LOQ for each impurity is presented in Table C.1.2.4.1. Applicant: It has been found in a later study (26/2015) that █████ was unstable at room temperature and that the degradation was enhanced at elevated temperatures. GC-FID analysis was conducted at elevated temperatures during which █████ was	Addressed EFSA supports proposal for min. purity of the active substance 990 g/kg See comment 1(6)

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		<p>([REDACTED]) is (highly) questionable, especially when proposed in the reference specification. This however can be found acceptable for impurities not included in the proposed specification. Additional information (e.g. QC-data) should be provided for this impurity with an validated method (including an reference standard, which is now available) to support the proposed specification.</p>	<p>completely degraded producing [REDACTED]. Therefore, the availability of a [REDACTED] standard for use in the 5-batch analysis would not have significantly added to the findings of this study.</p> <p>RMS: For the active substance, although the rule of thumb (mean-3sd) gives [REDACTED], it was considered that 990 g/kg is a more appropriate level based on the actual levels in the batches ([REDACTED]). Due to the nature of application of chloropicrin it is considered important that the purity of the TGAI is as high as possible to limit the potential levels of impurity applied to the soil. The level of 990 g/kg was agreed upon in the previous specification, so taking the above points into account it was considered appropriate to maintain this specification. A justification for the specification can be added to the DAR.</p> <p>The LOQ for each of the impurities can be added to Table C.1.2.3-2 if required (although it is noted that full details of the LOQs are given in table C.1.2.4-1)</p>	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>Addressed</p> <p>With respect to determination of Impurity D, please see RMS response to 1(6).</p> <p>Regarding quantification of Impurity D, RMS notes that use of reference standards to re-validate the method of analysis would potentially provide increased confidence in the quantification of impurity D in the five batches, and based on this, QC data from batches analysed using this method may be appropriate to support the level in the specification</p>	
1(12)	Vol. 4, C.1.4.1.2. Residues Trials	EFSA: Please clarify LOQ for the chloropicrin and correct if it is needed 0.005 g/kg or 0.01 g/kg	<p>Applicant: For the purposes of monitoring and enforcement, the LOQ for chloropicrin has been established as 0.005 mg/kg. The methods used to determine residues of chloropicrin in field samples were validated to 0.01 mg/kg, however the limit of detection was determined to be ≤0.003 mg/kg.</p> <p>RMS: In the residues trials outlined in this</p>	Addressed

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>section the validated LOQ for chloropicrin is 0.01 mg/kg. Based on analysis of the available chromatograms, no traces of chloropicrin were determined in the samples.</p> <p>Addressed</p>	
1(13)	<p>Vol. 4, C.1.4.1.2.</p> <p>Residues Trials,</p> <p>Magnitude of residues of chloropicrin,</p> <p>[REDACTED],</p> <p>[REDACTED]</p> <p>[REDACTED] impurities in strawberries, zucchini, melon, tomatoes and pepper grown in protected fields following professional drip application in Italy in 2015, 2015</p>	<p>EFSA: Please check the levels of chloropicrin and DCNM. In the table are reported as <0.01 g/kg, however it seems that the methods have been validated with LOQs 0.005 g/kg as it is stated in <i>Discussion and conclusions</i> (p.49)</p>	<p>Applicant: For the purposes of monitoring and enforcement, the LOQ for chloropicrin has been established as 0.005 mg/kg. The methods used to determine residues of chloropicrin in field samples were validated to 0.01 mg/kg, however the limit of detection was determined to be ≤0.003 mg/kg. Suggest that the LOQ reference is amended in Vol. 4, C.1.4.1.2 accordingly.</p> <p>RMS: In the residues trials outlined in this section the validated LOQ for chloropicrin is 0.01 mg/kg. This can be corrected in the DAR. Based on analysis of the available chromatograms, no traces of chloropicrin were determined in the samples.</p> <p>Addressed</p>	<p>Addressed</p> <p>RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.</p>

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Identity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

Physical and chemical properties of the active substance				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(14)	Vol. 3CA-CP, Table B2.1-1, point B2.1.5	FR: According to OECD 104, vapour pressure should be measured at least at 2 temperatures in the 0-50 °C range. This is particularly important in this dossier, considering the intended use.	Applicant: The cited study used the static method to measure the vapour pressure at 18 different temperature between 0 and 30 °C, then the vapour pressure at 25 °C was estimated using linear regression. For completeness, using the data in the report and the equation $y=mx+c$, the vapour pressure is estimated to be 4033.8 Pa (30.3 mm Hg) at 20 °C. RMS: The vapour pressure at other temperatures can be added to the DAR. Addressed	Open point RMS to add in the DAR information on the vapour pressure measured at different temperatures
1(15)	Vol. 3CA-CP, Table B2.1-1, point B2.1.6	FR: It should be notified that Henry's law constant has been estimated from the vapour pressure measured at 25 °C and density measured at 20 °C.	Applicant: noted RMS: The DAR can be updated to reflect this Addressed	Addressed RMS to include the information in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the active substance				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(16)	Vol. 3CA-CP, Table B2.1-1, point B2.1.11	FR: According to OECD 105, pH of the solution should be reported.	<p>Applicant: The pH of the Chloropicrin aqueous solution tested in the cited study is not stated in the report. The pH of a 1% aqueous solution of "Chloropicrin 99" was measured to be 3.47 (IIIA 2.4.2-01).</p> <p>RMS: As noted by the applicant the pH was not stated in the study report. As the purity of the TGAI is sufficiently similar to the product 'Chloropicrin 99', it is considered that the pH of the product would be comparable to the pH of the TGAI</p> <p>Addressed</p>	Addressed

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the active substance				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(17)	Vol. 3CA-CP, Table B2.1-1, point B2.1.22	FR: As the technical substance contains some explosive impurities (████████), the representativeness of the batch used for the test compared to the specifications should be argued.	<p>Applicant: As confirmed by the five batch analysis, the composition of ██████████ and other possible explosive impurities within the technical active substance is very low, so their presence would be unlikely to impact the explosive properties of the technical active substance as a whole. The cited study, which experimentally determined chloropicrin not to be explosive, is therefore considered valid.</p> <p>RMS: Levels of the stated impurities are <1g/kg in all batches in the five batch analysis from 2012, therefore as outlined by the applicant, their presence is unlikely to impact the explosive properties of the TGAI. In addition the manufacturing process used to produce the TGAI for the explosivity tests is substantively similar to that used in the current manufacturing process, therefore it can be considered that a similar impurity profile would be expected. On this basis it is considered that the results of the explosive properties test remain valid.</p> <p>Addressed</p>	Addressed

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Physical and chemical properties of the active substance				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(18)	Vol. 3, B.2.1.2 Boiling temperature p. 5.	NL: Is the method used for the boiling point similar/equal to the EC A.2 method. <i>This also applies to B.2.1.3 (EC A.3), B.2.1.12 (EC A.6), B.2.1.13 (EC A.8), B.2.1.15/16 (EC C.7)</i>	<p>Applicant: The studies cited to address these endpoints were evaluated and deemed to be acceptable in the original DAR. The study methods used are considered sufficiently similar to the preferred OECD/ EC methods and valid.</p> <p>RMS: These studies were evaluated in the original DAR/DAR addendum, and considered acceptable, with the methods sufficiently similar to the OCED/EC methods</p> <p>Addressed</p>	Open point RMS to include a statement about the acceptability of the used methods (on their similarity to the OECD/EC methods)
1(19)	Vol. 3, B.2.1.10 Spectra p.7-8.	NL: Is it possible to include the spectra of the UV/VIS, IR, NMR and MS into the results column for completeness.	<p>Applicant:</p> <p>UV/VIS spectra (200-750 nm) Neutral aqueous solution: $\lambda_{\max}=203.7 \text{ nm}, \epsilon=1648 \text{ mol}^{-1}\text{cm}^{-1}$ $\lambda_{\max}=274.0 \text{ nm} \epsilon=32 \text{ mol}^{-1}\text{cm}^{-1}$</p> <p>Acidic aqueous solution (pH 1.9): $\lambda_{\max}=204.4 \text{ nm}, \epsilon=1512 \text{ mol}^{-1}\text{cm}^{-1}$ $\lambda_{\max}=274.2 \text{ nm}, \epsilon=28 \text{ mol}^{-1}\text{cm}^{-1}$</p> <p>Alkaline aqueous solution (pH 11.0): $\lambda_{\max}=275.0 \text{ nm}, \epsilon=33 \text{ mol}^{-1}\text{cm}^{-1}$</p> <p>IR (KBr)</p>	Addressed

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Physical and chemical properties of the active substance				
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			<p>2500-3000 cm⁻¹: N=O combination bands 1609 cm⁻¹: NO₂ (symmetric) 1280-1350 cm⁻¹: NO₂ (asymmetric) 870-900 cm⁻¹: N-O, C-N stretches <800 cm⁻¹: C-Cl stretch</p> <p>NMR (CDCl₃/TMS) Single resonance at 114 ppm</p> <p>GC-MS. Peaks (m/z): 201: addition of Cl to molecular ion 164: molecular ion 117: loss of NO₂ from molecular ion</p> <p>RMS: The spectra can be added into the DAR if required, although it should be noted that the print quality of the spectra in the study reports is low</p> <p>Addressed</p>	

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Physical and chemical properties of the active substance				
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1(20)	Vol. 3 CA-CP, B.2.1.10 (IIA 2.5) Spectra (UV/VIS)	EFSA: Here it is reported: " $\lambda_{max} = 274.0\text{ nm}$ $\epsilon = 321\text{ mol}^{-1}\text{ cm}^{-1}$ " In LoEP is: " $\lambda_{max,:} 203.7\text{ nm} (\epsilon 1648)$, 274.0 nm ($\epsilon 32$)" Please check and correct where it is needed	Applicant: ϵ at 274.0 nm is $32\text{ mol}^{-1}\text{cm}^{-1}$ RMS: The LOEP can be updated to reflect the correct value Addressed	

Physical and chemical properties of the plant protection product				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(21)	Vol. 3CA-CP, Table B2.2-1, point B2.2.12	FR: It should be clarified that it is <i>kinematic</i> viscosity. Moreover, the shear rate at which the measure was performed should be specified according to OECD 114.	Applicant: The study cited to address this endpoint was evaluated and deemed to be acceptable in the original DAR, which measured the viscosity using a u-tube viscometer. The study is considered valid and it is not anticipated the viscosity of chloropicrin varies with shear rate. RMS: This can be clarified in the DAR. As the applicant notes viscosity was determined using a u-tube viscometer Addressed	Addressed RMS to include the information in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.

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Physical and chemical properties of the plant protection product				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(22)	Vol. 3 CA-CP, 'Chloropicrin 99', B.2.2.14 (IIIA 2.7), Accelerated Storage Stability	EFSA agrees with RMS additional data is needed in relation with the accelerated storage stability of "Chloropicrin 99"	Applicant: Please see comment 1(23) RMS: Noted thank you, this will be included as a data gap Data gap	See data requirement in 1(23)
1(23)	Vol. 3, B.2.2.14 (IIIA 2.7), Storage stability, 'Chloropicrin 99'	Applicant: It is appreciated the cited study was not run for the advised length - 2 weeks at 54 °C - to emulate storage at ambient temperature for two years, but this reflects the age of the study. The accelerated study, run for 7 days at 54 °C (C. M. Sparacino, 1994), found the test item to be stable after storage: the study found a (relatively small) 1.5% reduction in chloropicrin content, and the test item was also stable in other endpoints measured. If this study was extended for a further 7 days, it would be expected that the formulation would remain within acceptable limits, assuming a linear rate of degradation. Additionally, existing data confirms this formulation is stable for up to 35 months at ambient temperature, and the 2011 EFSA conclusion set no requirement for an additional study to be conducted to address the elevated temperature storage endpoint. It is	RMS: The applicant's comments are noted, however RMS considers further data are required to confirm stability for 14 days at 54°C. As outlined in the DAR it is also noted that validation data for the method of analysis used in the study is not available, therefore the determined levels in the formulation cannot be considered reliable without further supporting data Data gap	Data requirement Accelerated storage stability study for 'Chloropicrin 99' in accordance with Regulation (EU) 545/2011 should be submitted See also 1(22)

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Physical and chemical properties of the plant protection product				
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		therefore considered that a new accelerated study for 14 days is not necessary since existing data demonstrates the formulation to be stable at elevated temperatures.		
1(24)	Vol. 3 CA-CP, 'Chloropicrin EC', B.2.2.11 (IIIA 2.5) Surface tension	EFSA: Surface tension was determined using the technical material. Additional justification on the acceptability of the submitted study is required.	<p>Applicant: The content of the co-formulant within this formulation, acting as an emulsifier, is very low and so the cited study on the technical active substance is considered valid for the EC formulation, and a new study on EC formulation is considered unnecessary. The presence of a small amount of co-formulant not functioning as a surfactant would not be expected to reduce the surface tension to below 60 mN/m (from 71.1 mN/m - see IIIA 2.5.3-01 for "Chloropicrin 99")</p> <p>RMS: Please see the justification presented by the applicant above. Addition of a small amount of co-formulant to the TGAI is not considered likely to have a substantial impact on surface tension such that it would be decreased below 60 mN/m. This further discussion can be included in the DAR</p>	<p>Data requirement The surface tension of the preparation 'Chloropicrin EC' should be provided. According to Vol. 4, the co-formulant added indeed is a surfactant and therefore extrapolation from the surface tension of the technical material to the preparation is not acceptable.</p> <p>See also 1(29), 1(32)</p>

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Physical and chemical properties of the plant protection product				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			Addressed	
1(25)	Vol. 3 CA-CP, 'Chloropicrin EC', B.2.2.14 (IIIA 2.7), Accelerated Storage Stability	EFSA agrees with RMS data on the accelerated storage stability for "Chloropicrin EC" is required	Applicant: Please see comment 1(28) RMS: Noted thank you, this will be included as a data gap Data gap	Data requirement Accelerated storage stability study for 'Chloropicrin EC' in accordance with Regulation (EU) 545/2011 should be submitted See also 1(32), 1(33)
1(26)	Vol. 3 CA-CP, 'Chloropicrin EC', B.2.2.14 (IIIA 2.7), Shelf life	EFSA: The final report on the 2 years shelf life study to be submitted including determination of the technical characteristics relevant for EC before and after storage	Applicant: Please see comment 1(28) RMS: Noted thank you, this will be included as a data gap Data gap	Data requirement Applicant to submit the final report on the 2 years shelf life study including determination of the technical characteristics relevant for the EC formulation before and after storage. See also 1(31), 1(32), 1(33)
1(27)	Vol. 3CA-CP, Table B2.2-1, point B2.2.15	FR: Please make sure that there is no typo in the unit of the reported corrosion rate.	Applicant: The units are as listed in the study report - g/m ² h (grams per unit area per hour). RMS: The units are in line with those in the study report Addressed	Addressed
1(28)	Vol. 3CA-CP, Table B2.2-1, point B2.2.15	FR: Considering the reported corrosion rate, a test of corrosion to metal according to UN RTDG Manual of tests and criteria ST/SG/AC.10/11/Rev. 6 Part III Section	Applicant: The study reported the corrosion rate of steel coupons to be very low, with "a worst case scenario" of 9.10x10 ⁻⁵ g m ⁻² h ⁻¹ (or 0.797 g m ⁻² yr ⁻¹) - the average weight change	Addressed

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Physical and chemical properties of the plant protection product				
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		37.4 should be required.	<p>was a loss of only 0.03% after 24 months. This data supports the formulation not being corrosive to metals and therefore additional testing is considered unnecessary.</p> <p>RMS: Agree with applicant's comments, it is not considered that further testing is required based on the observed results</p> <p>Addressed</p>	
1(29)	Vol. 3CA-CP, Table B2.2-2, point B2.2.11	FR: The coformulant included in this preparation being a surfactant, the result on the substance alone cannot be extrapolated and the surface tension test should be required.	<p>Applicant: Please see comment 1(24)</p> <p>RMS: Please see the justification presented by the applicant above 1(24). Addition of a small amount of co-formulant to the TGAI is not considered likely to have a substantial impact on surface tension such that it would be decreased below 60 mN/m. This further discussion can be included in the DAR</p> <p>Addressed</p>	See 1(24)
1(30)	Vol. 3CA-CP, Table B2.2-2, point B2.2.12	FR: It should be clarified that it is <i>kinematic</i> viscosity. Moreover, the shear rates at which the measures were performed should be specified according to OECD 114.	<p>Applicant: The cited study measured the viscosity using a u-tube viscometer. The study is considered valid and it is not anticipated the viscosity of "Chloropicrin EC" will vary with shear rate.</p>	<p>Addressed</p> <p>RMS to include the information in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.</p>

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Physical and chemical properties of the plant protection product				
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			RMS: This can be clarified in the DAR. As the applicant notes viscosity was determined using a u-tube viscometer Addressed	
1(31)	Vol. 3CA-CP, Table B2.2-2, point B2.2.15	FR: We agree that further data are needed to demonstrate a 24 months shelf-life. Moreover, emulsifiability and emulsion stability of the aged product should be provided (preferably according to CIPAC MT 36.3).	Applicant: Please see comment 1(33) RMS: Noted thank you, this will be included as a data gap Data gap	See data requirement in 1(26)
1(32)	Vol. 3CA-CP, Table B2.2-2, conclusion	FR: Considering the lack of information concerning "Chloropicrin EC" formulation, both on physical and chemical properties (no surface tension test, no stability study), analysis (no analytical method to determine a.i. in the formulation) and identity (no MSDS nor CAS number of the co-formulant), it should be made clear that some additional data will be required for this preparation to be authorized.	Applicant: Please see comment 1(33) RMS: Noted. Additional stability data is required, however, RMS considers that surface tension, method of analysis and identity of the co-formulant have been satisfactorily addressed Addressed	See data requirement in 1(24), 1(25) and 1(26)
1(33)	Vol. 3, B.2.2.15 (IIIA 2.7), Storage stability, 'Chloropicrin EC'	Applicant: Chloropicrin 99 data confirms this formulation is stable for up to 35 months at ambient temperature (Chloropicrin 99, B.2.2.15), and the difference in composition between both representative formulations is slight: Chloropicrin EC	Applicant: please note the availability of the accelerated storage stability study on the Chloropicrin EC (Paulson, 2011) which can be submitted on request as additional information	See data requirement in 1(25) and 1(26)

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Physical and chemical properties of the plant protection product				
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		<p>contains an additional 60 g/kg surfactant only. It is therefore considered that Chloropicrin 99 storage data can be used to support the registration of Chloropicrin EC, endorsing the stability of Chloropicrin EC for two years at ambient temperature, so it can be concluded that Chloropicrin EC is stable at ambient temperature for two years when stored in commercial containers. An accelerated storage stability study on the Chloropicrin EC is available (Paulson, 2011), confirming the formulation is stable when stored at 40 °C for 8 weeks, and can be provided upon request. Additionally, Chloropicrin EC is expected to be stable at elevated temperatures in line with the Chloropicrin 99 formulation. However, if the requirements are confirmed in the peer review, accelerated and ambient temperature storage studies on Chloropicrin EC will be conducted for submission at Member State level to support product authorisations.</p>	<p>RMS: Additional accelerated storage stability study for evaluation can be requested from the applicant and reviewed by the RMS in an updated DAR.</p> <p>RMS notes the applicant's comments with respect to the similarity of the formulations, however it is considered that data to support the ambient storage stability of Chloropicrin EC is required.</p> <p>Data gap</p>	

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Data on application and efficacy				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(34)	Vol. 3 – B.3, B.3.3, Details of intended use	DE: The indicated application rate per treatment for both products and for all proposed uses is specified as 188-376 kg as/ha. Please define when it is necessary to use the lower and the higher application rate.	Applicant: the rate depends on the target disease to be controlled. Generally vascular wilts, Sclerotinia, Cylindrocarpon, Macrophomina needs highest rates, while control of Rhizoctonia and Pythium is possible at lower rates. RMS: The applicant has indicated the species where the higher dose can be supported, but there are likely to be other species where a lower dose may be sufficient. The application rate will be fully assessed at the product assessment stage. Addressed	Addressed
1(35)	Vol. 3, CA-CP B.3.3., Details of intended use (Chloropicrin EC, p.12 to 20) Vol. 1, 1.5., Detailed uses of the plant protection product (Chloropicrin EC, p.17 to 26)	FR: Please explain or correct the unit used in the column 12 about the water volume: mm/ha.	Applicant: the unit mm means L/m ² 1 mm = 10 m ³ /ha. RMS: the applicant's clarification will be added to the GAP table. Addressed	Open point RMS please present the GAP table in the agreed harmonised template including presentation of the water amount in L/ha See also comment in 2(62).

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Data on application and efficacy				
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1(36)	Vol. 3 – B.3, Appendix 1	DE: In the tabular summary of published efficacy trials only 2 references refer to nematodes as target pest. One of these references presents results of trials on pine nursery production. This cannot be extrapolated to the proposed uses.	<p>Applicant: the primary target for chloropicrin is fungal diseases effects on nematodes are considered secondary to control of soil fungi. Further data will be submitted in support of applications for product authorisation to address product efficacy requirements.</p> <p>RMS: Considers chloropicrin is sufficiently effective. All claims of effectiveness will need to be fully supported at the product evaluation stage.</p> <p>Addressed</p>	Addressed
1(37)	Vol. 3 – B.3, in general	DE: There are no details given to the nematode species to be controlled by chloropicrin. According to the study of Lopez-Aranda et al. (2009) there are differences in the susceptibility of different nematode species to chloropicrin. It seems to be less effective at controlling <i>Pratylenchus</i> spp.	<p>Applicant: see comment at 1(36).</p> <p>RMS: All claims of effectiveness will need to be fully supported at the product evaluation stage.</p> <p>Addressed</p>	Addressed

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Data on application and efficacy				
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1(38)	Volume B Section B.3.9 Effectiveness	We note that chloropicrin was widely authorised prior to 2011 and emergency authorisations have been granted since that time. Use against specific apple replant disease was effective and allowed successful replanting. The causes of replant disease are complex causes by a range of factors including a build-up of soil pathogenic organisms that can be effectively suppressed by chloropicrin. Effectiveness for replant disease can be demonstrated in support of product registrations. A single use can allow replanting without detrimental long-term effects as treatments are not repeated during the life of the crop. Currently there are no suitable effective alternatives.	<p>Applicant: comment noted. Soil borne diseases and nematodes are very difficult to control effectively and there are currently very few effective fumigants available to ensure the competitiveness of European agricultural and horticulture production in those specific and limited situations where crops are at risk.</p> <p>RMS: Noted</p> <p>Addressed</p>	Addressed

Further information				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(39)	Vol. 3, B.4, packaging and procedures for cleaning application equipment	DE: Information for packaging and procedures for cleaning application equipment is missing.	Applicant: information was provided in the dossier. Chloropicrin is packaged in returnable steel cylinders. These are returned to the formulator for refilling rather than being left at the application site or elsewhere.	Addressed

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Further information				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>The cylinders are traceable.</p> <p>It should be noted that application of chloropicrin is only made by trained specialist applicators. Farmers/growers are not involved in the application process nor in the handling of chloropicrin.</p> <p>In terms of the application equipment it should be noted that, in the field, application is by closed systems. For shank application it should be noted that at the end of each treatment row the fumigant flow is switched off and the delivery system purged into the soil with nitrogen. Nitrogen purging of the application system into the soil is made at the end of the application process to clear the application equipment of chloropicrin.</p> <p>Similarly, for drip irrigation, on completion of an application, the system is purged, the cylinder sealed with all the valves closed in sequence, and delivery lines are flushed with water into the soil and beneath the VI film.</p> <p>Information on cleaning of application equipment is provided in the dossier. The purging used in the field will clear chloropicrin from the application equipment, Further cleaning of application equipment is a procedure never done in rural areas, but in a separate area where the application</p>	

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Further information				
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			<p>equipement is maintained. Further information can be provided as additional information if requested.</p> <p>RMS: This was covered in the dossier and is reiterated by the applicant above. The submitted information is sufficient for the active assessment and further consideration will be made at the product assessment stage.</p> <p>Addressed.</p>	
1(40)	Volume B Section 3.3 Details of Intended Use	<p>Public comment – French Chambers of Agriculture (AFCA)</p> <p>We support the use on tree crops as reflected in the supported uses for chloropicrin. Apple replant disease is a cropping in France. This disease has limited the replanting of apple trees in many situations and is an important factor resulting in a decline in cropped area. The availability of chloropicrin, used under properly regulated conditions, would help to restore the competitiveness of French and, more generally, European horticulture. Use would be on limited areas and, as indicated by the applicant, no more than 1 year in 15 with consequent minimal impact on the environment.articular concern for horticultural</p>	<p>Applicant: comment noted – see our response at 1(38) above.</p> <p>RMS: Noted</p> <p>Addressed.</p>	Noted

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Further information				
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1(41)	B 3.5 Method of application	<p>Public comment – French Chambers of Agriculture (AFCA)</p> <p>We support the conditions set out in this section to minimise human and environmental exposure. The use of specialist application equipment and trained operators is supported. We consider that this ensures that there a strong stewardship process in place which ensures compliance with any necessary measures to minimise exposure and risk resulting from chloropicrin use.</p>	<p>Applicant: comment noted. As chloropicrin is applied by a limited number of specialist operators and not by farmers/growers a very high degree of compliance with procedures, safety requirements and mitigation measures can be expected.</p> <p>RMS: Noted.</p> <p>Addressed.</p>	Noted
1(42)	Vol. 3CA-CP, B4.1., storage and handling	FR: Temperature storage should be made explicit in this section.	Applicant: further information on storage can be provided if requested.	<p>Data requirement</p> <p>Applicant to provide information on the temperature of storage</p>

Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(43)	Vol. 1, 2.13.2 and list of end points	DE: The residue definitions for monitoring for the environmental matrices given in Vol. 1 differ from the information in the list of endpoints. Please align.	Applicant: The correct residue definitions for monitoring and enforcement are those presented in the list of endpoints. The residue definitions in volume 1 will be corrected accordingly.	<p>Open point</p> <p>RMS to check and correct, where it is needed, the residue definition in the environmental compartments. Please note that even in the LoEP there is a</p>

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Methods of analysis				
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			RMS: The residue definitions can be updated in Vol. 1 of the DAR Addressed	discrepancy between components of the residue definition reported on p.23 and p. 97 See also 1(60)
1(44)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: The analytical method for plant commodities with high water content is not acceptable. The LOQ of the primary method is not sufficiently low for the currently valid MRL of 0.005 mg/kg for commodities with high water content and the ILV is not acceptable due to significant modifications of the method. This is a data gap.	Applicant: The method for the determination of chloropicrin in high water crops (tomatoes) was originally validated down to 0.01 mg/kg (Gatti 2001). The method was then further validated down to 0.005 mg/kg in tomatoes in study Gatti 2009. The method is therefore sufficiently validated to determine residues of chloropicrin in tomatoes down to the current EU MRL of 0.005 mg/kg. Applicant: The extraction procedure adopted for the ILV (Todd 2007a) is identical to that used in the original validation study (Gatti, 2001). The GC-ECD conditions are also comparable for each study, including the column which although it is made by a different manufacturer, incorporates a comparable stationary phase. It is necessary to optimise instrument conditions from one GC-ECD instrument to another, therefore minor changes to the instrument parameters can reasonably be considered to be acceptable. The ILV clearly demonstrates	Data requirement Additional validation data according to SANCO/825/00/rev. 8.1 should be submitted for the method Gilberto, 2009 in order the method to be considered validated as a monitoring method for high water content matrices, in particular: additional samples at each fortification level for the confirmatory method and an ILV. See also 1(51), 1(57)

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Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>that the analytical method validated for the determination of chloropicrin in tomatoes (Gatti 2001) can be successfully transferred to another laboratory.</p> <p>Applicant: A further ILV for the determination of chloropicrin in tomatoes was also conducted in Gandhi 2008 which was sufficient to demonstrate that the method can be transferred to another laboratory while still achieving an LOQ of 0.005 mg/kg.</p> <p>RMS: The original monitoring method for chloropicrin in high water crops (Gatti, 2001) had an LOQ of 0.01 mg/kg was considered fit for purpose by the RMS, acceptable ILV data was presented for this method (Todd, 2007).</p> <p>The method was then re-validated (Gilberto, 2009) with an LOQ of 0.005 mg/kg, this method was also considered fit for purpose by the RMS, noting that acceptable ILV data was not available (the ILV data presented (Gandhi, 2008) used a different method of analysis).</p> <p>Therefore, based on the data RMS considers that sufficient validation data are available to demonstrate chloropicrin in high water commodities can be analysed for with an</p>	

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Methods of analysis				
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			LOQ of 0.005 mg/kg, however there is a data gap for acceptable ILV data to support this method/LOQ. Data gap	
1(45)	Vol. 3CA-CP, Table B.5.1.3-4	FR: Please correct the typo $R^2=1$ instead of $R^2>1$	Applicant: This comment is noted. RMS to note when revising DAR. RMS: This can be corrected in the DAR Addressed	Addressed RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
1(46)	Vol. 3CA-CP, Tables B.5.2-6, B.5.2-10, B.5.2-14, B.5.3.2-3 and B.5.3.3-2	FR: The linear range should not be said appropriate, as it does not fulfil SANCO/825/00 rev.8.1. However, we agree with the RMS evaluation of the validity of the analytical methods.	Applicant: We agree with the overall conclusion that each method is fit for purpose. RMS: Noted, thank you. The wording in the DAR can be updated with respect to the linear range Addressed	Addressed
1(47)	Vol. 3CA-CP, B.5.2. Residues in plant products	FR: Only analytical methods in high water content (tomato) and acidic (strawberry) matrices are discussed in this section. Dry matrices or matrices with high oil content are not described and are lacking. Whatever the claimed uses, analytical	Applicant: Agreed. Monitoring methods have only been provided for high water content and high acid content commodities. Additional data can be provided on request. RMS: Noted, RMS can evaluate and include	Data requirement Monitoring methods for analysis of the residue definition in high oil content and dry matrices according to SANCO 825/00/rev. 8.1 are required. See also 1(52), 1(53), 1(54), 1(58)

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Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		methods validated according to SANCO/825/00 rev 8.1 for determining residues in plant products are required for each type of plant matrix.	monitoring methods for other commodity groups if the data is requested by EFSA Data gap	
1(48)	Vol. 3CA-CP, B.5.2. Residues in plant products	FR: Extraction efficiency has not been evaluated in all types of matrices. It should be clearly indicated that these data will be required if a preparation including chloropicrin claims some uses where extraction efficiency data are lacking.	Applicant: Extraction efficiency has not been assessed for a number of matrices. The efficiency of each method has however been demonstrated by acceptable recovery and precision data therefore the methods are considered to be acceptable for the purposes of monitoring and enforcement. RMS: It is agreed extraction efficiency has not been demonstrated, however in line with SANCO 825/00 rev 8.1, based on the metabolism study and residues trials, residues >0.005 mg/kg are not expected in any plant commodity; therefore it is not considered that extraction efficiency is required to be addressed in this case. However, it is noted that due to deficiencies in the metabolism study it is not possible to conclusively determine the absence of residues. Therefore if further uses are agreed for a product, additional data to demonstrate acceptable extraction efficiency may be required.	Addressed

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Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			Addressed	
1(49)	Vol. 3CA-CP, B.5.3.2. Residues in water	FR: An ILV is required for the analytical method for the determination of residues of chloropicrin in water, and it is lacking.	<p>Applicant: The data supporting this application is to be evaluated against the 'old' data requirements of Commission Regulation (EU) No 544/2011. An ILV of the method for determining residues of chloropicrin in water (drinking) is not a requirement of the old data requirements therefore no further data is required.</p> <p>RMS: MS agrees with the applicant, ILV for drinking water is not required under Reg. (EU) 544/2011</p>	Addressed ILV for drinking water is not required under Regulation (EU) 544/2011 See also 1(59)
1(50)	Vol. 3, B.5.2. ANALYTICAL METHODS (RESIDUE) FOR TREATED PLANTS, PLANT PRODUCTS, FOODSTUFFS OF PLANT AND ANIMAL ORIGIN AND FEEDING STUFFS p. 9-10	NL: 'Fit for purpose' is not a characterisation which is appropriate and acceptable for post-registration methods used for monitoring/enforcement purposes. Please indicate if the reviewer accepts or does not accept this analytical method (for monitoring/enforcement purposes) in light of the SANCO/825/00 rev. 8.1 guidance. Additional data is therefore required and should be provided, to prove the analytical method is satisfactorily validated according	<p>Applicant: The monitoring and enforcement methods presented in section B.5.2 meet the requirements of SANCO/825/00 rev.8.1 with the exception on occasion of assessments of matrix effect and extraction efficiency. Assessment of matrix effect and extraction efficiency were not a requirement when the methods were initially validated.</p> <p>The acceptable accuracy and precision data obtained during the validation of each method demonstrates that there was no</p>	Open point RMS to make it clear in an amended DAR which methods are considered acceptable as monitoring methods although some deviations from SANCO/825/00 rev. 8.1 were identified and which methods are not considered acceptably validated unless additional data are provided. The additional data requirements should be clearly stated.

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Methods of analysis				
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		<p>to SANCO/825/00 rev. 8.1. <i>This also applies to the ILV studies provided on p. 11-16, primary method study on p. 17-18, ILV study on p. 21-22, primary method study soil p. 23-24, primary method study water p. 25-27, primary method study air p.28-30 and primary method studies body fluids and tissues p. 31-35.</i></p> <p>NL: The conclusion stated on p. 36 is therefore not correct and incomplete and additional data gap's should be stated. This is unless it can be sufficiently substantiated that is not needed in light of possible residues in the plant/animal matrices, environmental matrices and human fluids and tissues.</p>	<p>significant matrix effect and that the extraction procedure was efficient. The monitoring and enforcement methods presented to support this application are therefore considered acceptable for monitoring and enforcement purposes.</p> <p>RMS: The term 'fit for purpose' is used by the RMS in case where the method cannot be considered fully validated in accordance with SANCO 825/00 rev 8.1 but nevertheless is considered acceptable for regulatory purposes. Therefore, where this conclusion is drawn, RMS is accepting the method, but notes further data would be required for the method to be considered fully validated.</p> <p>The RMS does not consider that additional data is required to address these relatively minor deficiencies on the basis that they do not significantly impact on the acceptability of the methods, and as residues \geqLOQ are not expected in any commodity.</p> <p>Addressed</p>	
1(51)	Vol. 3 CA-CP, B.5.2. Analytical methods	EFSA: The methods presented could be considered as validated for high water and	Applicant: The RMS considers that the methods presented for monitoring and	<p>Data requirement</p> <p>A confirmatory method is required for</p>

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Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
	(residue) for treated plants, plant products, foodstuffs of plant and animal origin and feeding stuffs (IIA 4.2.1, IIIA 5.2)	high acid content matrix groups, providing that the deficiencies pointed out by RMS are addressed.	<p>enforcement are fit for purpose. Although some methods do not address matrix effect or extraction efficiency, the acceptable accuracy and precision data obtained is considered sufficient to confirm the lack of any significant matrix effect and the efficiency of the extraction procedure.</p> <p>RMS: These methods are currently considered as fit for purpose (pending ILV data for high water commodities), however it is agreed that if the deficiencies in the methods were addressed the methods could be considered validated.</p> <p>Addressed</p>	<p>the monitoring method in high acid content matrices (strawberry) See data requirement in 1(44)</p>
1(52)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: We support the data requirement for an analytical method for plant commodities with high fat content.	<p>Applicant: This comment is noted and a validated method for the analysis of high fat/oil content crops can be provided on request.</p> <p>RMS: Noted, thank you. RMS can evaluate and include monitoring methods for other commodity groups if the data is requested by EFSA</p> <p>Data gap</p>	See data requirement in 1(47)

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Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(53)	Vol. 5, B.5.5, Evaluation and assessment	Applicant: Within the evaluation and assessment of the methods section B5, it is stated that a monitoring method is required for high oil commodities. This comment is noted and suitable data will be provided on request.	RMS: Noted, RMS can evaluate and include monitoring methods for other commodity groups if the data is requested by EFSA Data gap	See data requirement in 1(47)
1(54)	Vol. 3 CA-CP, B.5.2. Analytical methods (residue) for treated plants, plant products, foodstuffs of plant and animal origin and feeding stuffs (IIA 4.2.1, IIIA 5.2)	EFSA agrees with RMS a validated monitoring method for determination of residue definition in high oil content matrix is needed.	Applicant: Within the evaluation and assessment of the methods section B5, it is stated that a monitoring method is required for high oil commodities. This comment is noted and suitable data will be provided on request. RMS: Noted, RMS can evaluate and include monitoring methods for other commodity groups if the data is requested by EFSA Data gap	See data requirement in 1(47)
1(55)	Vol. 3 CA-CP, B.5.2. Analytical methods (residue) for treated plants, plant products, foodstuffs of plant and animal origin and feeding stuffs (IIA 4.2.1, IIIA 5.2), Method SXC0033	EFSA: Please clarify the reason of reporting method SXC0033. The method has deficiencies: no confirmatory method is present, matrix effects are not investigated. It is stated that the intention is the method to be an ILV of the LN96-A, however better validated method (S13-03747) is reported as an ILV for LN96-A.	Applicant: Method SXC0033 is presented as supporting information to further demonstrate that method LN96-A can be successfully transferred to another laboratory. This study should be assessed alongside validation study S13-03747 and the requirement for an ILV study for the determination of chloropicrin in strawberries has been fully addressed.	Open point RMS either delete the study or make it clear that it is reported only for completeness

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No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			RMS: As noted by the applicant this study is presented as additional ILV data for the determination of chloropicrin in strawberries. It is agreed the method is not fully validated, however the study was included for completeness. This study can be removed from the DAR if required Addressed	
1(56)	Vol. 3 CA-CP, B.5.3.1. Residues in soil (IIA 4.2.2) B.5.3.2. Residues in water (IIA 4.2.3) B.5.3.3. Residues in air (IIA 4.2.4) B.5.4. Analytical methods (residue) in human and animal tissues and fluids (IIA 4.2.5, IIIA 5.2)	EFSA: Level of the matrix effects needs to be addressed.	Applicant: The acceptable accuracy and precision data obtained during the validation of each method demonstrates that there was no significant matrix effect observed when analysing any environmental matrices or human body fluids and tissues. RMS: In one study matrix effects have been considered (Brown, 2013, ILV strawberry). In the other methods, matrix effects have not been formally determined and matrix matched standards have not been used for validation. However, in every study, two or more fortification levels were used for the determination of accuracy (via spiking), and acceptable recoveries were obtained. As accuracy is determined by a comparison of the known fortified level and the detected	Open point RMS to include consideration on the matrix effects for the monitoring methods in an amended DAR

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No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>level (determined using the linear calibration curve generated using solvent standards), it is possible to determine that significant matrix effects are not observed, as if there were significant effects, unacceptably high/low recoveries would be observed.</p> <p>On this basis RMS considers that further data to address matrix effects is not required. The DAR can be updated to reflect this.</p> <p>Addressed</p>	
1(57)	Vol. 5, B.5.5, Evaluation and assessment	Applicant: Within the evaluation and assessment of the methods section B5, it is stated that Todd, 2007a (B.6.1.2.2) is not considered acceptable as an independent laboratory validation (ILV) of method LN78-01 because a different method was used. The extraction method is the same as used in the original validation study, it was only the chromatographic conditions that were changed. Different instruments (in this case GC-ECD) often require different conditions in order to optimise the performance, however the acceptable recovery and precision data demonstrated	<p>RMS: For the analysis of chloropicrin in high water commodities Todd, 2007a is considered as acceptable ILV for Gatti, 2001, which supports an LOQ of 0.01 mg/kg. This is stated on p 12 and 36 of B5.</p> <p>However, Gandhi 2008, is not considered as acceptable ILV for Gilberto, 2009, which supports an LOQ of 0.005 mg/kg, as the ILV uses different sample preparation and method of analysis. On this basis RMS considers that additional ILV data is required to support the LOQ of 0.005 mg/kg.</p>	See data requirement in 1(44)

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Methods of analysis				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		that the method was sufficiently independently validated and could be used for monitoring purposes. Although the ILV was only conducted down to an LOQ of 0.01 mg/kg, compared with an LOQ of 0.005 mg/kg for the method validation itself, this was considered acceptable for monitoring purposes.	Data gap	
1(58)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: In the SANCO/825/00 rev. 8.1 guidance document it is stated that analytical methods for the 4 plant commodities should be submitted. An analytical method for dry crops is missing and should be provided. This is a data gap.	Applicant: Agreed. Additional data can be provided on request. RMS: Noted, RMS can evaluate and include monitoring methods for other commodity groups if the data is requested by EFSA	See data requirement in 1(47)
1(59)	Vol. 3, B.5.5 and Vol. 1, 2.5.2	DE: An ILV for the analytical method for drinking water is missing but required according to Regulation (EU) No. 283/2013. This is a data gap.	Applicant: The data supporting this application is to be evaluated against the 'old' data requirements of Commission Regulation (EU) No 544/2011. An ILV of the method for determining residues of chloropicrin in water (drinking) is not a requirement of the old data requirements therefore no further data is required. RMS: MS agrees with the applicant, ILV for drinking water is not required under Reg.	See comment in 1(49)

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Methods of analysis				
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			(EU) 544/2011 Addressed	

Other comments				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
1(60)	Vol. 1, 2.13.2. Definition of residues for monitoring, LoEP Residue definition for monitoring purposes p. 23 and p.97	EFSA: Please check and correct where it is needed the components of the residue definition in the environmental compartments. They are reported differently at different parts of DAR	Applicant: The correct residue definitions for monitoring and enforcement are those presented in the list of endpoints. The residue definitions in volume 1 will be corrected accordingly. RMS: The residue definitions can be updated in Vol. 1 of the DAR Addressed	See open point in 1(43)
1(61)	Volume 1. Overall comment Level 3	Public comment – French Chambers of Agriculture (AFCA) We consider that in order to maintain competitiveness European horticulture access to a suitable range of soil fumigants is required. It is noted that by their very nature these substances will	Applicant: We agree with this comment from the AFCA. RMS: Noted Addressed	Noted

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Other comments				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		have effects on non-target organisms however as indicated in the overall summary these effects are limited in extent and duration. This is especially the case for the use for apple replant disease. Uncertainties identified can be resolved taking into account national conditions and use situations with if necessary additional information and national measures to minimise impacts on non-target organisms.		

Section 2 – Effects on human and animal health

2. Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, B.6.1.1.1, ADME in rats by oral route, p.9	EFSA: It should appear in one of the tables how the oral absorption was estimated to be higher than 80% (based on table B.6.1.1-2, it could be considered to be only 75%, but it seems the tissue residues are missing).	<p>Applicant: following a single low dose, oral absorption based on radioactivity in expired air and urine is 75.7% and 79.0% in males and females respectively. Following repeated oral low doses the values are 80.4% and 79.2%. Taking into account tissue residues of 5-8% as stated on Page 10, oral absorption can be assumed to be at least 80%.</p> <p>UK RMS: Agrees with the applicant. The data and conclusion are as previously considered in the EFSA Final conclusion on chloropicrin (2011). The applicant may provide additional tables of tissue residues (conversions as a percentage of administered radioactivity) upon request from EFSA. These can be included in an updated DAR.</p> <p>Open point</p>	<p>Data requirement:</p> <p>Applicant to provide revised tables of tissue residues (including conversions as percentage of administered radioactivity) for the ADME study in rats by oral route, in order to reflect clearly the calculation of the oral absorption value.</p>

Section 2 – Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(2)	Vol. 3, B.6.1.1.2, Metabolism in mice, p.11	EFSA: In the available metabolism studies, chloropicrin is described as metabolised into dichlorodinitromethane and chloronitromethane. It seems that these metabolites were identified but not precisely quantified and therefore cannot be concluded as major metabolites of chloropicrin.	<p>Applicant: dichlorodinitromethane and chloronitromethane were not quantified but can be concluded to be major metabolites of chloropicrin based on the available animal and in vitro data.</p> <p>UK RMS: Agrees with the applicant. Chloropicrin is a relatively small molecule with a simple formula and is rapidly metabolised in vivo, plausibly demonstrated by depletion of the thiol reserve both in vivo and in vitro. As a significant proportion of the administered radioactivity is excreted in the urine which is the major route of excretion of thiol-metabolites and considering the molecular structure of the compound, it is believed that the major metabolites are dichloronitromethane and chloronitromethane. No further conclusion can be drawn from the data. Considering the likely technical difficulties (see applicant comment 2(3)) and in the interests of minimising the use of vertebrates, no additional data is sought.</p> <p>The RMS considers that this point is addressed</p>	See data requirement in 2(42).
2(3)	Vol. 3, B.6.1.3:	Applicant: The study of Cinelli <i>et al.</i> , 2004	UK RMS: Noted.	Addressed.

Section 2 – Effects on human and animal health

Absorption, distribution, metabolism and excretion in mammals				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
	comparative <i>in vitro</i> metabolism	(B.6.1.2.2) demonstrates that investigation of the <i>in vitro</i> metabolism of chloropicrin is associated with significant technical difficulties due to its reactivity and volatility. Furthermore the metabolism of chloropicrin is shown to be mediated via its direct (chemical) reaction with glutathione and is therefore unlikely to be influenced by microsomal enzyme activity.	The RMS considers that this point is addressed	

Section 2 – Effects on human and animal health

Acute toxicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	Vol. 3, B.6, general	AT: RMS has stated that no acute toxicity studies have been provided but that the applicant has referred to harmonised C&L. AT is of the opinion that applicant should show access to data and that the acute toxicity studies should be evaluated in the DAR. If applicant has no physical access to these studies, the data owner can provide them, upon agreement with the applicant, to RMS for inclusion in the DAR.	<p>Applicant: We are trying to identify the data owners and obtain the full reports of the relevant studies. These can be provided, if available, as additional information on request.</p> <p>UK RMS: Applicant to provide available data upon request from EFSA.</p> <p>Data gap identified.</p>	<p>Data requirement</p> <p>Applicant to provide the full study reports and robust study summaries for the missing acute toxicity studies with chloropicrin (i.e. acute oral and dermal toxicity studies, skin irritation, eye irritation), including data on human cases if available (for consideration of C&L).</p> <p>See also comments 2(5), 2(6), 2(7), 2(8), 2(10), 2(11), 2(12), 2(16), 2(17), 2(19).</p>
2(5)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.1. Oral	EL: A more specific reference to the source of the study would be useful (<i>i.e.</i> type of study). Since the LD ₅₀ of 250 mg/kg bw/day has been agreed, classification as Acute Tox. 3 – H301 is supported. Please, correct the classification reported in the summary Table B.6.2-1.	<p>UK RMS: Agreed. the text will be revised.</p> <p>The DAR B.6.2.1 last sentence will be updated with the text in parentheses as follows:</p> <p>“In the absence of new data, the value of 250 mg/kg bw/day (Acute LD₅₀ for rats; The Pesticide Manual 15th Ed. 2009) can be supported for hazard and risk assessment purposes.”</p> <p>This information will also be added to the first row in Table B.6.2-1.</p>	See data requirement in 2(4).

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Acute toxicity				
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			The RMS considers this point is addressed.	
2(6)	Vol. 3 B.6, B.6.2.1 Acute toxicity by oral route and table B.6.2-2	FR: According to US EPA data*, a LD50 of 37.5 mg/kg bw is available by oral route. In the absence of acute oral toxicity study in the renewal dossier, this value would support a more severe classification proposal (Acute oral tox. 2). * US EPA - Chloropicrin. Human health assessment scoping document in support of registration review, Sept 2013. https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0153-0003	Applicant: We are trying to identify the data owner and obtain the full report of this study. This can be provided, if available, as additional information on request. UK RMS: Noted. The RMS has presented the harmonised classification for the substance as obtained from the Classification & labelling Inventory (Annex VI of Reg 1272/2008) which is public domain as well the information from The Pesticide manual 15 th Ed. 2009. This publication also references the US EPA toxicity classification of chloropicrin as Cat II which is defined for liquids as (Oral LD ₅₀ 200 – 2000 mg/L). In light of the conflicting references to US EPA information, the RMS prefers to give more weight to the information currently available in the EU. See response to 2(4) Data gap identified.	See data requirement in 2(4).
2(7)	Vol. 3, B.6.2	NL: Since the information is based on public literature, it would be informative to have the information on these publications with a (short) summary.	Applicant: We are trying to identify the data owners and obtain the full reports of the relevant studies. These can be provided, if available, as additional information on	See data requirement in 2(4).

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Acute toxicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>request.</p> <p>UK RMS: Noted. See response to comment 2(4). Data gap identified</p>	
2(8)	Vol 3, B.6.2.2.	<p>AT: Acute dermal toxicity is a data requirement according to Regulation 283/2013 ("The acute dermal toxicity of the active substance shall be reported unless waiving is scientifically justified (for example where oral LD 50 is greater than 2 000 mg/kg). Both local and systemic effects shall be investigated").</p> <p>We do not consider the acute inhalation study as sufficient to address dermal toxicity, since the study design of dermal toxicity study is different. Since chloropicrin is liquid, dermal toxicity study is technically feasible.</p> <p>However, in order not to promote animal testing we would propose either to apply for dermal toxicity the same hazard as for oral toxicity, as a worst case assumption or to justify more in detail why no acute dermal toxicity is expected.</p> <p>The sentence in the DAR that chloropicrin is not classified for acute dermal toxicity according to CLP is not substantiated by data, since it appears that no appropriate</p>	<p>Applicant: the EPA document referred to in the previous comment (2(6)) from FR cites an acute dermal LD50 of 100 mg/kg bw in the rat. This would result in Classification in CLP Category 2. We are trying to identify the data owner and obtain a full study report. This can be provided, if available, as additional information on request.</p> <p>UK RMS: Please note that the dossier was submitted under the interim data requirements Reg 544/2011, not Reg 283/2013.</p> <p>Regarding the lack of a dermal toxicity study and the technical feasibility of such a study, this is questionable as the substance is a highly irritating and volatile liquid; studies of acute dermal toxicity are not considered to be scientifically justified and additionally are not in the interests of animal welfare.</p> <p>Nonetheless, we support the applicant's</p>	See data requirement in 2(4).

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Acute toxicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		data (study) on dermal toxicity is available.	efforts to obtain existing data generated from sources outside the EU. Open point.	
2(9)	Vol. 1, 2.6.2, Summary of acute toxicity, p.34	EFSA: In the list of end points, for acute toxicity, a line should be added to report the result triggering the classification STOT SE Cat. 3.	UK RMS: The classification STOT SE3 'May cause respiratory irritation' is taken from the harmonised classification of chloropicrin in accordance with Annex VI of CLP Reg 1272/2008. Classification in Cat 3 is based on data primarily derived from humans (not submitted in this dossier). The point the RMS was trying to make is that the information in [REDACTED], 1999 B.6.2.3.a is supportive of the existing harmonised classification. The RMS considers this point is addressed.	Addressed.
2(10)	Vol. 3, B.6.2.1, Acute oral toxicity	DE: On one hand, it is stated that no studies have been submitted. On the other hand, an LD ₅₀ of 250 mg/kg bw is mentioned, referring to the "Pesticide manual". Is there any indication where this information might come from and how reliable it is? The proposed classification into category 3 is supported but only on condition that the basis is reliable. Otherwise, a firm conclusion on classification for acute oral toxicity cannot be drawn, Formally, a data gap should be	Applicant: We agree that further testing for acute toxicity is not required and is not in the interests of animal welfare. UK RMS: Regarding the lack of an acute oral toxicity study and the feasibility of such a study: this is questionable as the substance is a highly irritating and volatile liquid; studies of acute dermal toxicity are not considered to be scientifically justified and additionally are not in the interests of animal welfare. There may be significant difficulties in	See data requirement in 2(4).

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		set. However, since further animal testing with this very toxic substance should be avoided and because of its high volatility, acute toxicity should be assessed solely on the basis of the inhalation experiments.	extrapolating route-to-route because chloropicrin manifests its primary toxicity in the form of local effects (Guidance on the application of the CLP criteria v 4.1, ECHA). See RMS response to comment 2(4), data gap identified.	
2(11)	Vol. 3, B.6.2.1, Acute oral toxicity	DE: A high acute oral toxicity to rats is also likely when the death rate in the published 10-day study in SD rats with gavage application (see B.6.3.2.2) is taken into consideration even though the exact time of death was not reported. And what about using the micronucleus assay in mice (████████, 2003, See B.6.4.2.1) as an alternative source of information even though the post-observation period, of course, was too short? Is there any information on unscheduled deaths within the 24 or 48 hours in this study?	Applicant: Deaths occurred in the mouse micronucleus assay at the highest dose level of 250 mg/kg bw (3/14 males). Mortality (1 of 4 mice tested) is also reported in the associated range-finding study at a dose level of 300 mg/kg bw. All deaths occurred within 20-24 hours of dosing. These data support the agreed acute oral LD50 of 250 mg/kg bw. UK RMS: Agrees with applicant's summary of mortality in the mouse micronucleus assay. There were moderately severe clinical signs (Guidance Document on the Recognition, assessment and Use of Clinical Signs as humane Endpoints for Experimental Animals Used in Safety Evaluation. Environmental Health and Safety Monograph Series on Testing and Assessment No 19. OECD 2000) in the micronucleus assay at 125 mg/kg	See data requirement in 2(4).

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No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>bw/day which led to no deaths whilst there were 3 deaths at 250 mg/kg bw/day (and at 300 mg/kg bw/day in the preliminary toxicity test) which were accompanied by significant and severe clinical signs.</p> <p>The RMS considers this point is addressed.</p>	
2(12)	Vol. 3, B.6.2.1, Acute oral toxicity, p.16	<p>EFSA: In the absence of a detailed acute oral toxicity study in the dossier, the more severe proposal for classification (Toxic if swallowed) is difficult to support.</p> <p>It is also noted that in the micronucleus test, the maximum dose administered is 250 mg/kg bw and is considered that maximum tolerated dose.</p>	<p>Applicant: See comments above</p> <p>UK RMS: The previous conclusion of the EFSA review on chloropicrin has been maintained in the current assessment. The oral LD50 concluded in the previous review (250 mg/kg bw/day) is also now supported by the findings in the in vivo micronucleus assay.</p> <p>The RMS considers this point is addressed.</p>	See data requirement in 2(4).
2(13)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.3 Inhalation	<p>EL: Classification as Acute Tox. 1 – H330 is supported.</p> <p>Please, include the classification related to acute inhalation toxicity in the summary Table B.6.2-1.</p>	<p>Applicant: RMS to consider when revising DAR.</p> <p>UK RMS: Classifications will be added to the 4 acute inhalation studies in Table B.6.2-1</p> <p>The RMS considers this point is addressed.</p>	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.

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Acute toxicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(14)	Vol. 3 B.6, B.6.2.3 Acute toxicity by inhalation route and table B.6.2-2	FR: supports the newly proposed classification Acute tox. 1 H330.	UK RMS: Noted, thank you. The RMS considers this point is addressed.	Addressed.
2(15)	Vol. 3, B.6.2.6	NL: As it is currently written down here, it indicates that chloropicrin is a sensitiser ("Since, chloropicrin is a skin irritant and sensitiser"). From Vol. 1, and the current harmonised classification it can be concluded that chloropicrin is not a skin sensitiser. Please adjust the wording in Vol. 3, B.6.2.6.	Applicant: Agreed – there is no indication that chloropicrin is a skin sensitiser UK RMS: Noted and agreed with both the NL CA and the applicant. However, we cannot locate the sentence that the commenter has quoted in the preceding column in the DAR, therefore we consider this point is addressed.	Addressed.
2(16)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.4 Skin Irritation	EL: A reference and if possible a summary of the available information/data for classification as Skin Irrit. 2 – H315 should be provided.	Applicant: RMS to consider when revising DAR. UK RMS: Summary can be requested from the applicant and reviewed by the RMS in an updated DAR. Open point	See data requirement in 2(4).
2(17)	Vol. 3, B.6.2 Acute Toxicity, B.6.2.5 Eye Irritation	EL: A reference and if possible a summary of the available information/data for classification as Eye Irrit. 2 – H319 should be provided.	Applicant: RMS to consider when revising DAR. UK RMS: Summary can be requested from the applicant and reviewed by the RMS in an updated DAR.	See data requirement in 2(4).

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No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			Open point	
2(18)	Vol. 3, B.6.2.4, Skin irritation; B.6.2.5, Eye irritation	DE: Taking into account the brief justifications given to explain that, in the absence of specific studies, classification is needed, we do not understand why, in both cases, category 2 is assigned but not category 1. Please clarify!	<p>Applicant: Although there is a harmonised classification for skin and eye irritation in Cat 2, there appear to reports of skin burns and eye damage following exposure to liquid chloropicrin. A precautionary classification in Cat 1 (Corrosive, serious eye damage) may therefore be appropriate</p> <p>UK RMS: Applicant to submit the reports which support the Cat 1 classification. If the applicant is able to provide further information (i.e. reports of adverse effects in humans) upon request from EFSA, this can be incorporated into a revised DAR.</p>	See data requirement in 2(4).
2(19)	Vol. 3 B.6, B.6.2.5 Acute toxicity, Eye irritation and table B.6.2-1 and 2	FR: Further available data (human data see section B.6.9 and US EPA data) indicate that a corrosive classification could be relevant for chloropicrin. Furthermore, as no skin/eye irritation studies are available, a corrosive effect cannot be excluded on this basis. Could you please discuss this point?	<p>Applicant: See preceding comment</p> <p>UK RMS: It is not currently possible to evaluate the human data as this was not submitted by the applicant. Furthermore, no relevant literature regarding acute toxicity or irritation has been identified by the</p>	See data requirement in 2(4).

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Acute toxicity				
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		If classification as corrosive is not considered appropriate, it has to be taken into account that the harmonized CLP classification is a translation from the former directive. For eye irritation, the classification criteria of CLP are less permissive. Without the results of the study/data used to classify H319 (R36), it cannot be certain that chloropicrin is not more dangerous for this endpoint. Furthermore, H318 is supported by the effects observed in human.	applicant's literature review. The existing classification included in Annex VI to CLP Reg 1272/2008 has been proposed by the applicant. We would agree with this classification, however, if the applicant is able to provide further information (i.e. reports of adverse effects in humans) upon request from EFSA, this can be incorporated into a revised DAR. The RMS notes that there are currently 43 notifications for chloropicrin on the ECHA C&L inventory and all of them are for Cat 2 skin & eye irritation. Open point	
2(20)	Vol. 3, B.6.2, Summary of acute toxicity, including irritancy and sensitisation, studies	DE: Is respiratory depression part of the likely mode of action resulting in the very high inhalative toxicity? If so, the proposal STOT-SE would mean a double classification for the same effect.	Applicant: The findings of the acute inhalation toxicity studies indicate that chloropicrin is essentially locally acting (i.e. causing toxicity via severe irritation). The same mechanism (irritation) is likely to cause respiratory depression via stimulation of receptors in trigeminal nerve endings. This rodent-specific effect to inhaled irritant chemicals causes a reduced breathing rate. Toxicity results from local cytotoxicity rather than from the induced respiratory depression.	Addressed.

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			<p>UK RMS: We agree with the applicant, noting that there are currently no animal tests which deal with respiratory tract irritation, which is the endpoint for which chloropicrin holds harmonised classification (STOT-SE3). The classification of "fatal if inhaled" Acute Tox Cat 2 inhal. is driven by the lethality following acute inhalation exposure to the substance which is not confirmed as being primarily due to respiratory depression.</p> <p>The RMS considers that this point is addressed.</p>	

Genotoxicity				
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2(21)	Vol. 3 B.6, B.6.4.1 <i>In vitro</i> studies Ames test	<p>FR: Could you please provide the whole tabulated data for every strains of every assay with and without S9?</p> <p>FR agrees that the Ames test is positive on</p>	<p>Applicant: See comment 2(22) below</p> <p>RMS: Thank you, however we disagree with</p>	<p>Experts' consultation</p> <p>Genotoxic potential of chloropicrin to be discussed by the experts.</p>

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Genotoxicity				
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		<p>several strains as concluded by the RMS. It can also be added that strain TA100 shows borderline results, i.e. reproducible dose-related increases with a maximum value just below the threshold of 2-fold increase. In the first assay with S9 mix, the increase for this strain is 1.7-fold. Without S9, no results were provided for this strain. In the confirmatory assay with and without S9 mix, the increase of revertants is dose-related and represents a 1.8- and 1.7-fold increase respectively. Moreover, a strain able to detect cross-linking mutagens (<i>Salmonella typhimurium</i> strain TA102 or <i>E. coli</i> strain WP2 or WP2 (pKM101)), as required by OECD Guidance Document 471, was not used in this assay.</p>	<p>the insertion of unnecessary tables into the DAR, especially considering the outcome of this test. We can see no value in providing the additional tables or repeating the study as the data clearly support the conclusion that the study is 'positive'. In addition, the tabulated data are available in the original study report if the reader wishes to scrutinise the numbers further.</p> <p>If the table is considered essential, the applicant shall provide it upon request from EFSA.</p> <p>The RMS considers that this point is addressed.</p>	<p>See also data requirement in 2(23). See also open point in 2(24). See also comments 2(22), 2(26), 2(27), 2(28), 2(29), 2(30).</p>
2(22)	Vol. 3, B.6.4.1.1	NL: The AMES test does not include <i>E. coli</i> WP2 uvrA or TA 102, therefore, no strain was included that can detect cross-linking mutagens.	Applicant: the study was performed in compliance with the guideline in place at the time; however it is recognised that the study does not fully comply with the current (1997) version of the guideline in that it does not include all recommended bacterial tester strains. However the study gives a positive result in strain TA 98 in the presence of metabolic activation; repeating the study would therefore be of questionable benefit to the risk assessment.	See experts' consultation in 2(21).

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			<p>UK RMS: Is in agreement with the applicant. No further regulatory conclusion can be drawn from repeating an Ames test to current guidelines. This is because the current test is concluded to be 'positive' and it is considered in a weight of evidence to inform on both the hazard and risk assessment.</p> <p>The RMS considers that this point is addressed.</p>	
2(23)	Vol. 3, B.6.4.1.1	AT. We agree that AMES test can be considered as positive. However, we miss an appropriate follow-up test for gene mutation. Indeed, there is no single assay deemed sufficient to mitigate concerns with an AMES positive finding. However, one in vivo option is transgenic gene mutation assay. RMS/applicant is kindly asked to add justification for no follow up test for positive AMES assay. Please note that neither MN assay in vivo nor UDS assay are appropriate or sufficient follow up for genotoxicity in bacterial cells.	<p>Applicant: The current application for approval of chloropicrin was submitted in December 2013 therefore the applicable active substance data requirements are those set out in Commission Regulation 544/2011. According to those requirements, the unscheduled DNA synthesis (UDS) assay is the suitable and required follow-up to the positive result for gene mutation reported in the Ames test. In addition, the mouse micronucleus assay is specified as a suitable follow-up to the positive result for cytogenicity reported in the study in vitro.</p>	<p>Data requirement Applicant to provide further assessment/data on the in vivo gene mutation potential of chloropicrin, as follow-up for a positive Ames test.</p> <p>See also experts' consultation in 2(21).</p>

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			<p>Recently, since the submission of the chloropicrin dossier, the applicability of the UDS assay has been reconsidered by EFSA. The recent EFSA Scientific Opinion (published in December 2017) proposes that the UDS assay should no longer be recommended for 'future assessments'. The Opinion recommends for 're-assessments' that existing UDS studies may be considered adequate to assess genotoxic potential if the results are positive but that the reliability and significance of negative results will need to be considered carefully in a weight of evidence approach (taking into account all available information on mode of action, metabolism, toxicokinetics etc.) before a decision is taken on the need for more sensitive tests.</p> <p>In the current application, both the RMS (UK) and co-RMS (Italy) are in agreement that the existing data are sufficient to show that chloropicrin is not genotoxic <i>in vivo</i>. This conclusion was reached with both the RMS and co-RMS being aware of the discussions surrounding the applicability of the UDS assay. Therefore, given that the submission meets the applicable data</p>	

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			<p>requirements, it is proposed that the results of the UDS assay are carefully considered by Member States, in line with the weight of evidence approach proposed for re-submissions, in order to avoid unnecessary animal testing. Following that consideration should a requirement be identified for further <i>in vivo</i> testing such a requirement should be considered as being confirmatory given that, in line with Article 6 (f) of Regulation 1107/2009, this would clearly represent a situation where "new requirements are established during the evaluation process or as a result of new scientific and technical knowledge."</p> <p>It should be noted that Chloropicrin is a locally acting toxin; therefore effects of concern are most likely at the site of contact. In the case of chloropicrin (as a highly volatile liquid fumigant), the relevant site of contact is clearly the respiratory tract. In this regard it is notable that studies of the carcinogenicity of chloropicrin in two species using inhalation exposure give negative results. Although genotoxicity is considered an endpoint in its own right, the absence of carcinogenicity in inhalation</p>	

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Genotoxicity				
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			<p>studies and the absence of reproductive/developmental toxicity potential should be taken into account.</p> <p>While the limitations of the UDS assay as a follow-up <i>in vivo</i> assay are recognised, this tissue is likely to be relevant for chloropicrin as a reactive and rapidly metabolised substance. Highest tissue residues of radioactivity are reported for the liver (the first site of systemic contact) in the ADME studies; this organ is also a target of toxicity following oral exposure (e.g. the increased periportal hepatocyte vacuolation) reported in all groups of rats in the chronic toxicity/carcinogenicity study.</p> <p>If further testing is required, the relevance of the two available assays (Comet assay, TGR assay) and the route of exposure need to be carefully considered. Clearly for chloropicrin as a volatile substance with predominantly local action, the respiratory tract is the most relevant tissue. In this regard it is unclear if the TGR assay is validated for inhalation exposures.</p> <p>The EU TF are aware of ongoing work in the</p>	

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Genotoxicity				
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			<p>USA, investigating the genotoxicity of chloropicrin in the respiratory tract of rats following inhalation exposure. The study is expected to report later this year and is likely to be informative in any assessment of the genotoxic potential of chloropicrin.</p> <p>UK RMS: The submitted chloropicrin dossier fulfilled the data requirements applicable at the time of submission. In addition, the available mammalian gene mutation is negative. Therefore, no further animal testing is required and the RMS is in agreement with the applicant's response to this comment. The justification presented can be incorporated in the revised DAR.</p> <p>The RMS considers that this point is addressed.</p>	
2(24)	Vol. 3, B.6.4.1.3	AT: RMS is kindly asked to add information on positive controls, which are not mentioned in the study summary. Positive controls are needed to demonstrate the ability of the laboratory to identify mutagens. The validity of results without positive controls is questionable. RMS is also kindly asked to add the exposure	Applicant: information on positive controls is available in the study and the RMS can consider this in revision of the DAR. Ethyl methanesulfonate (EMS) was used as the positive control in the non-activated study at two final concentrations of 0.5 and 0.25 µL/mL. 7, 12-Dimethylbenz(a)anthracene (7, 12-DMBA) was used as the positive	Open point: For the in vitro gene mutation test in mammalian cells (mouse lymphoma mutagenesis assay), the RMS should provide in a revised DAR: - additional information on positive

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Genotoxicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		<p>time, as well as to check the units for mutant frequency.</p> <p>RMS is kindly asked to extend the description of this study, and also add deficiency of the study comparing to current OECD Guideline.</p>	<p>control in the S-9 activated study at two final concentrations of 5.0 and 2.5 µg/mL. The performance of the positive control substance confirmed the sensitivity of the study.</p> <p>UK RMS: We agree. The details (as indicated by the applicant in their response to this comment) will be added to the updated DAR. Please note that the exposure duration (4 hours) is mentioned in the last sentence of the "Methods" section of the study summary presented in the DAR. The expression times were 24 and 48 hours. Additional clarification of the method shall be added to an updated DAR. The RMS is confident that the critical quality criteria for a well-performed mammalian cell forward mutation assay has been met. This study followed the methodology of Clive (1975) which is the basis of the OECD TG. A preliminary cytotoxicity test was used to define the main test concentration levels, suitable positive and negative controls were used and standard exposure and expression times employed.</p> <p>Summary can be requested from the applicant and reviewed by the RMS in an</p>	<p>controls</p> <ul style="list-style-type: none"> - a check of the units for mutant frequency values - a more extensive description of the deviations when comparing to the current OECD guideline <p>See also comment 2(25).</p> <p>See also experts' consultation in 2(21).</p>

Section 2 – Effects on human and animal health

Genotoxicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			updated DAR. Open point	
2(25)	Vol. 3 B.6, B.6.4.1.3 In vitro genotoxicity testing- Test for gene mutation in mammalian cells, RHC and Sigler, 1990	FR: Please indicate the meaning of "V.C." in the tables of this study. Could you please also provide the positive control data and detail the deviations of this study. Based on these additional data, the reliability of the negative result of the study should be discussed.	Applicant: see comment immediately above in relation to the positive controls. V.C. stands for viable count. RMS to consider in revision of the DAR. UK RMS: See RMS response to comment 2(24) where a data gap was identified.	See open point in 2(24).
2(26)	Vol. 3 B.6.4 Summary of genotoxicity studies	FR: Chloropicrin was positive in several strains of <i>Salmonella typhimurium</i> in the Ames test available and in the literature review. Moreover, a strain able to detect cross-linking mutagens was not used in this assay. It is acknowledged that the <i>in vitro</i> gene mutation study was considered negative (pending clarifications on the reliability of the result, see above comment). Nevertheless, the UDS test is not considered as sufficiently sensitive. Therefore, it is considered that there is an uncertainty on the mutagenic potential of chloropicrin.	Applicant: Please see applicant response at 2(23) above and comment at 2(27) below. RMS: The RMS, applicant and the previous EFSA conclusion (2011) are consistent in concluding that based on the entire genotoxicity database, chloropicrin is not genotoxic in-vivo. The absence of a strain which specifically detects cross-linking mutagens in the Ames test is not of concern when viewing the entire genotoxicity database (considered complete under the applicable data requirements) which is presented in the DAR.	See experts' consultation in 2(21).

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Genotoxicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			The RMS considers this point is addressed.	
2(27)	Vol. 3, B.6.4: Summary of genotoxicity	Applicant: We agree with the RMS and co-RMS conclusion that chloropicrin is not genotoxic <i>in vivo</i> , based on the negative results in the bone marrow micronucleus and UDS assays. This is consistent with the conclusion presented in the EFSA Conclusion ¹ on the pesticide peer review for chloropicrin published in 2011 which concludes that chloropicrin is weakly genotoxic <i>in vitro</i> and non-genotoxic <i>in vivo</i> . The overall conclusion being that chloropicrin has no genotoxic potential relevant to humans.	RMS: Agreed, thank you. This point is addressed.	See experts' consultation in 2(21).
2(28)	Vol. 3 B.6, B.6.4.1.2 <i>In vitro</i> genotoxicity testing-test for clastogenicity in mammalian cells, Puttman and Morris, 1990 Vol. 3 B.6.4.2.1 <i>In vivo</i> genotoxicity testing (somatic cells)-	FR: FR agrees that the test is positive at cytotoxic concentrations. However, as a negative <i>in vivo</i> test on the same endpoint is available (micronucleus test), with proof of the bone marrow exposure (supported by the data in ADME), chloropicrin can be considered non-clastogenic <i>in vivo</i> .	Applicant: Agreed; the evidence shows that chloropicrin is not clastogenic <i>in vivo</i> . RMS: Noted, thank you. This point is addressed.	See experts' consultation in 2(21).

¹ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance chloropicrin. EFSA Journal 2011;9(3):2084. [58 pp.].
doi:10.2903/j.efsa.2011.2084

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Genotoxicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
	micronucleus test in rodents, [REDACTED], 2003a			
2(29)	Vol. 3, B.6.4.2.1, In vivo micronucleus test, p.83	EFSA: Considering the results of the chromosome aberration test in CHO cells, it is important to demonstrate that the results of the in vivo micronucleus test can be relied upon. Based on the ADME data, the exposure of the bone marrow after oral administration of a single dose has been demonstrated (up to 47-48 ppm).	Applicant: Agreed, the ADME data show exposure of the bone marrow. Furthermore there is evidence of target tissue exposure (cytotoxicity) from the in vivo study as a significant decrease in the proportion of immature erythrocytes at the highest dose level. UK RMS: Noted, thank you. This point is addressed.	See experts' consultation in 2(21).
2(30)	In vivo MN assay	AT: in MN assay in vivo only 2000 erythrocytes were examined per animal for micronuclei instead of 4000. This appears to be somehow acceptable in cases where only negative vitro results were observed but is questionable for follow up of positive in vitro results.	Applicant: The study is considered to be adequate as it was performed in compliance with guideline in place at the time, and shows a clearly negative results. UK RMS: Is in agreement with the applicant. This point is addressed.	See experts' consultation in 2(21).

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Long-term toxicity and carcinogenicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(31)	Vol. 3, B.6.5.2, 2-yr inhalation rat study, p.99	EFSA: For the changes in body weight gain during the first weeks of the study at 0.5 ppm, it is noted that in females (based on Table B.6.5.2-6), the change at 0.5 ppm is higher than 10% when compared to the control group and therefore should still be considered as adverse. It is acknowledged that the conclusion of the previous peer-review is maintained.	Applicant: RMS proposes an overall NOAEC for non-neoplastic effects of 0.1 ppm, taking into account mortality and decreased survival times in males and the effects on bodyweight gain at ≥0.5 ppm. UK RMS: is in agreement with the applicant's response; the effect on bodyweight gain has been taken into account when establishing the NOAEC for this study. This point is addressed.	Addressed.
2(32)	Vol. 3 B.6.5.3, Long-term toxicity and carcinogenesis, Chloropicrin: Vapor inhalation oncogenicity study in CD-1 mice, [REDACTED], 1995b	FR: Increased incidence of lung adenomas was observed in males and females. Please provide relevant HCD for this finding. Could you please provide the tabulated results for organ weights and non-neoplastic lesions observed in the respiratory tract? Regarding the incidence of non-neoplastic findings, statistically significant and dose-related increased incidence of lung peribronchial lymphocyte infiltration was observed from 0.1 ppm for both males and females (percent incidences for the control, 0.1 ppm, 0.5 ppm and 1.0 ppm groups: 2.8%, 22%, 27%, 29% and 12%, 26%, 45%, 72% in males and females	Applicant: Please see the comments of the RMS in relation to historical data for this study. The corresponding ranges for lung (alveolar / bronchiolar) adenoma for males are 2.00-42.00% and for females are 1.67-26.67%. For this study, therefore, the incidences of lung adenoma in males do not show a dose-response relationship and are within the historical control range. For females, the incidences at the two highest concentrations exceed the historical control range; however the concurrent control value is also at the limit of the historical control range. Incidences were not significantly increased in any group. The conclusion of the RMS (and the	Data requirement: Applicant to provide summary tables of results for the organ weight changes and non-neoplastic lesions observed in the respiratory tract during the long term mouse study with chloropicrin. Experts' consultation Long term inhalation mouse study to be discussed by the experts. See also comment 2(33).

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Long-term toxicity and carcinogenicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		<p>respectively). Moreover, this finding was associated with bronchiectasis from the low dose level (3 in males and 4 in females versus 0 in controls). These findings are therefore considered relevant and could be used to set a LOAEC of 0.1 ppm for the long-term mouse study.</p>	<p>previous EFSA review) that there is no evidence of carcinogenicity from this study is agreed.</p> <p>UK RMS: It will not be possible to obtain HCD for this laboratory. In isolation, Peribronchial lymphocyte infiltration is not considered sufficiently robust to base a LOAEC on. This finding has been used to support the setting of a LOAEC at the next concentration level of 0.5 ppm which was based on clearer markers of respiratory tissue damage.</p> <p>Addressed.</p>	
2(33)	Vol. 3, B.6.5.3, 78-wk inhalation mouse study, p.114	<p>EFSA: The peribronchial lymphocytic infiltration at the low dose and the lung tumours at all doses are not considered adverse. Considering that the respiratory tract is a target organ for the toxicity of chloropicrin (including for humans), the relevance of the lung tumours should be further considered.</p> <p>It is noted that for the conversion from ppm to mg/kg bw per day, there will also be the need for normalisation for 5 days of exposure per week (to 7 days).</p>	<p>Applicant: See preceding comments.</p> <p>UK RMS: In isolation, peribronchial lymphocyte infiltration is not considered sufficiently robust to base a LOAEC on as it is commonly found under laboratory conditions. See previous comment 2(32). Although the respiratory tract is a target organ, there was no dose response in carcinomas or adenomas in either the rat or mouse. The conversion from ppm to systemic dose shall be presented in the revised DAR</p>	<p>Open point: RMS to present additional details on the conversion from ppm to systemic dose for the long term mouse study in a revised DAR.</p> <p>See experts' consultation in 2(32).</p>

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Long-term toxicity and carcinogenicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			Open point	

Reproductive toxicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(34)	Vol. 3, B.6.6.1, 2-generation study, p.125	EFSA: During the first peer review, based on the tables B.6.6.1-3 and B.6.6.1-5, the increased incidences at the high dose of animals who died or were euthanised in extremis was considered potentially treatment-related.	Applicant: We support the RMS' conclusion that there was no treatment-related mortality in this study UK RMS: Thank you for the comment. As stated in the DAR, there were no deaths in the F1 generation to support a consistent effect, the deaths occurred at a very low frequency, including in the control group in Table B.6.6.1-5. In addition, there were no indications of respiratory distress which would be expected (similar to other inhalation studies in which chloropicrin vapour induced mortality) to support the mortality being a test-substance related effect. The RMS considers this point is addressed.	Experts' consultation: Mortality in the multigeneration rat study to be discussed by the experts. See also comment 2(35).

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Reproductive toxicity				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(35)	Vol. 3 B.6.6.1 Reproductive toxicity, generational studies, [REDACTED], 1994	FR: Considering the observed mortality in several other studies, the deaths observed at the high dose in this 2-generation study should be considered as treatment-related. Nevertheless, there is no impact on the set NOAEC.	Applicant: We support the RMS' conclusion that there was no treatment-related mortality in this study UK RMS: See response to previous comment 2(34). The RMS considers this point is addressed.	See experts' consultation in 2(34).
2(36)	Vol. 3, B.6.6.2.1, Rat developmental toxicity study, p.139	EFSA: The calculation used for conversion of the inhalation levels (in ppm) to the systemic levels (in mg/kg bw per day) should also be briefly mentioned in this chapter.	Applicant: RMS to consider in revision of DAR. UK RMS: Noted, this shall be presented in an updated DAR. Open point	Open point: RMS to present additional details on the conversion from ppm to systemic doses for the reproductive and developmental toxicity studies with chloropicrin in a revised DAR.
2(37)	Vol. 3 B.6.6.2.2 Reproductive toxicity, Developmental toxicity studies, Inhalation development toxicity study in New Zealand white rabbits, [REDACTED], 1993	FR: Please provide the tabulated results for pulmonary pathology (necropsy findings) mentioned in the conclusion of the study. Abortions can be considered related to developmental toxicity. Therefore, it is proposed to set the developmental NOAEC at 0.4 ppm.	Applicant: RMS to consider in revision of DAR. UK RMS: The pulmonary pathology findings were mentioned on page 151 'Maternal observations'. A table will be presented in an updated DAR. The abortions were not considered relevant as they were found in the presence of significant (50%) maternal mortality at the high dose and in a single dam at the mid-	Open point: RMS to provide tabulated results for the pulmonary pathology (necropsy findings) in the developmental rabbit study. Experts' consultation: Maternal and developmental toxicity in the rabbit developmental toxicity study with chloropicrin to be discussed by the experts.

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Reproductive toxicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			dose. Open point	

Neurotoxicity				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(38)	Vol. 3, B.6.7	NL: A waiver is included indicating that no effects indicative of neurotoxicity were observed in the database. However, in some of the short-term studies effects were mentioned that might be related to neurotoxicity (e.g. decreased activity and tremor in the 8-week dog study; impaired limb function in the 90-day rat study).	Applicant: The isolated clinical signs are seen at high dose levels, are associated with marked general toxicity and are not indicative of neurotoxicity. UK RMS: The overall database of effects across a range of species support the conclusion that these infrequently noted signs are due to general toxicity, not a neuro-active effect of the active substance. The RMS considers this point is addressed.	Data requirement: Applicant to provide further assessment of the potential of chloropicrin for neurotoxicity. Experts' consultation: Neurotoxic potential of chloropicrin to be discussed by the experts.

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Further toxicological studies				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(39)	Vol. 3 B.6.8.2.1 Supplementary studies on the active substance, [REDACTED], 2004	FR: Considering the summary provided, it is not clear whether the concentration of 75 ppb could be considered as a NOAEC. Indeed, in the "Phase 2" results, effects were noted at 75 ppb.	<p>Applicant: We agree with the RMS' conclusion that the results of this study showed that exposure to chloropicrin vapour concentrations at or below 75 ppb (0.075 ppm) is not likely to cause noticeable sensory irritation in the test population.</p> <p>UK RMS: At 75 ppb in "Phase 2", the volunteers' responses over time did not cross the confidence threshold which determined whether or not the subject perceived very mild ocular irritation. So although the curve at 75 ppb has a positive gradient, it flattens out before it crosses the level at which there is confidence in the subjective perception of the existence of any ocular symptoms. Therefore, 75 ppb is considered to be the NOAEC.</p> <p>The RMS considers that this point is addressed.</p>	<p>Experts' consultation: Human sensory irritation data and testing with chloropicrin to be discussed by the experts.</p> <p>See also data requirement in 2(40).</p>
2(40)	Vol. 3 B.6.8.2.2 Supplementary studies on the active substance, [REDACTED], 2007	FR: Could you please detail how the BMCL10 was derived (e.g. software used...)?	<p>Applicant: this can be provided as additional information in response to a request from EFSA.</p> <p>UK RMS: Additional information can be requested from the applicant and reviewed</p>	<p>Data requirement: Applicant to provide additional details on how the BMCL 10 was derived in the use of human sensory irritation data in exposure standard setting for chloropicrin.</p>

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Further toxicological studies				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			by the RMS in an updated DAR. Open point	See also experts' consultation in 2(39).
2(41)	Vol. 3, B.6.8.3, Studies on endocrine disruption, p.167	EFSA: Has chloropicrin been screened with ToxCast for potential ED properties ?	Applicant: Chloropicrin has not been screened for ED endpoints in ToxCast. The literature search did not reveal any publications demonstrating endocrine disrupting properties. Based on the regulatory studies submitted in the dossier, chloropicrin has not been shown to have adverse effects on the endocrine organs. Therefore chloropicrin should not be considered an endocrine disruptor. UK RMS: Further information from a Toxcast report can be requested from the applicant and reviewed by the RMS in an updated DAR. Open point	Data requirement: Applicant to provide an additional scientific assessment of the potential ED properties of chloropicrin, following the OECD Conceptual Framework (as analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors, 2013). Experts' consultation Experts to discuss the endocrine disruption potential of chloropicrin.

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Toxicological data on metabolites				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(42)	Vol. 1 2.11 Relevance of metabolites in groundwater 2.11.3.2 STEP 3, Stage 2: screening for genotoxicity	FR: It is stated that DCNM was "found at levels of approximately 20% of the parent compound". Please detail how this value was derived.	Applicant: No comment provided UK RMS: The value of 20% was as concluded by the previous EU review of chloropicrin. Please see Revised Additional Report Vol 3.B.6.8.1 further information on where this was derived from can be requested from the applicant and reviewed by the RMS in an updated DAR. Open point	Data requirement: Applicant to provide further assessment of the levels of DCNM (as % of the administered parent) identified in the rat metabolism study. See also comments 2(2), 2(44). See also experts' consultation in 2(43).
2(43)	Vol. 1 2.11 Relevance of metabolites in groundwater 2.11.3.3 STEP 3, Stage 3: screening for toxicity	FR: DCNM should be considered relevant considering the uncertainties on the genotoxicity profile of chloropicrin and the lack of data for acute oral and inhalation toxicity.	Applicant: The RMS concludes in the LOEP that DCNM is a relevant metabolite; however not on the basis of its genotoxicity. We support the RMS' conclusion that, since a full data package on the active substance supports the conclusion that chloropicrin is not genotoxic, the same conclusion covers the hazard of DCNM. Therefore, in terms of genotoxicity, DCNM is not a relevant metabolite in groundwater. Furthermore it is noted that based on the transient nature of DCNM, and similarity to its parent compound, its toxicological nature and the fact that it occurs as a 20% dechlorination breakdown product of chloropicrin, it would be highly	Experts' consultation: Toxicological profile of the metabolite DCNM to be discussed by the experts. See also data requirements in 2(42) and 2(45).

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Toxicological data on metabolites				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>unlikely that this metabolite could be of any more concern than its parent compound.</p> <p>UK RMS: Agree with the applicant. Overall, a conclusion can be made on the genotoxic potential of chloropicrin – the substance is not genotoxic for the purposes of addressing human health and the environment. In addition, there is sufficient justification to address the oral toxicity of DCNM in relation to the active substance, however the same cannot be said for the inhalation toxicity of DCNM, hence why the RMS has concluded that it is a relevant metabolite. The RMS considers that this point is addressed</p>	
2(44)	Vol. 3, B.6.8.1.1, Groundwater metabolites, p.160	<p>EFSA: For the metabolite DCNM, it should be clarified what are the data (in the DAR) supporting that it was found at levels of approximately 20% of the parent.</p> <p>The considerations given in this chapter on the toxicological profile of DCNM should be supported by more robust data in order to allow the conclusion that it is less toxic than chloropicrin.</p>	<p>Applicant: It is clear from the proposed metabolic pathway that DCNM is a major metabolite of chloropicrin (resulting from the initial dechlorination step). The toxicity of DCNM is therefore covered by studies with chloropicrin and it can be concluded that DCNM is not of greater toxicological concern compared to chloropicrin.</p> <p>UK RMS: See response to comment 2(42), Open point</p>	See data requirement in 2(42).
2(45)	Vol. 3, B.6.8.1.1	AT: It appears that no studies on DCNM were	Applicant: The applicant can provide more	Data requirement:

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Toxicological data on metabolites				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
	Groundwater metabolites	<p>provided, but publicly available data summarised in the position paper.</p> <p>AT is of the opinion that if public data are provided to support substance/metabolite evaluation than these data have to be considered for their relevance and reliability and in case that these two criteria are fulfilled than the data have to be summarised in a robust study summary. Nothing like this could be found in the DAR. Therefore, the data are presented are not considered as sufficient to conclude on toxicity of DCNM.</p>	<p>detailed summaries of public domain studies as additional information, if requested by EFSA.</p> <p>UK RMS: Detailed summaries can be requested from the applicant and reviewed by the RMS in an updated DAR.</p> <p>Open point</p>	<p>Applicant to provide a more detailed assessment of the available toxicological information/data for the metabolite DCNM (including an assessment of the relevance and reliability of the public data).</p> <p>See also experts' consultation in 2(43).</p>

Medical data and information				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

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Toxicological end points: ADI, ARfD, AOEL				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(46)	Vol. 1 Level 2 2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI	FR: Agreed. It is noted that the proposed value covered the results of the 2-year rat study by inhalation.	Applicant: noted. UK RMS: Noted, thank you. Point is addressed	See experts' consultation in 2(51).
2(47)	Vol. 1 Level 2 2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)	FR: Agreed. The setting of an ARfD is supported by the results of the rat and rabbit developmental studies by inhalation where body weight loss was observed in the dams at the beginning of the treatment.	Applicant: noted. UK RMS: Noted, thank you. Point is addressed	See experts' consultation in 2(51).
2(48)	Vol. 1 Level 2 2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL chloropicrin	FR: FR agrees with the use of an AOEC instead of an AOEL, given the toxicological profile of chloropicrin. It is noted that clarifications/details on the derivation of BMCL10, and on the study used to derive this value (see above comment), are needed to conclude on the reliability and relevance of this value as the point of departure to determine the AOEC.	Applicant: the use of an AOEC is clearly more relevant for chloropicrin than a systemic AOEL. The AOEC was derived from the most sensitive human endpoint (eye irritation) and is protective of other potential health effects. Calculation of the BMCL10 is supported as a conservative estimation of the NOAEC for eye irritation. UK RMS: Noted, thank you. See responses to comments 2(40) and 2(41) Open point	See experts' consultation in 2(51). See also data requirement in 2(40).
2(49)	Vol. 1, 2.6.11 ADI	EL: The ADI proposed by the RMS, i.e. the value already agreed by the previous EU	Applicant: noted.	See experts' consultation in 2(51).

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Toxicological end points: ADI, ARfD, AOEL				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		review, is supported.	UK RMS: Noted, thank you. Point is addressed	
2(50)	Vol. 1, 2.6.12 ARfD	EL: The ARfD proposed by the RMS, i.e. the value already agreed by the previous EU review, is supported.	Applicant: noted. UK RMS: Noted, thank you. Point is addressed	See experts' consultation in 2(51).
2(51)	Vol. 1, 2.6.13 AOEL/AOEC	EL: The proposed AOEC/AOEL value is significantly higher than the AOEL agreed by the previous EU review. Considering the systemic toxicity of chloropicrin the basis of the AOEC derivation, i.e. the BMCL10 of 0.073 ppm for ocular symptoms in a human volunteer sensory irritation study, should be discussed in a meeting of experts.	Applicant: noted – see applicant response at 2(48) and also background on the study at 2(52) below. UK RMS: Agreed with the EL CA comment, further consideration is required. Open point	Experts' consultation Reference values for chloropicrin (ADI, ARfD, AOEL, AAOEL) to be discussed by the experts. See also comments 2(46-50), 2(52-57).
2(52)	Vol. 1, 2.6.13	NL: The RMS proposes a new AOEL value based on a human volunteer study, contrary to the previous evaluation where the AOEL was based on animal studies. The setting of the AOEL should be discussed in an expert meeting	Applicant: It should be noted that the volunteer study (████, 2007) was not specifically conducted to set an AOEL/AOEC for use in a regulatory risk assessment to support the registration of chloropicrin in plant protection products. Chloropicrin is used in low concentrations as an alerting/warning agent with other fumigants. The aim of the study was to determine levels at which humans could detect the presence of chloropicrin (odour threshold), at levels below irritation became apparent.	See experts' consultation in 2(51).

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Toxicological end points: ADI, ARfD, AOEL				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			See also applicant response at 2(48). UK RMS: Noted, thank you. Open point	
2(53)	Vol. 1, 2.6.13, AOEL for chloropicrin, p.41	EFSA: Consideration should have been given to the derivation of an AAOEL as well.	Applicant: the proposed AOEC is intended to cover all periods of exposure and is therefore by default also an AAOEC. UK RMS: We agree with the applicant. The RMS considers this point is addressed.	See experts' consultation in 2(51).
2(54)	Vol. 1 2.6.14 Toxicological endpoint for assessment of occupational, bystander, and residents risks -- AOEL phosgen	FR: FR supports the use of SCOEL information. However, could you please detail the rationale used for choosing the 15-min STEL value of 2 mg/m ³ (0.5 ppm) instead of the 8h-TWA value (0.4 mg/m ³ or 0.1 ppm)?	Applicant: Agreed – the TWA would appear to be a more appropriate reference value for phosgene exposure. UK RMS: Agree with FR CA. The DAR will be updated and a revised risk assessment will be provided. Open point	See experts' consultation in 2(51).
2(55)	Vol. 1, Section 2.6.3: Toxicological endpoints for assessment of occupational, bystander	Applicant: we support the UK RMS' position on the use of human data for derivation of the chloropicrin AOEC as this is based on the most sensitive endpoint of relevance	UK RMS: Noted, thank you. This point is addressed.	See experts' consultation in 2(51).

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Toxicological end points: ADI, ARfD, AOEL				
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	and residents risks	to chloropicrin exposure (i.e. sensory irritation). The application of an assessment factor of 3 (to cover potential intraspecies variation) to the BMCL10 represents a conservative and protective position.		
2(56)	Vol.1, Level 3, 3.1.1.4, Criteria for the approval, p.85, Impact on human health	EFSA: Considering the derivation of the AOEL, the limited uncertainty factor of 3 applied to a human study might not ensure an appropriate safety margin of at least 100.	<p>Applicant: The PoD for NOAEC derivation is the BMCL10 for the most sensitive effect in humans (ocular irritation). This gives a conservative estimation of the NOAEC. As eye irritation is a local effect, variability in sensitivity is likely to be limited and it is debatable whether an assessment factor is required. The assessment factor of 3 proposed by the RMS is considered to give a highly protective and conservative NOAEC. There is no scientific reason for a safety margin of at least 100 when the PoD is based on a local effect and on human data.</p> <p>UK RMS: We disagree with the use of a 10 x 10 uncertainty factor. The factor of x 3 is justified and clearly explained in the DAR.</p>	See experts' consultation in 2(51).

Section 2 – Effects on human and animal health

Toxicological end points: ADI, ARfD, AOEL				
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			The RMS considers that this point is addressed.	
2(57)	Volume 1 Section 2.6.13	<p>Public comment – French Chambers of Agriculture (AFCA)</p> <p>The conclusion indicates eye irritation is the most sensitive measure against which to consider applicator exposure and exposure to others. This appears a logical basis for the assessment to protect humans. We have commented on the assessment below.</p>	<p>Applicant: noted.</p> <p>UK RMS: Noted. The RMS considers that this point is addressed.</p>	See experts' consultation in 2(51).

Product exposure and risk assessment, including dermal absorption				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(58)	Vol. 1-Level 2, 2.6.15, Summary of product exposure and risk assessment	FR: The respective operator and worker activities need to be clearly differentiated. Indeed, it seems that activities allocated to workers (theoretically dedicated to re-entry tasks) in part 2.6.13 have been allocated to operators (theoretically	Applicant: In operator studies carried out by Labcam the professional operators act for test item application, film cut and film removal. Other activities, done at transplanting simulation are carried out by workers (= growers).	<p>Addressed.</p> <p>For the purpose of the risk assessment, taking into account the specific exposure scenarios for chloropicrin, it is considered that operators are those involved with the</p>

Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		dedicated to application tasks) in part 2.6.15.	RMS: Agree with applicant's comment. The differentiation between operators and workers in the context of chloropicrin is more complicated than standard scenarios. For the purposes of this risk assessment it was considered appropriate to consider all those involved with the application process which included film laying and removal as being operators as they would be the same personnel and would therefore be suitably trained in the use of this niche product, the use of relatively sophisticated RPE, etc. compared with re-entry workers who are not specifically trained in the use of chloropicrin and are involved only in aspects of crop production / husbandry which in this case was portrayed by the transplanting scenario. Addressed	application process (including film laying and removal), and are suitably trained in the use of this niche product, compared with re-entry workers who are involved only in aspects of crop production / husbandry such as transplanting scenario. See also comments 2(59) and 2(60).
2(59)	Volume 1 Section 2.6.15	Public comment – French Chambers of Agriculture (AFCA) The assessment sets standards (PPE/RPE and other requirements) to protect users and these are supported. These are the responsibility of the specialised	Applicant: noted. As mentioned, in response to comments in other sections of the Reporting Table, as chloropicrin is applied by a limited number of specialist operators and not by farmers/growers, a very high degree of compliance with procedures,	See comment 2(58).

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Product exposure and risk assessment, including dermal absorption				
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		applicators and compliance can be expected. The exposure to others can be managed during the period of application and the necessary 50 m zone can be implemented in site specific considerations by the applicators supported by the farmer. Given the nature of the application with trained professionals we consider the proposed measures can be put in place on the farm to allow safe use.	safety requirements and mitigation measures can be expected. RMS. Comment noted. Addressed	
2(60)	Vol. 1-Level 3, 3.1.1.3. Restrictions on approval	FR: RMS stated that, as a restriction to approval, « Professional users only (Chloropicrin 99 is supplied directly from the manufacturer to professional applicators)" should be involved. The tasks allocated to the professional users need to be specified for a better understanding of the targeted mitigation measures related to each of the personnel involved.	Applicant see comment immediately below. RMS. The specific tasks and their associated risk mitigation measures are specified in Table 3.3.1 Addressed	Addressed. See also comment 2(58).
2(61)	Vol. 1-Level 3, 3.1.1.3. Restrictions on approval	FR: As for Chloropicrin 99, could you please specify that the representative preparation Chloropicrin EC is also supplied directly from the manufacturer to professional applicators?	Applicant: application of chloropicrin is only made by trained specialist applicators. Farmers/growers are not involved in the application process nor in the handling of chloropicrin. This applies to both formulations. RMS: No additional comment	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.

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Product exposure and risk assessment, including dermal absorption				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			Addressed	
2(62)	Vol. 1-Level 1, 1.5.1. Details of representative uses	FR: Could you please define the unit given for the water supply in the drip irrigation system for Chloropicrin EC (mm/Ha)?	Applicant: mm = L/m ² RMS: No additional comment Addressed	See open point in 1(35).

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Product exposure and risk assessment, including dermal absorption				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(63)	Vol. 3 – B.6.4. Exposure data	FR: A summary table with the number of monitored individuals by task (ie fumigation tasks, VIF cutting, VIF removal and transplanting) and the number of monitoring points (for the estimation of bystander/resident exposure) would be of value by type of application (shank injection vs drip irrigation; field vs greenhouse, large vs small areas treated), by study and by analysed substance (chloropicrin and phosgene). This will allow a better visibility on the number of data available for each of the exposure categories in each experimental condition.	<p>Applicant: the applicant can provide a comprehensive summary table as requested – it is agreed this would improve visibility on the extensive data available and other clarifications requested by EFSA and MSs in this section could also be provided with that comprehensive summary to aid discussion of the exposure studies in the peer review [this comprehensive summary would also incorporate the results of the new monitoring study that is available for submission – see comment at 2(91)].</p> <p>This comprehensive summary can be provided on request by EFSA.</p> <p>RMS. Table's 2 (Shank) and 24 (Drip) provide most of this information already stipulated by FR but agree they can be expanded to include specific tasks and associated number of replicates per task as requested.</p> <p>Addressed</p>	<p>Data requirement</p> <p>Applicant to provide more detailed summary tables for exposure scenarios for each representative use (shank and drip). They should also reflect the number of monitored individuals by task, and the number of monitoring points by study and by analysed substance (chloropicrin and phosgene).</p> <p>See also experts' consultation in 2(64).</p>
2(64)	Vol. 3 – B.6.4. Exposure data	FR: It appears that there is far less analytical data collected for phosgene than for chloropicrin. Information is lacking on kinetic and rate conversion from chloropicrin to phosgene in air. This	Applicant: It is correct that fewer data are available for phosgene. However it should be noted that, in addition to operator and worker monitoring, atmospheric sampling for phosgene was also conducted in the	<p>Experts' consultation</p> <p>Non dietary exposure estimates for the representative uses of chloropicrin to be discussed by the experts.</p>

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Product exposure and risk assessment, including dermal absorption				
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		information is needed for a more objective interpretation of these data and to ensure that the experimental conditions reflect the optimal conditions for this conversion process.	<p>majority of the trials at 1 m with measurements at 50 and 200m in five trials. No phosgene was detected above the LOQ in air samplers of any operators/workers monitored in the studies. In the atmospheric monitoring phosgene was only detected at 50m or beyond in one study (application by drip irrigation under protection). The maximum measured value at 50m was 0.0104 mg/m³ and 0.0081 mg/m³ at 200m which is equivalent to 5% and 4% respectively of the AOEC proposed for phosgene for bystanders and residents [AOEC of 0.2 mg/m³ based on the EC Scientific Committee on Occupational Exposure Limits 15-minute short-term exposure limit value of 2 mg/m³ with an additional uncertainty factor of 10 for intra-species variation]. The maximum estimated 15 min peak exposure for phosgene occurring at 50m is below the proposed AOEC.</p> <p>It should be noted that the conversion of chloropicrin to phosgene is a theoretical possibility and the available data do not indicate that this occurs to any great extent. As noted above the majority of phosgene measurements were <loq and measured values were very low. The proposed AOEC</p>	<p>See also data requirements in 2(63), 2(76) and 2(91).</p> <p>See also comments 2(65-69), 2(72-74), 2(77), 2(79-80), 2(84-87), 2(89-90), 2(92-94).</p>

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Product exposure and risk assessment, including dermal absorption				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			<p>for chloropicrin is low compared to that proposed for phosgene; therefore even if chloropicrin were quantitatively converted to phosgene, based on the more comprehensive chloropicrin measurements, levels of phosgene would not be of concerns.</p> <p>RMS. Phosgene was monitored in 8 out of the 11 studies. Based on the very low levels detected in almost all cases it is reasonable to conclude that the risk of exposure to phosgene is very low by comparison to chloropicrin and further information in this area is unlikely to add anything to the overall conclusions.</p> <p>Addressed</p>	
2(65)	Vol. 3, B.6.4, Exposure data (maximum air concentrations)	DE: For shank application, the surface area treated in the available studies ranged from 7500 to 9200 m ² . Therefore, acceptable application should be restricted to less than 1 ha.	<p>Applicant: the summary of the areas treated is correct: the surface area treated in the available studies ranged from 7500 to 9200 m². However, it is considered that the basis for the area restriction proposed is arbitrary.</p> <p>RMS. There is a relationship between area treated and air concentration and this is one of the factors taken into account in the US EPA system for setting buffer zones for soil fumigants (see https://www.epa.gov/soil-</p>	See experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
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			<u>fumigants/buffer-zone-requirements-soil-fumigant-applications</u>). This issue was not explored as part of the applicant's submission and the RMS would agree that uncertainty remains for treated areas >1ha which would need to be considered probably at the authorisation stage when information on potential treatment areas in individual MS could be provided in conjunction with suitable atmospheric modelling. Data gap	
2(66)	Vol. 3 – B.6.4. Exposure data	FR: For operators and workers, the given maximum air concentrations are said "time weighted averages over the duration of exposure". Could you please clarify whether these values represent actual quantified data (over the actual time of exposure), or a weighting of the raw values? The same question applies to bystanders/residents ("concentrations reported are time weighted averages over approx. 8h »).	Applicant: the reported maximum air concentrations represent actual concentrations measured over periods of typically 8 hours. As such they are average concentrations and do not show any peak concentrations experienced over shorted time periods during the measurement period. See also applicant comment on new monitoring study at 2(91) that provides measured values at shorter (1hr) time periods. RMS. DAR will be updated to remove the reference to time weighted averages which is potentially misleading. As the applicant	See experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
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			<p>states the values reported are the actual values measured during the entire monitoring period and are not scaled or averaged in any way.</p> <p>Open point</p>	
2(67)	Vol. 3 – B.6.4. Exposure data	FR: Since the volatilization rate of gas from soil is highly dependent on soil type, could you please clarify the representativeness of the experimental grounds compared to the type of soil on which the claimed plants usually grow?	<p>Applicant: All activities have been conducted in horticultural areas where fumigation is commonly used – this is stated in the study reports.</p> <p>RMS. Soil type is a contributory factor to the volatilisation rate. The US EPA buffer zone factsheet 2012 (see link at 2(65) above) assigns credits for site conditions that reduce emissions which includes soils with high organic or clay content. Most of the chloropicrin studies appear to have been conducted on soils described as sandy, sandy/loam or sandy/silt and therefore provide a good level of representativeness of soil types that may potentially result in higher emissions.</p> <p>Addressed</p>	See experts' consultation in 2(64).
2(68)	Vol. 3 – B.6.4. Exposure data	FR: Many studies were performed outside the indicated period in the GAPs (June to	Applicant: a limited number of studies were performed in April and October a statement	See experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
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		September): study 14/2013 (shank injection), studies 12/2012, 13/2012 and CEMS-5732 (drip irrigation). The influences of these differences on the results need to be addressed.	<p>to address the influences of these differences can be provided as additional information.</p> <p>RMS: It is assumed that the main basis for this comment is the possible impact of lower temperatures on volatilisation and if the applicant is able to provide a statement they could compare and contrast mean temperatures and measured air concentrations for the studies undertaken outside the GAP relative to those within.</p> <p>Open point</p>	
2(69)	Vol. 3, B.6.4, Exposure data (maximum air concentrations)	DE: Please, specify whether measured concentrations in the studies for operators and bystanders were weighted averages over one hour of exposure, maximum concentrations during exposure or total concentrations collected over the entire duration of the task and thus related to the duration of worker exposure.	<p>Applicant: Measured concentrations reflect the amount of chloropicrin collected over the specified time period (typically 8 hours).</p> <p>RMS. In all cases the values reported are the total measured amount for the duration of the activity with regard to operators or monitoring period in the case of bystanders.</p> <p>Addressed</p>	See experts' consultation in 2(64).
2(70)	Vol. 3, B.6.4, Exposure data (maximum air concentrations)	DE: The measured maximum air concentrations during shank application as depicted in Table 34 are not congruent	Applicant: The values in Section 8 Table B.8.8-1 seem to be incorrect.	<p>Addressed.</p> <p>The values in Table 8.8-1 are peak air emission values while those in the first</p>

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Product exposure and risk assessment, including dermal absorption				
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		with those listed in Section 8, Table B.8.8-1. Please, specify which values are correct.	RMS. see RMS reply to comment 4(62)	row of Tables B.8.6-34 and 35 are worst case air concentrations over a 24 hour time period. In conclusion, they should differ.
2(71)	Vol 3 – B.6.4.1.1. Chloropicrin 99 – shank injection. Table 2. Summary of shank application studies	FR: Could you please confirm that, based on the description of the sampling phase for bystander, we should read in table 2, 16 chloropicrin stations (instead of 20) and 12 phosgene stations (instead of 12) for bystander data of study 08/2012?	RMS. Thank you for the correction. Table 2 should read 16 chloropicrin stations and 12 phosgene stations for 08/2012 and will be amended accordingly. Open point	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
2(72)	Vol 3 – B.6.4.1.1. Chloropicrin 99 – shank injection. Table 2. Summary of shank application studies	FR: It should be noted that in the case of shank injection, data from a single study (study 08/2012) are available to assess the bystander/resident exposure to phosgene. A more robust argument needs to be added in order to support the conclusion related to the bystander/resident exposure to phosgene for this type of application.	Applicant: see applicant response at 2(64) in relation to phosgene exposure. RMS. See also RMS comment at 2(64). Addressed	See experts' consultation in 2(64).
2(73)	Vol. 3, CP, B.6.4.1.1, Chloropicrin 99 – shank injection, p.4	EFSA: We support the idea that the 2 modifications introduced with the years should not be considered standard for all applicators and maximum reported values without these modifications should still be taken into account. It is noted that phosgene was not monitored in all studies, and the levels were reported	Applicant: Please see applicant comment at 2(84) and comment on the fan system at 2(77). Applicant: see applicant response at 2(64) in	See experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
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		<p>at or below the LOQ. A worst case approach could be to consider phosgene as always present at the LOQ.</p> <p>With regard to possible standardisation of parameters, it could be appropriate to consider a workday with a duration of 6 or 8 hours.</p>	<p>relation to phosgene exposure.</p> <p>RMS: The assumption that phosgene is always present at the LOQ does not affect the outcome of the risk assessment as we are not trying to derive 75th or 95th percentile exposures from a distribution of exposure but rather are only interested in identifying the maximum values observed for the purposes of comparison with the short term local effects AOEC.</p> <p>Addressed</p>	
2(74)	Vol. 3, CP, B.6.4.1.1, Chloropicrin 99 – shank injection, p.4	EFSA: It is noted that phosgene was not monitored in all studies, and the levels were reported at or below the LOQ. A worst case approach could be to consider phosgene as always present at the LOQ.	<p>Applicant: see applicant response at 2(64) in relation to phosgene exposure.</p> <p>RMS. See comment at 2(73)</p> <p>Addressed</p>	See experts' consultation in 2(64).
2(75)	Vol. 3, B6opex, B.6.4.1.1. Table 2 page 7	Applicant: The fifth column of this table is incorrectly headed Area (ha) this should be headed Area (m ²).	<p>RMS. Noted. Table to be amended accordingly and DAR will be updated.</p> <p>Open point</p>	<p>Addressed.</p> <p>RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.</p>
2(76)	Vol 3 – B.6.4.1.1. Chloropicrin 99 – shank injection/ B.6.4.1.2. Chloropicrin EC –drip	FR: There is a lack of night time sampling of phosgene after DAT0. An argument needs to be added to address this point.	Applicant: as phosgene is a postulated photodegradation product of chloropicrin, sampling during the night is	<p>Data requirement:</p> <p>Applicant to provide further information on the phosgene</p>

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Product exposure and risk assessment, including dermal absorption				
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	irrigation.		<p>considered less relevant. Further information could be provided on the link between phosgene generation and visible and UV light if required.</p> <p>RMS. Confirmation of the link between phosgene generation and visible and/or UV light ought to be sufficient to address this point given the relatively low levels of phosgene that were observed during the day.</p> <p>Open point.</p>	<p>generation by photodegradation of chloropicrin (by visible and UV light).</p> <p>See also experts' consultation in 2(64).</p>
2(77)	Vol. 3, B6opex, B.6.4.1.3, Disconnection study 1 st para. P8	Applicant: The RMS considers the fan system (which results in much reduced air concentrations for the tractor driver) used in some trials to minimise exposure to the tractor driver to be "somewhat rudimentary". It is considered that this modification (which is simple rather than 'rudimentary') has potential for use to minimise operator exposure. The California Department of Pesticide Regulation determined that the fan system was very effective in reducing driver exposure to methyl bromide. As a result, CDPR included the requirement for this fan system in the California Code of	<p>RMS: The performance of the in cab air filtration system must be to a recognised standard and it is not possible to assign any such level of protection to the equipment described.</p> <p>Addressed</p>	<p>Data requirement:</p> <p>Applicant to provide further information on the use of fan system and robust evidence (eg supported by analytical data) supporting its adoption as a suitable engineering control.</p> <p>See also experts' consultation in 2(64).</p>

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Product exposure and risk assessment, including dermal absorption				
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		Regulations, Title 3, Division 6, 6447.3. Further information on this system and evidence supporting its adoption as a suitable engineering control (as an alternative to the recommended closed cab/RPE) can be provided in the context of application for product authorisations at Member State level.		
2(78)	Vol 3 – B.6.4.1.2. Chloropicrin EC –drip irrigation. Table 30. Summary of samples collected.	FR: Could you please confirm that in table 30, for operator chloropicrin samples corresponding to the studies 12/2012, 13/2012 and 15/20013, we should read the value 13 instead of 26 (in accordance with the content of table 24)?	<p>Applicant: The numbers appear to be correct – operators in these studies wore two sampling tubes on the left and right hand side of the chest</p> <p>RMS: Applicant response is correct.</p> <p>Addressed</p>	Addressed.

Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption				
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2(79)	Vol. 3, CP, B.6.4.1.2, Chloropicrin EC – drip irrigation, p.19	EFSA: The duration of the worker exposure might have been extended to 6 or 8 hours per day.	<p>Applicant: Exposures were measured for different activities over representative time periods</p> <p>RMS: This is not relevant when considering local effect AOEC for which maximum measured values are needed. NB The highest reported concentrations occurred during the shorted operation i.e. disconnection phase of between 4 and 11 minutes. It would not be appropriate to either scale the maximum values up or average it out over a 6-8 working hour day.</p> <p>Addressed</p>	See experts' consultation in 2(64).
2(80)	Vol. 3, CP, B.6.4.1.2, Chloropicrin EC – drip irrigation, p.19	EFSA: Considering the Table 32, it might be realistic to sum up the exposures measured for the different activities, knowing that in some countries, the same worker might perform all activities.	<p>Applicant: Summing of exposures is not relevant for airborne concentrations as the AOEC is based on local effects.</p> <p>RMS. Agree with applicant response.</p> <p>Addressed</p>	See experts' consultation in 2(64).
2(81)	Vol. 3, CP, B.6.4.1	EFSA: It should be clarified why the previously submitted field studies (eg by Trevisan) have been discarded from the exposure assessment.	<p>Applicant: During the evaluation the RMS requested the submission of the study: Trevisan, M (2009) Chloropicrin: concentration in air and operators exposure assessment during and after soil application.</p>	Addressed.

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Product exposure and risk assessment, including dermal absorption				
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			<p>Istituto di Chimica Agraria ed Ambientale, Sezione Chimica Vegetale, Università Cattolica del Sacro Cuore and, Centro Ricerche per la Zootecnica e l'Ambiente (CERZOO) Report no.: CZ/08/013/UCSC/CHLAIR. GLP Unpublished Report.</p> <p>A copy was provided and added to the updated dossier at the request of the RMS. This study was submitted as part of the resubmission process under Commission Regulation 33/2008. The study was been evaluated in the Additional Report prepared by Italy in 2010 and considered in the EFSA process. The study was not submitted in the originally submitted dossier for this new active substance application as it does not reflect the current GAP (the study was conducted a higher rate and the post-application procedures do not reflect currently supported practice). The ECG therefore considers the study not to be relevant to the current GAP and to be superseded by the studies conducted in 2012-2013.</p> <p>RMS: Agree with Applicant, no additional comment.</p>	

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Product exposure and risk assessment, including dermal absorption				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			Addressed	
2(82)	Vol. 3, B.6.4, Exposure data (operator)	DE: We do not consider it practicable to work with power-assisted RPE for several hours, especially when conducting labour-intensive tasks, such as cutting and sheeting removal.	<p>Applicant: appropriate power-assisted equipment is available from many suppliers with specific recommendations for prolonged use – additional information on this point can be provided on request.</p> <p>RMS: UK Health and Safety Executive advice concerning (see http://www.hse.gov.uk/pubns/books/hsg53.htm) is that continuous wear time for tight-fitting (unpowered) RPE is less than an hour, after which the wearer should take a break (the RPE can become uncomfortable to wear, leading to loosening or removal of the mask in the work area). Where RPE is required to be worn continuously for long periods, powered respirators with a loose-fitting facepiece such as a hood or helmet, are considered suitable options.</p>	Addressed. Time restriction for the use of appropriate RPE can be further considered at MS level but it is noted that this might lead to increased exposure to chloropicrin/phosgene.

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Product exposure and risk assessment, including dermal absorption				
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2(83)	Vol. 3, B6opex, B.6.4.1.3, Disconnection study 2nd para. p33	Applicant: The RMS speculates that the <i>“reduced application rate could be the reason why the measured values are significantly less in the drip disconnection trial compared to the original drip trials.”</i> It should be noted that disconnection exposure is due to release of chloropicrin from the application equipment and not related to the application rate. The release during disconnection is independent of whether the rate of application is high or low.	RMS. Agree. The statement will be removed from the text and the DAR will be updated. Open point	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
2(84)	Vol. 3, B6opex, B.6.4.1.3, Disconnection study 2 nd para. p33	Applicant: In relation to the two methods for minimising exposure during disconnection (long handled wrench and partial loosening with operator standing away from the cylinder for 5 minutes) the RMS states <i>“Whilst these methods certainly do not eliminate the need for RPE they do represent further measures that can be undertaken by the operator to further reduce the risk of exposure”</i> It should be noted that the ECG has incorporated these methods into the standard operating procedures for chloropicrin application. Evidence of the inclusion in the operating procedures can	RMS. Noted. Addressed	See experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
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		be provided on request if necessary.		
2(85)	Vol. 3, B.6.4, Exposure data (bystander)	DE: We share the RMS' concerns that substantial uncertainty remains with regard to the capturing of bystander peak concentrations and the potential underestimation of child exposure. With regard to the high acute toxicity of chloropicrin, the level of remaining uncertainty might be too high to conclude a safe use.	<p>Applicant: a more recently performed study (see applicant comment at 2(91) shows that measured chloropicrin concentrations at a height of 1 m are only marginally higher than those measured at 1.5 m and none exceed the proposed AOEC. Furthermore this study also measured peak (1-hour) exposures of chloropicrin and demonstrates that the power law approach followed by the RMS provides a conservative method of estimating peak exposures. This study that provides additional support for the RMS assessment can be provided in response to a request from EFSA.</p> <p>RMS. No further comment.</p> <p>Open point</p>	See experts' consultation in 2(64).
2(86)	Vol. 3 – B.6.4. Exposure data	FR: No data were generated for the child bystander (no measurements taken below 1.50 meters height) while it appears to be necessary to have some measurements at least at a reasonable infant height since the density of chloropicrin and phosgene is higher than that of air resulting in a higher concentration of both chloropicrin and phosgene at this height.	<p>Applicant: a more recently performed study (see applicant comment at 2(91) shows that measured chloropicrin concentrations at a height of 1 m are only marginally higher than those measured at 1.5 m and none exceed the proposed AOEC.</p> <p>RMS: We can evaluate the study if</p>	See data requirement in 2(91). See also experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
			requested to do so but the greater uncertainty lies with using the power law approach to predict peak exposures. Open point	
2(87)	Vol 3 – B.6.5. Exposure and risk assessment	FR: Since a buffer zone of 50m has been proposed as a mitigation measure for bystander/resident, until all concentrations of chloropicrin are below the AOEC, could you please clarify for how long this buffer zone should be maintained? The same comment applies to phosgene.	Applicant: Based on the monitoring data, maintaining the buffer zone for 24 hours following treatment would seem to be appropriate. RMS A consideration of an appropriate period for maintaining the buffer zone can be incorporated into the assessment. Open point	See experts' consultation in 2(64).
2(88)	Vol. 3, B.6.5, Exposure and risk assessment	DE: Please, include the specific requirements for operator and resident/bystander safe use in the LoEP. Details should be provided on the specification of the application vehicle, RPE, and buffer zone.	Applicant: RMS to update LoEP. RMS: The LoEP will be updated accordingly. Open point	Open point: RMS to provide a revised version of the list of end points including all agreed endpoints during the peer review assessment.
2(89)	Vol. 3, B.6.4, Exposure data (bystander)	DE: In the absence of appropriate data, the RMS modelled bystander short-term exposure by applying the CALMET/CALPUFF model with refined assessment factors adjusting for model uncertainty.	Applicant: The chloropicrin submission includes probably the most extensive dataset of monitoring studies to address operator/worker and bystander/resident exposure for any substance considered under Regulation 1107/2009. For bystanders and residents, the studies cover	See experts' consultation in 2(64).

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Product exposure and risk assessment, including dermal absorption				
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			<p>a range of environmental and meteorological conditions and provide a very large number of measurements of chloropicrin concentrations at distances of 50 meters or more from the treated area (in total over 5000 individual measurements are available at 50 metres or more). None of the measured (c.6-12 hour) concentrations at these distances comes close to exceeding the AOEC of 0.164 mg/m³ proposed by the RMS and co-RMS. In order to address the potential risk from 'peak' concentrations the 'power law' formula has been adopted and accepted by the RMS and co-RMS. This provides a conservative predictor of peak 1-hour concentrations. Using this approach, no predicted 1-hour exposures derived from the monitoring data exceed the proposed AOEC at 50 metres. The RMS assessment, underpinned by this extensive data set, is supported. In addition, a recently conducted (2017) monitoring trial is available to provide further confidence in the assessment – see applicant comment at 2(91) below.</p> <p>RMS: Taken in isolation, the power law estimation can be used to provide a rough</p>	

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Product exposure and risk assessment, including dermal absorption				
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			<p>approximation of the relationship between short and long-term concentrations. It is based on a limited number of observations and has no way to account for any specifics about the site including terrain, land use, time of day or local meteorology. It was anticipated that the use of a more sophisticated approach using a suitably validated atmospheric dispersion modelling tool would give much more accurate site specific predictions. However, CALPUFF has not previously been validated and used for similar regulatory purposes. The proposed assessment factors reflected significant uncertainty in the model outputs and further work would be required to fully validate the model and accept its use for regulatory purposes.</p> <p>Open point</p>	

Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption				
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2(90)	Vol. 3, B6opex, B.6.4.2, Bystander and Resident exposure	Applicant: Although it is a possibility that released gas may not pass directly through the measurement locations, it should be recognised that each study included measurements at multiple locations. In view of this and the large number of monitoring studies (including hundreds of individual measurements), it is considered unlikely that the released gas would have not passed directly through the measurement locations in all studies.	RMS: Comment noted. Addressed	See experts' consultation in 2(64).
2(91)	Vol. 3, B6opex, B.6.4.2, Bystander and Resident exposure	Applicant: In view of the theoretical possibility that concentrations of chloropicrin may be higher at heights below 1.5 m, an additional monitoring study has been performed. This study includes directly comparable measurements at sampling heights of 1.5 and 1 m, in order to address concerns raised by the RMS in relation to the exposure of child residents. The study included measurements using different sampling heights and at distances of 15, 25 and 50 meters from the site of application. The study indicates that airborne concentrations at a sampling height of 1m are (on average) marginally	RMS: The study can be requested from the applicant and reviewed by the RMS in an updated DAR. Open point	Data requirement Applicant to provide the additional monitoring study including measurements of chloropicrin at sampling heights of 1.5 and 1m (in order to address the concerns raised in relationship with the exposure of child residents). See also experts' consultation in 2(64). See also comment 2(86). See also data requirement in 4(52).

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Product exposure and risk assessment, including dermal absorption				
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		(1.04 times) higher than those at 1.5m, but do not exceed the proposed AOEC. The study is available for submission.		
2(92)	Vol. 3 Bystander/resident exposure assessment	EL: The exposure assessment has been performed considering that bystanders/residents would not be present at 1m from the edge of the treatment area, i.e. not present at 50m from the treated area. The acceptance/applicability of a 50 m buffer zone restriction should be further discussed.	Applicant: noted. RMS. Agreed Open point	See experts' consultation in 2(64).
2(93)	Vol. 3, CP, B.6.4.2, Bystander and resident exposure, p.34	EFSA: It is noted that the measured values during the field studies could potentially underestimate the exposure of children since they were not done below 1.5 m height. How has this been taken into account for the bystander/resident exposure assessment ?	Applicant: see applicant responses at 2(85) and 2(86) above and applicant comment at 2(93). RMS: Whilst this presents some uncertainty the greater uncertainty relates to the use of the power law approach for estimating peak exposures. The study can be requested from the applicant and reviewed by the RMS in an updated DAR. Open point	See experts' consultation in 2(64).

Section 2 – Effects on human and animal health

Product exposure and risk assessment, including dermal absorption				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(94)	Vol. 3, B6opex, B.6.4.2.3, CALMET/CALPUFF air dispersion modelling; p39	Applicant: The use of additional 'assessment factors' to take into account the potential for peak chloropicrin exposures over shorter periods of 15 minutes and 1 hour is not supported. In many cases, the use of this approach results in airborne concentrations of chloropicrin in excess of the maximum theoretically possible.	RMS. See comment 2(89) Addressed	See experts' consultation in 2(64).
2(95)	Vol. 3, B.6.10 Acute toxicity of plant protection products, B.6.10.1 Oral toxicity	EL: The proposed classification of chloropicrin is Acute Tox. 3 – H301 and therefore, based on the calculation method (Regulation (EC) No. 1272/2008), the product should be also classified as Acute Tox. 3 – H301.	UK RMS: Agreed and the DAR will be updated. Open point	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
2(96)	Vol. 3 B.6.10 Acute toxicity of plant protection products	FR: Please update the product classification according to chloropicrin classification.	Applicant: RMS to consider in updated DAR. UK RMS: Agreed and the DAR will be updated. Open point	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1.
2(97)	Vol. 1 Level 2 Summary of available studies and 3 B.6 Tabulated summary and Overall summary Toxicology and metabolism data – RMS	FR: Agreed with the equation provided to convert external dose in ppm to mg/l. However, it seems that the correction for the exposed days per week was not considered by the RMS.	Applicant: RMS indicates that the number of exposed days per week was taken into account (footnote to Table on p.177 of B.6 Overall Summary Toxicology and Metabolism data)	Open point: RMS to present revised summary tables of toxicology studies in a revised DAR (Vol. 1 and 3), including the correction factor of (5d/7d), when relevant, for conversion of dose levels

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Product exposure and risk assessment, including dermal absorption				
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	inhalation concentration conversion		UK RMS: Agreed, thank you. The DAR tables will be revised to include the correction factor of (5d/7d) for relevant inhalation studies. Although the correction factor was presented in a footnote to the table, it now seems that the calculation was did not include this factor. Open point	in inhalation studies (in mg/kg bw per day), and including also local and systemic NOAEL(C)/LOAEL(C) where appropriate. See also comments 2(98) and 2(99).
2(98)	Vol. 1 Level 2 and 3 B.6 general	FR: Please report in the summary tables, when necessary, both the local and the systemic NOAEL/C and LOAEL/C.	Applicant: RMS to consider in updated DAR UK RMS: Agreed and the DAR will be updated. Open point	See open point in 2(97).
2(99)	Vol. 1 Level 2 Summary of available studies	FR: Please correct the LOAEC value of the mouse inhalation 90-day study from 0.54 to 0.96 mg/kg bw/d. To be noted also that these values would be lower when taking into account the correction for exposed days per week (see comment above).	Applicant: RMS to consider in updated DAR UK RMS: Agreed, thank you. The new value will be 0.68 mg/kg bw/d once corrected for 5d/7d exposure regime. DAR will be amended Open point	See open point in 2(97).
2(100)	Vol.1 Level 2 2.10 classification and labelling	FR: Mortality was observed in several toxicity studies by inhalation at doses leading to STOT RE 1 H372. Therefore, this	Applicant: Mortality seen in the repeated dose inhalation toxicity studies is a	Addressed.

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Product exposure and risk assessment, including dermal absorption				
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		classification could be considered for chloropicrin.	<p>reflection of local effects. Separate classification for STOT-RE would not appear to be appropriate according to CLP Guidance.</p> <p>UK RMS: We agree with the applicant. The RMS considers that this point is addressed.</p>	

Other comments, incl comments on volume 4 (impurities, batches)				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
2(101)	Vol. 4, C.1.2.2, Identity of impurities, p.7; and C.1.2.5, Proposed specification, p.25; and C.1.4, Information on the batches used for the mammalian toxicity tests, p.26	EFSA: Pending confirmation of the acceptability of the technical specification at the end of the commenting period, further consideration might need to be given to the toxicological relevance of the potential impurities and to the representativeness of the batches used in the toxicity studies.	<p>Applicant: the technical specification is considered acceptable and the evaluation of the RMS is supported.</p> <p>UK RMS: Noted. Open point</p>	<p>Data requirement:</p> <p>Applicant to provide further assessment of the toxicological relevance of the impurities (Table C.1.2.3.2). It is noted that impurities below 1 g/kg might also need to be included in the technical specification if their toxicological profile is such that they might contribute significantly to the toxicological properties of the parent.</p>

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Other comments, incl comments on volume 4 (impurities, batches)				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
				<p>Therefore as a first step, the hazardous properties of the identified impurities have to be further assessed (in comparison with the parent's).</p> <p>Pending on the conclusion about the toxicological relevance of the impurities (and the need to include them in the technical specification), it will have to be considered if the composition of the batches used for the toxicity studies (including the levels of impurities) is sufficiently representative of the proposed technical specification.</p> <p>See also data requirement in 2(45). See also data requirement in 4(66). See also comment 1(6).</p>
2(102)	Vol. 3, B.6.11, References relied on, p.181	EFSA: It is briefly mentioned that a literature review has been done. A more detailed assessment of this literature review should be provided in a revised DAR, demonstrating that it has been performed in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA,	<p>Applicant: RMS to consider. If necessary a revised search could be submitted.</p> <p>UK RMS: The literature search was conducted by the applicant was broadly in line with the relevant (EFSA) guidance and the relevant studies were summarised by the RMS in the DAR. Additional justification to support the results of the search were provided to the RMS during the evaluation</p>	<p>Data requirement:</p> <p>Applicant to provide a revised report for the literature review, including a clear description for the search terms, the selection criteria (to identify relevant articles) and the reliability criteria that have been applied to each selected article for weight of evidence considerations in comparison with</p>

Section 2 – Effects on human and animal health

Other comments, incl comments on volume 4 (impurities, batches)				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		2011). A clear description should be given for the search terms, the selection criteria (to identify relevant articles) and the reliability criteria that have been applied to each selected article, in order to determine a weight of evidence for comparison with regulatory studies.	which can be inserted into a revised DAR. Alternatively, a revised literature review report, may be provided by the applicant upon request from EFSA. Open point	regulatory studies.
2(103)	Vol. 1, 2.8.6.3, Predicted environmental concentrations in groundwater	DE: Concerning the groundwater aspect only, approval of this substance should be granted only for application conditions under which no exceedance of the trigger value of 0.1 µg/L is predicted neither for chloropicrin nor for its metabolite DCNM. The latter must be considered a relevant metabolite. This should be clearly mentioned in the EFSA conclusion and MS should consider this issue very seriously when granting authorisations.	Applicant: responses from the applicant in relation to the potential for chloropicrin to reach groundwater is provided in the fate section of this Reporting Table. RMS: Noted. Open point.	See experts' consultation in 4(57). See data requirement in 4(61).

section 3 – Residue data

3. Residue data

Storage stability of residues				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol.3, B.7.1	DE: We agree to the assessment of RMS. According to the data requirements, storage stability in strawberries is not addressed by a study, nor in water-dominant matrices except tomato, where the proposed compound of the residue definition is investigated. However, since the results show almost immediate instability, we agree to extrapolate this finding to the other water- and acid dominant matrices by default.	<p>Applicant: Unless there is clear reason to believe that instability is crop related, it is only necessary to assess stability for representative crops for each crop group detailed in OECD guidance document 506. Instability of chloropicrin is not crop specific therefore assessing stability in tomatoes is sufficient to cover high water content crops.</p> <p>We agree with the overall conclusion that the storage stability data can be extrapolated to other high water matrices as well as high acid content crops.</p> <p>RMS: Noted, thank you</p> <p>Addressed</p>	See 3 (5)
3(2)	Vol. 3, B.7.7.1. Tomato	FR: The storage stability of chloropicrin in tomato is not clear, sometimes 3 days and sometimes 4 days. Please clarify	<p>Applicant: The stability of chloropicrin in strawberry is at least 4 days as stated throughout the DAR.</p> <p>RMS: The conclusion is that analysis should be within four days of sampling, this can be updated to make it consistent throughout the section.</p>	See 3 (5)

section 3 – Residue data

Storage stability of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Open point	
3(3)	Vol. 3, B.7.7.2, Strawberry	NL: Stability of dichloronitromethane in strawberry is demonstrated for 4 days instead of the concluded 7 days.	<p>Applicant: Agreed. The conclusion will be updated.</p> <p>RMS: Mean recovery at 7 days was 72% (accounting for the recovery at the 0 day time point). Therefore significant decline (>30%) can be expected after day 7. If recovery at the 0 day time point is not accounted for then it is agreed that stability is demonstrated for 4 days. The conclusion can be updated if required.</p>	See 3 (5)
3(4)	Vol. 3, B.7.7.2, Storage stability in strawberries	EFSA: According to SANCO guideline 7032/VI/95 rev.5 individual results should not be corrected to 100 % yield. The procedural recoveries for the corresponding days are all in the range of 79 to 83 % indicating sufficient performance of the analytical method. However, the recovery rates in strawberries indicate that the stability of dichloronitromethane in this matrix is limited to only 1 day as the recovery at day 2 is already below 70 % (68%).	Applicant: Although the recovery data from stored samples was below 70%, the data is sufficient to confirm stability of DCNM in strawberries for at least 7 days. In addition, for practical reasons it would not be possible to analyse the related residue samples for DCNM within 1 day of harvest. The residue samples were analysed for residues of DCNM as soon after harvest as reasonably possible and the storage stability data is sufficient to confirm the acceptability of these results.	See 3 (5)

section 3 – Residue data

Storage stability of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>RMS: It is understood that generally individual results should not be corrected, however given that 0 day and fresh recovery samples all show results of ~80% it was considered more realistic to consider degradation from this level as 100% recovery is never expected even where samples are analysed immediately.</p> <p>Uncorrected recoveries show fairly constant levels on day 1(71%), day 2 (68%) and day 4 (69%). Therefore RMS considers that if it is preferred to use the original values the data can be considered to support frozen storage of up to four days.</p> <p>As the applicant notes, it is not usually feasible to analyse the samples within one day of harvest (see also 3(5)), whereas for the majority of trials samples were analysed within 4 days of harvest.</p> <p>The conclusion can be amended to reflect this.</p> <p>Open point</p>	

section 3 – Residue data

Storage stability of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	Vol. 1, 2.7.1, Summary of storage stability of residues	NL: Since storage stability is a problem for both chloropicrin and its metabolite dichloronitromethane, storage stability studies for both analytes in high acid as well as high water content commodities are required, instead of extrapolating between the crop groups.	<p>Applicant: Unless there is clear reason to believe that instability is crop related, it is only necessary to assess stability for representative crops for each crop group detailed in OECD guidance document 506. Instability of chloropicrin is not crop specific therefore assessing stability in tomatoes is sufficient to cover high water content crops.</p> <p>We agree with the overall conclusion that the storage stability data can be extrapolated to other high water matrices as well as high acid content crops.</p> <p>RMS: Noted, thank you</p> <p>Addressed</p>	<p>Experts' consultation:</p> <p>Experts to discuss the storage stability of all compounds covered by the residue definition in the studies on strawberries and tomatoes and if possible conclude on the maximum storage stability for both crop groups and whether it is possible to extrapolate to other water- and acid matrices by default.</p> <p>See also 3(1) – 3(4)</p>

Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(6)	Vol. 3, B.7.1.1, Metabolism, distribution and expression of the	NL: In the metabolism study, already two days after treatment, the plastic covering was removed, and 14 days after treatment	Applicant: The metabolism study was considered adequate to support the proposed GAP because the time between	see 3(8)

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Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	residue in primary crops	<p>the crops were planted. This is in contrast with the representative uses, where the soil is covered with a film for at least 21 days after treatment, with an additional 7-14 days before planting. Please provide argumentation whether the metabolism study can be considered acceptable to cover the representative uses.</p>	<p>application and planting of the crop is shorter in the metabolism study compared with the GAP, making the metabolism study worst case. In addition, in the metabolism study the period between removal of the film and planting of the crop falls within the window given in the GAP. In addition, the package of residue trials presented to support this application confirm a no residue situation.</p> <p>See also applicant response at 3(7) below.</p> <p>RMS: It is agreed that the treatment protocol in the study is not in line with the cGAP with respect the duration of covering and the time between treatment and planting, although the period between removal of the covering and planting is in line with the GAP. As the time between treatment and planting in the study is much less than in the cGAP it is considered worst case in terms of the expected residues, and so in this respect is acceptable to cover the representative uses.</p> <p>It should be noted that due to other deficiencies in the metabolism study it cannot be considered fully reliable.</p>	

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Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Addressed	
3(7)	Vol. 3, B.7.1.1	<p>DE: Given the high toxicity of chloropicrin, the lacking intermediate samplings, the inadequate extraction and identification of terminal harvest samples and the proven instability of parent and DCNM over much shorter storage intervals than applied in the metabolism study (4 days versus 290 days), we support the conclusion of the RMS to invalidate the metabolism study (but why is the data then considered reliable by RMS and no data requirement set in Vol. 1?).</p> <p>The EFSA conclusion of 2009 on not setting a data requirement for a new study is also not supported.</p> <p>The RMS conclusion that no residues are expected is not supported unless further data on plant metabolism are provided.</p>	<p>Applicant: Disagree. Although the plant metabolism study contains some deficiencies, there is substantial residue data supporting this submission, demonstrating a no residue situation. There is therefore no reason to believe that a new metabolism study would provide a different conclusion.</p> <p>We agreed with the RMS in not setting a data requirement for a new metabolism study in the current evaluation and this is consistent with the conclusion reached in the EFSA peer review that concluded in 2011 (see below). Given the weight of evidence from the remaining data, no significant information would come from a new study.</p> <p>This is position, with which we agree, is clearly set out in the DAR (Section 2.7.2. Volume 1) where it is concluded, in relation to the plant metabolism study, that: This study was considered in the original peer review, as well as by EFSA (EFSA Journal 2011;9(3):2084). During the peer review the unsuitability of this study due to the time between sampling and analysis was noted, but it was</p>	see 3(8)

section 3 – Residue data

Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>considered by EFSA that a further metabolism study was not required, on the basis that for a limited number of residues trials on tomato, where analysis was performed shortly after sampling, residues of chloropicrin and dichloronitromethane were not detected above the LOQ (0.005 mg/kg). These data demonstrated that chloropicrin appeared to be extensively degraded in plants. As such, further trials data were required to confirm the lack of residues. In addition, in the EFSA conclusion, only a provisional MRL was proposed for tomatoes, pending further data."</p> <p>RMS: RMS considers that the metabolism study is deficient on the basis of the period of storage of the samples. However, the study can be considered in conjunction with the residues trials to demonstrate that no residues of chloropicrin (or possible metabolites/impurities) are present following treatment at the proposed GAP.</p> <p>On this basis, and in line with the previous EFSA Conclusion, it is not considered that an additional metabolism study would provide</p>	

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Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			further useful information as no residues are expected in plants. Addressed	
3(8)	Vol. 3, B.7.1, Metabolims, Distribution and expression of the residues in plants	EFSA: possible metabolism of chloropicrin including possible metabolites should be discussed.	<p>Applicant: Additional information could be added to the DAR although due to the lack of any chromatographic analysis, we do not feel this discussion would add anything to the submission.</p> <p>See also applicant response at 3(7) above.</p> <p>RMS: As noted by the applicant, further discussion could be added to this section if required, but due to the absence of chromatographic analysis any discuss would be theoretical rather than based on the outcome of the metabolism study. Therefore it is not considered that such a discussion would be of benefit.</p> <p>Open point</p>	<p>Data requirement: Applicant to provide further data/information not yet presented in the DAR to support his claim that the metabolism study with strawberries, green beans, and red beets is sufficiently addressing the data requirement.</p> <p>Experts' consultation: Experts to discuss the suitability of the metabolism studies on strawberries, green beans, and red beets for risk assessment in the light of</p> <ul style="list-style-type: none"> a) the suitability to cover the representative uses (see 3(6)) b) shortcoming (lacking intermediate samplings, the inadequate extraction and identification of terminal harvest samples and the proven instability of parent and DCNM over much shorter storage intervals than applied in the metabolism study)

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Metabolism, distribution and expression of residues in plants				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
				c) the need for a new metabolism study to address the data requirement. If possible experts should discuss and agree on a residue definition. See also 3(6) - 3(7), 3(9), 3(11), 3(30), 3(28bis), 3(33)

Metabolism, distribution and expression of residues in poultry, lactating ruminants, pigs and fish				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

Residue definition				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol. 1, 2.7.3	DE: Residue definition should be considered as provisional due to the lack of reliable metabolism data.	Applicant: Disagree. Given the nature of the active substance, the length of time between soil application and eventual planting and harvest of the crop and the residue data obtained, there is no reason to believe that a	See 3(8)

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Residue definition				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>new plant metabolism study would yield a different conclusion regarding the metabolism of chloropicrin when applied in accordance with the proposed GAP. See also applicant response at 3(7) above.</p> <p>RMS: It is considered that none of the available data indicates that no residues of any compound (parent or metabolite) are expected in the representative uses. It is not considered that a new metabolism study is required as there is no evidence to suggest that a different conclusion would be reached in a new study.</p> <p>On the basis of all of the available data it is considered that parent chloropicrin is the most appropriate compound to include in the residue definition.</p> <p>However, RMS has concluded that further consideration may be needed if uses are considered on other crops in future.</p> <p>Addressed</p>	

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Vol. 1 Section 2.7.4	<p>Public comment – French Chambers of Agriculture (AFCA):</p> <p>We note that the residue trials result in no detectable residues being present in the horticultural crops for which studies have been conducted. For use on apples and other tree crops no trials have been submitted however we support the conclusion reached that, because of the duration of several years between planting and cropping, no residues will occur in apples and other similar tree crops by logical extrapolation from the results of the submitted trials. We seek confirmation that no specific residue trials will be necessary to support chloropicrin use on tree crops.</p>	<p>Applicant: We agree with the comments from AFCA and maintain that no residue trials are required for apples and similar tree crops. Given the GAP proposed and the nature of the active substance, it is reasonable to expect that no residues will be found in the harvested fruit.</p> <p>RMS: Noted, thank you. RMS does not consider that a data requirement for residue trials on tree crops is necessary</p> <p>Addressed</p>	Addressed.
3(11)	Vol. 3, 7.6	<p>DE: Suitability of trials for the representative uses may be given in case the residue definition "parent compound" (and probably DCNM) is supported by acceptable plant metabolism studies.</p>	<p>Applicant: It is reasonable to conclude that the current metabolism study is sufficient to support this application. Given the nature of the active substance, the length of time between soil application and eventual planting and harvest of the crop and the residue data obtained, there is no reason to believe that a new plant metabolism study would yield a different conclusion regarding the metabolism of chloropicrin when applied in accordance with the proposed GAP. The residue definition both for monitoring and</p>	See 3(8)

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>enforcement and for risk assessment will remain 'chloropicrin' alone.</p> <p>RMS: Please see RMS response to 3(7) and 3(9). It is not considered that a further metabolism study is not considered to be required, and based on the available data 'chloropicrin' is considered the most appropriate compound to include in the residue definition.</p> <p>The trials also analysed for DCNM as a possible metabolite, as well as several other possible impurities (see Vol 4) and residues of all analytes were shown to be <LOQ, on this basis it is considered that the available trials are suitable to support the proposed uses.</p> <p>Addressed</p>	
3(12)	Vol. 3, B.7.6.1-6, Residues arising from supervised trials	EFSA: Although the field trials are very detailed described information is requested on the location of the trials. Currently only the region is given and thus it cannot be concluded whether the trials can be considered as independent. Pls report – also for the greenhouse and protected (polytunnel) trials the exact	Applicant: This additional information relating to the location of the trials can be added and each trial is considered to be independent. In addition, comparable results have been obtained from trials in northern and south Italy, as well as Slovenia (see availability of additional residue trials – applicant comment 3(21))	<p>Open point:</p> <p>RMS is kindly asked to update the DAR with the details of the locations where the residue trials were conducted and conclude before experts' consultation whether they can be regarded as independent.</p>

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		location.	<p>below - that can be submitted as additional information in response to a request from EFSA)</p> <p>RMS: Please see RMS responses to comments 3(15)-3(20) as these provide details of the independence of the trials. In summary, all trials are considered independent based on location except two on tomato and two on pepper as they were conducted at the same site/greenhouse in the same season.</p> <p>The DAR can be updated to include additional information on trial location, and update the trials details to outline that the trials which are replicates.</p> <p>Open point</p>	
3(13)	Vol. 3, B.7.6.3, Residues arising from supervised trials, strawberries	<p>EFSA:</p> <p>It is reported that in one trial with strawberries chloropicrin was detected at an estimated level of 0.2 ug/kg thus a 'zero' residue situation is not given as this would imply that "no detectable residues occur in studies with exaggerated application rates compared to the envisaged ones."</p> <p>Is information available to verify that the observed signal in the chromatogram is</p>	<p>Applicant: Disagree that a zero residue situation does not occur. There is no additional data available to confirm the identity of the trace response in one strawberry sample. Given that a trace level of what appears to be chloropicrin was only detected in one sample out of 36 trials for various crops and that the response is below the limit of detection, it can reasonably be concluded that a no residue situation has occurred. A further</p>	See 3(15)

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		the active substance, e.g. analysis with GC-MS?	<p>30 trials on various crops are now also available, all of which demonstrate no residues of chloropicrin detected in the crop. This data can be presented on request.</p> <p>Guidance document SANCO 7525/VI/95 rev. 10.2 states that when residues are <LOD in all trials, only two trials are normally required and this is considered to be a non-relevant residue situation. Similarly, Guidance document SANCO 7529/VI/95 rev. 5 states that when residues are all <LOD, the number of trials can be reduced.</p> <p>Given that all the residue trials show that residues of chloropicrin are expected to be <LOD, a non-relevant situation has occurred and sufficient residue trials have been presented to support this application.</p> <p>RMS: No data other than retention time is available to identify the observed peak in the chromatogram as chloropicrin. Given the level is 25x times lower than the LOQ it would not be possible to undertake analysis of this peak with any certainty, as it is barely distinguishable from the spectral noise.</p>	

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>Therefore RMS considers that the 36 available residue trials are sufficient to demonstrate a 'no residue' situation, and sufficient trials are available to support the commodities given no residues are detected.</p> <p>Addressed</p>	
3(14)	Vol. 3, B.7.6.1, Tomato	<p>NL: Minor comment regarding study S12-003523: as is mentioned in the text, <i>in one trial (S12-03523-01) the time between harvest and analysis for DCNM was 24 days, therefore this result hasn't been considered further, as stability data does not support this length of storage.</i> The corresponding result in table B.7.6.1-1 should not be underlined.</p>	<p>Applicant: This comment is noted and agreed with. RMS to note in relation to DAR amendment.</p> <p>RMS: Noted, the underline can be removed</p> <p>Open point</p>	<p>Open point: RMS to remove in Vol. 3, B.7.6.1, Tomato the underline for the result from S12-003523-01 to clearly mark it as not compliant due to storage time of 24 days and therefore not suitable for risk assessment.</p>
3(15)	Vol. 3, B.7.6.1, Tomato	<p>NL: Trial S24/2014-01 and trial S24/2014-03 seem to be not independent, since the application took place at the same day and location. Similar observations are made for trial S26/2015-01 and trial S26/2015-06, and trial S26/2015-14 and trial S26/2015-15.</p>	<p>Applicant: The reports demonstrate that S24/2014-01 and 03 are approximately 30 miles apart, with different crop varieties used at each trial.</p> <p>Trials S26/2015-01 and 06 were approximately 100 miles apart, with different crop varieties used at each trial.</p> <p>These trials can be considered independent.</p> <p>Trials S26/2015-14 and 15 were</p>	<p>Open point: RMS is kindly asked to update the DAR with the details of the locations where the residue trials were conducted and conclude before experts' consultation whether they can be regarded as independent.</p> <p>Experts' consultation:</p>

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>conducted at the same location, but on different varieties so can also be considered independent. Details of the trial locations will be added to the DAR.</p> <p>Further trials have been conducted at different locations in Italy and Slovenia and the additional data can be presented on request. All the trials demonstrated a non-relevant residue situation (see availability of additional residue trials – applicant comment 3(21) below - that can be submitted as additional information in response to a request from EFSA).</p> <p>RMS: The trials S24/2014-01 and 03 were conducted in different greenhouses approximately 3 km apart. The trials S26/2015-01 and 06 were conducted in different greenhouses approximately 60 km apart. On this basis it is considered these four trials are independent.</p> <p>The trials S26/2015-14 and 15 were conducted in the same greenhouse, and therefore cannot be considered independent as the crop varieties use are not considered sufficiently different.</p>	<p>Experts to discuss and conclude on the independency of the residue trials with respect to distance between the trial locations (tomato) and other factors and whether a sufficient number of valid residue trials is available.</p> <p>Experts should also address the Limit of Quantification of the various methods used and the question which limit should be chosen to establish a MRL.</p> <p>The finding of residues in one strawberry trial should be discussed and a conclusion drawn whether a non-residue situation can be established.</p> <p>See also 3(12), 3(13), 3(16) – 3(19), 3(26), 3(28), 1(12), 1(13)</p>

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>The DAR can be updated to include this additional information, and update the trials details to outline that the trials S26/2015-14 and 15 are replicates.</p> <p>Open point</p>	
3(16)	Vol. 3, B.7.6.2, Pepper	NL: Whether or not trials are independent should also be checked for the pepper trials of report S26/2015, since it seems that the application was conducted at the same day and at the same location.	<p>Applicant: Trials S26/2015-02 and 07 were approximately 100 miles apart, with different crop varieties used at each trial. These trials can be considered independent.</p> <p>Trials S26/2015-16 and 17 were conducted at the same location, but on different varieties so can also be considered independent.</p> <p>Details of the trials locations will be added to the DAR.</p> <p>Further trials have been conducted at different locations in Italy and Slovenia and the additional data can be provided on request (see applicant comment at 3(21) below).</p> <p>RMS: S26/2015-02 and 07 were conducted in different greenhouses approximately 60</p>	See 3 (15)

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>km apart. On this basis it is considered these two trials are independent.</p> <p>The trials S26/2015-16 and 17 were conducted in the same greenhouse, and therefore cannot be considered independent as the crop varieties used are not considered sufficiently different.</p> <p>The DAR can be updated to include this additional information, and update the trials details to outline that the trials S26/2015-16 and 17 are replicates.</p> <p>Open point</p>	
3(17)	Vol. 3, B.7.6.3, Strawberry	NL: See also previous comments: can strawberry trials from the reports S12-03522, S24/2014 and S26/2015 be considered independent?	<p>Applicant: All the strawberry trials from these studies were conducted at locations at least 30 miles apart, with the exception of two trials, S24/2014-02 and 04 that were conducted 3.3 miles apart. At these trials, different crop varieties were used. The trials are therefore all considered to be independent.</p> <p>Details of the trial locations will be added to the DAR.</p> <p>Further trials have been conducted at different locations in Italy and Slovenia and the additional data can be presented on request (see applicant comment at</p>	See 3(15)

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>3(21) below).</p> <p>RMS: All trials on strawberry were conducted in different greenhouses a minimum of approximately 3 km apart. On this basis it is considered these trials are independent. The DAR can be updated to include this additional information on the location of the trials</p> <p>Open point</p>	
3(18)	Vol. 3, B.7.6.5, Courgette	NL: Please also check independency of courgette trials from report S26/2015.	<p>Applicant: All the courgette trials from S26/2015 were conducted at locations at least 30 miles apart and using different varieties, therefore they can be considered to be independent. Details of the trial locations will be added to the DAR.</p> <p>Further trials have been conducted at different locations in Italy and Slovenia and the additional data can be presented on request (see applicant comment at 3(21) below).</p> <p>RMS: All trials on courgette were conducted in different greenhouses a minimum of approximately 10 km apart. On this basis</p>	See 3(15)

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>it is considered these trials are independent. The DAR can be updated to include this additional information on the location of the trials</p> <p>Open point</p>	
3(19)	Vol. 3, B.7.6.6, Melon	NL: In line with previous comments, the independency of the melon trials of report S26/2015 should be checked.	<p>Applicant: All the melon trials from S26/2015 were conducted at locations at least 30 miles apart and using different varieties, therefore they can be considered to be independent. Details of the trial locations will be added to the DAR.</p> <p>Further trials have been conducted at different locations in Italy and Slovenia and the additional data can be presented on request (see applicant comment at 3(21) below).</p> <p>RMS: All trials on melon were conducted in different greenhouses a minimum of approximately 10 km apart. On this basis it is considered these trials are independent. The DAR can be updated to include this additional information on the location of the trials</p> <p>Open point</p>	See 3(15)

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(20)	Vol. 3, B.7.6.1, Residues arising from supervised trials, tomato	EFSA: In the report LN95 of the field trials with tomato it is stated that samples arrived in the lab at 9/3 and 30/3 and were analysed for chloropicrin and dichloronitromethane at 17/3; 26/3 and 1/4 resulting in storage periods > 3 days. This seems to be in contrast to the information given in the DRAR in table B.7.6.1-1 (page 25). Pls clarify.	<p>Applicant: There is a typographical error in Table 7.6.1-1 of the DAR. Only the data from the later sampling was included in the DAR therefore the PHI should be corrected from 88 to 109 days. The samples from the later harvest were harvested on 29 March 2009 and analysed on 31 March 2009, therefore the interval was 2 days.</p> <p>RMS: As stated by the applicant, only the second sampling (PHI 109 days) was analysed within a sufficiently short period (sampling 29/03, extraction 31/03, analysis 01/04). Therefore the storage period in total was 3 days for this sampling. Table B.7.6.1-1 will be updated to amend the PHI to 109 days</p> <p>Open point</p>	<p>Open point:</p> <p>RMS to correct the typo in Table 7.6.1-1 of the DAR with the correct storage period of 3 days in the residue trials for tomato.</p>
3(21)	Vol. 3 B.7., B.7.6.8. Summary of residues resulting from supervised trials p73-75	Applicant: we agree with the RMS assessment that in all of the submitted trials residues of chloropicrin and its metabolite dichloromethane (DCNM) were below the LOQ and, with the exception of one crop, no residues detected in the crops. [The exception was a single trial on strawberries where the submitted chromatograms	<p>RMS: Noted thank you. These additional trials can be requested (see responses to comments 3(22) - 3(24)), although RMS does not consider they are necessary to support the representative uses.</p> <p>Open point</p>	See data requirement in 3(29)

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		<p>indicated levels of 0.2 µg/kg (i.e. ~4% of the LOQ of 0.005 mg/kg).] We agree with the assessment that the chromatograms submitted to support the studies show no peaks were present in the treated samples which were not also present in the control samples for the same commodity (with the exception of the strawberry sample cited above) and agree this supports the conclusion that, in addition to the absence of chloropicrin and DCMN, other potential metabolites and impurities of chloropicrin were not present in the samples (further supported by the specific data on impurities provided in Volume 4).</p> <p>It should be noted that a further 22 supervised residue trials were conducted in 2016 (two trials (one drip and one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons, strawberries and lettuce) and these are available for submission in response to a request from EFSA. These additional trials provide further confirmation of the 'no residues' situation.</p>		
3(22)	Vol. 3, B.7.6.8, Summary of residues arising from	EFSA: It is noted that trials for all proposed crop commodities grown in glasshouses and	Applicant: There is no requirement for projected trials to be conducted in a	See data requirement in 3(29)

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	supervised trials	in "existing protected structure greenhouse/walkin tunnel" are performed only Sicily and Liguria. It is debatable whether these trials restricted to 2 locations in one country of the SEU can be regarded as representative for all European areas as e.g. outside temperature in this region might not represent the most critical conditions for SEU and NEU given the relatively high volatility of the active substance.	<p>different country or zone therefore these trials are acceptable and in line with current guidance. Further residue trials conducted in Italy and Slovenia are available (see 3(21) above), although these are outdoor trials. The data from these trials confirms a non-relevant residue situation and can be presented on request. Although open field trials, the treated area was covered by a film immediately post application, therefore it can be argued that these trials also effectively represent protected conductions.</p> <p>RMS: The OECD guidance on crop field trials (509) states the following with respect to greenhouse trials:</p> <p>"For such greenhouse trials, geographic distribution typically is not an issue; however for active ingredients which are susceptible to photodegradation, consideration should be given to locations at different latitudes and winter/summer periods."</p> <p>Photodegradation is not considered to be of</p>	

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>concern as the soil is covered barrier film before/immediately post treatment, so the active substance is not exposed to significant amounts light. On this basis it is considered that the trial locations meet with the current guidance.</p> <p>It is noted that the applicant has further trials available conducted outdoors in Italy and Slovenia, which also show a 'no residue situation' (according to the applicant – these trials have not been evaluated by RMS). These additional trials can be requested from the applicant and reviewed by the RMS in an updated DAR to demonstrate consistent results were obtained at other trial locations.</p> <p>Open point</p>	
3(23)	Vol. 3, B.7.6.8, Summary of residues arising from supervised trials	EFSA: It is noted that critical GAP compliant trials are not provided for open field applications (both SEU and NEU) for any of the proposed crop commodities with the exception of the two trials for tomatoes which cannot be considered independent as they were performed in the same location.	<p>Applicant: For both protected and open field uses, the soil is covered by a film either before or immediately post application, therefore it can be argued that both protected and open-field uses are essentially equivalent and that the location/EU zone is irrelevant.</p> <p>In addition, further open field residue trials from northern and southern Europe</p>	See data requirement in 3(29)

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Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>are now available and can be provided on request (see 3(21) above). These trials demonstrate that there is no difference in residue levels when the trials are conducted in either northern or southern Europe (non-relevant residue situation in both cases).</p> <p>RMS: As outlined by the applicant, following treatment the soil is covered barrier film before/immediately post treatment, therefore the trials are considered equivalent irrespective of whether the trial is indoor or outdoor. On this basis it is considered that the available protected trials are sufficient to support the proposed uses on outdoor and protected crops.</p> <p>However, it is noted that the applicant has further trials available conducted outdoors in Italy and Slovenia, which also show a 'no residue situation' (according to the applicant – these trials have not been evaluated by RMS). If requested by EFSA these additional trials could be evaluated to support the requested outdoor uses.</p>	

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Open point	
3(24)	Vol. 3, B.7.6.8, Summary of residues arising from supervised trials	EFSA: It is noted that in all trials for all proposed crop commodities are performed as drip application tarpred except for one trial where the active substance was applied to tomato via Shank injection, tarpred. However, this trial is not according to the critical GAP. Evidence should be provided that both application forms lead either to the same residue situation or that the drip application can be regarded as more critical.	<p>Applicant: For both drip and shank applications, the soil is covered by a film either before or immediately post application, therefore the treated soil and transplanted crops are essentially maintained under the same conditions therefore both techniques will lead to the same residue situation (no detectable residues).</p> <p>In addition, further drip and shank application trials from northern and southern Europe are now available and can be provided on request (see 3(21) above).</p> <p>RMS: As outlined by the applicant, following treatment the soil is covered barrier film before/immediately post treatment, therefore the trials are considered largely equivalent irrespective of the application type. On this basis it is considered that the available drip application trials are sufficient to support the shank application, given an essentially no residue situation is observed.</p>	See data requirement in 3(29)

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>However, it is noted that the applicant has further trials available conducted outdoors in Italy and Slovenia, conducted using both the drip and shank application method which also show a 'no residue situation' (according to the applicant – these trials have not been evaluated by RMS). These additional trials can be requested from the applicant and reviewed by the RMS in an updated DAR to support the requested shank application.</p> <p>Open point</p>	
3(25)	Vol. 3 B.7., B.7.6.8. Summary of residues resulting from supervised trials - first full para. p75	Applicant: we agree with the RMS conclusion that, given the 'non-residues' situation demonstrated from five crops (from three crop groups) where harvest of the edible part of the commodity is within a year of treatment, that no residues will be expected in tree crops taking into account the much longer time between treatment and first crop harvest. As mentioned in applicant comment 1 in this section, further supervised residue trials are available for submission on request from EFSA which confirm the 'no residues'	<p>RMS: RMS agrees with the applicant's comments, and as outlined on p75 does not consider further trials on tree crops are required to support the proposed uses.</p> <p>Addressed</p>	See data requirement in 3(29)

section 3 – Residue data

Residue trials in plants and identification of critical GAP				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
		situation. Therefore, the applicant considers that no supervised residues trials will be required on tree crops (to support use on pome fruit, stone fruit, citrus fruit and olives) at Member State level.		

Feeding studies in poultry, ruminants, pigs and fish				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

Effects of processing				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

section 3 – Residue data

Residues in rotational crops				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
3(26)	Vol. 3, B.7.2, Metabolims, Distribution and expression of the residues in rotational crops	EFSA: A study of metabolism in rotational crops might be necessary depending on the outcome of discussion on the residue field trials.	<p>Applicant: No detectable residues of chloropicrin were detected in any of the residue samples with the exception of one strawberry sample where the residue was equivalent to 0.0002 mg/kg. This data was obtained from crops planted into treated soil. A metabolism study in rotational crops is not therefore triggered as clearly no detectable residues of chloropicrin would be detected in rotational crops.</p> <p>RMS: Noted, although RMS considers that the available trials data which demonstrates a no residue situation in primary crops, the soil DT90 for chloropicrin and the proposed annual application restriction are sufficient to demonstrate that further data to address residues in rotational crops are not required.</p> <p>Addressed</p>	See 3(15)

Summary of other studies				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

section 3 – Residue data

Estimation of the potential exposure through diet and other sources				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
3(27)	Vol. 1, 2.7.9. Estimation of the potential and actual exposure through diet and other sources	FR: Contrary to TMDI calculation, IESTI calculation had to be performed only for the intended uses.	Applicant: IESTI was conducted using intended uses. RMS: If required the worst case IESTI can be removed from the DAR Addressed	Addressed. RMS will update Vol 1 accordingly.
3(28)	Vol. 1, 2.7.9. Estimation of the potential and actual exposure through diet and other sources	FR: Concerning exceedance of ARfD for orange, knowing that a no residue situation is expected, should it be preferable to use the LOQ at 0.005 mg/kg?	Applicant: Agreed and adopting this approach will result in a non-exceedance of the ARfD. RMS: It is agreed this would be a suitable approach for refinement of the risk assessment. The risk assessment in the DAR can be updated to reflect this Open point	See 3(15)
3(29)	Vol. 1 Section 2.7.9, Estimation of the potential and actual exposure through diet and other sources	Applicant: We agree with the overall conclusion that all of the submitted data support a 'no residues' situation and that there is no dietary risk to consumers from the use of chloropicrin in line with the supported GAP. It should be noted that to provide further confirmation of 'no-residues' a further 22 supervised residue trials were conducted in 2016 (two trials (one drip and	RMS: Noted thank you. These additional trials can be requested from the applicant and reviewed by the RMS in an updated DAR (see responses to comments 3(22) - 3(24)), although RMS does not consider they are necessary to support the representative uses. Addressed	Data requirement: Applicant is invited to submit "the further 22 supervised residue trials conducted in 2016 (two trials (one drip and one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons,

section 3 – Residue data

Estimation of the potential exposure through diet and other sources				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons, strawberries and lettuce). These studies are available for submission in response to a request from EFSA.		strawberries and lettuce)." See also 3(21)-3(25)
3(30)	Vol. 1, 2.7.9	DE: The compounds of dietary relevance are not known. RMS considers the plant metabolism as not addressed. While we agree to that, we do not support the conclusion without further proof, that no residues are expected and the risk for consumers is acceptable.	Applicant: Disagree. Although there are deficiencies in the plant metabolism study, a non-relevant residue situation was confirmed from the residue trial package therefore parent is the only compound of dietary relevance as discussed in the DAR. The risk to consumers can therefore be assessed and was concluded to be acceptable. See also applicant response at 3(7) above. RMS: DEs comments are noted, however the RMS considers that despite deficiencies in the metabolism studies, sufficient data is available overall to demonstrate that the proposed uses do not demonstrate a risk to consumers Addressed	See 3(8)

section 3 – Residue data

Proposed MRLs and compliance with existing MRLs				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Proposed import tolerances and compliance with existing import tolerances				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Other comments				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(28)	Vol. 1, 2.7.9	DE: The compounds of dietary relevance are not known. RMS considers the plant metabolism as not addressed. While we agree to that, we do not support the conclusion without further proof, that no residues are expected and the risk for consumers is acceptable.	Applicant: Disagree. Although there are deficiencies in the plant metabolism study, a non-relevant residue situation was confirmed from the residue trial package therefore parent is the only compound of dietary relevance as discussed in the DAR. The risk to consumers can therefore be assessed and was concluded to be acceptable (see also applicant response at 3(7) above and applicant comment at 3(21) above). RMS: DEs comments are noted, however the	See 3(8)

section 3 – Residue data

Other comments				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>RMS considers that despite deficiencies in the metabolism studies, sufficient data is available overall to demonstrate that the proposed uses do not demonstrate a risk to consumers</p> <p>Addressed</p>	
3(29)	Vol. 3, B.7.19. References relied on	EFSA: A the justification for choosing the databases for the literature search should be provided together with information on the main focus of the searched database.	<p>Applicant: The databases Chemical Abstracts Plus (CAPlus) and Toxicology Center (Toxcenter) were used for the literature search.</p> <p>CAPlus covers worldwide literature from all areas of chemistry, biochemistry, chemical engineering, and related sciences. Coverage includes applied, macromolecular, organic, physical, inorganic, and analytical chemistry.</p> <p>ToxCenter covers the pharmacological, biochemical, physiological, and toxicological effects of drugs and other chemicals. Toxcenter is composed of the following subfiles: BIOSIS (1969 to date), CAplus (1907 to date), IPA (1970 to date), and MEDLINE (1953 to date)</p> <p>Applicant: An additional updated search can be conducted and submitted if required.</p>	<p>Data requirement:</p> <p>Applicant to provide formally justification for choosing the databases for the literature search and information on the main focus of the searched database.</p>

section 3 – Residue data

Other comments				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>RMS: Additional information on the justification for choosing the databases and with information on the main focus of the searched database, can be included in the DAR if provided by the applicant.</p> <p>Addressed</p>	
3(30)	Vol.4, C. 1.4.1, consideration of residues of impurities from the TGAI in food commodities	EFSA: Are the analytical methods used to determine the impurities B, C, D and F in tomato and strawberries validated for all impurities and matrices. If so what are the performance characteristics of the analytical method?	<p>Applicant: Attempts were made to validate methods for the determination of [REDACTED] [REDACTED] [REDACTED] in tomatoes and strawberries as part of study 24/2014 (C.1.4.1.2). Details of the method validation analysis are presented in the summary for this study under point C.1.4.1.2.</p> <p>RMS: No analytical methods or validation data is available for [REDACTED], as these compounds were not analysed for in the trials.</p> <p>For impurity D ([REDACTED]), acceptable validation data is presented for [REDACTED] in B.7, but</p>	<p>Data requirement:</p> <p>Applicant to provide the details of the analytical methods including the details of the validation used to determine the impurities B, C, D and F in tomato and strawberries whenever available.</p>

section 3 – Residue data

Other comments				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>[REDACTED] was not analysed for directly. The available data is however considered sufficient to demonstrate the absence of both compounds in the food commodities analysed.</p> <p>For [REDACTED] the same method of analysis is used as for parent and impurity D, and this referred to in the Volume 4. Full details of this method can be copied into the volume 4 if required. Validation data are presented for each of the studies (C.1.4.1.2, p36 and p42).</p> <p>Addressed</p>	
3(31)	Vol.4, C. 1.4.1, consideration of residues of impurities from the TGAI in food commodities	EFSA: Are stability data of the eight impurities in food available?	<p>Applicant: Stability of the impurities in plant matrix was not determined, however for the impurities considered relevant and analysable, samples were analysed as quickly after harvest as practicably possible (within 4 days). A storage stability study would therefore be of no value in support of the residue trials.</p> <p>RMS: Stability data is not available for these impurities. Samples in the trials were</p>	<p>Data requirement: Applicant to formally submit information on stability of the eight impurities in food matrices.</p>

section 3 – Residue data

Other comments				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>analysed as quickly as possible (1-4 days), and no residues of the impurities were determined in any samples. Based on the limited storage stability data available for chloropicrin and DCNM, showing stability for up to 4 days, it is considered that additional storage stability data would not provide additional useful information, other than to confirm the very limited storage stability of the compounds.</p> <p>Addressed</p>	
3(32)	Volume 1 Overall conclusion	<p>Public comment – French Chambers of Agriculture (AFCA):</p> <p>The specific use on apples will be made to limited areas of the overall cropped area where there is a specific need to treat for replant disease. Use will not be on a large scale and limited to no more than 1 application in 15 years or longer. This is an important factor of the specific use which will minimise environmental exposure.</p>	<p>Applicant: Agreed.</p> <p>RMS: Noted</p> <p>Addressed</p>	Addressed.
3(33)	Vol. LoEP, Metabolism in plants	FR: Since the metabolism study on plants is not fully validated, should it be mentioned in the LoEP?	<p>Applicant: The deficiencies for this study are clearly presented in Volume 3. B7 and this is considered to be sufficient.</p> <p>RMS: The deficiencies are outlined in the body of the DAR, but the LoEP can be</p>	See 3(8)

section 3 – Residue data

Other comments				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			amended to include this additional information if considered necessary by EFSA. Addressed	

section 4 – Environmental fate and behaviour

4. Environmental fate and behaviour

Route and rate of degradation in soil				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8	FR (April, 2018): RMS should distinguish its own conclusions and opinions from the study summary and from notifier's conclusions for each study.	RMS : Noted. The study summaries provided were generally brief and were re-summarised by the RMS with more detail. Where the applicant has presented something that the RMS did not agree with or something that needed highlighting, the RMS has tried to be transparent and present the applicant view. Addressed Applicant: for RMS to consider	Addressed
4(2)	Vol. 3, B.8, Appendix 2, Literature review	FR (April, 2018): Only 2 databases were consulted for the literature review proposed for chloropicrin and its metabolite DCNM. This seems low compared to current literature reviews provided.	RMS : Comment noted. A more extensive literature search can be requested from the applicant and reviewed by the RMS in an updated DAR. See also comment 4(65). Applicant: An updated literature search will be provided if requested.	Seed data requirement in 4(66)

section 4 – Environmental fate and behaviour

Route and rate of degradation in soil				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(3)	Vol. 3, B.8.1.1, Route and rate of degradation	FR (April, 2018): Agrees that current European Guidelines may not fit the very specific characteristics of chloropicrin and in particular its very high volatility. Studies and endpoint determinations could be assessed using a consistent approach and weight of evidence.	RMS : The RMS agrees that the high volatility of chloropicrin has caused issues in the conduct of studies. A pragmatic approach was taken to the interpretation of studies and derivation of endpoints, but this approach is open to debate. Addressed	Addressed
4(4)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation 1).Craine, E.M. 1985	EFSA: It is agreed that results of study Craine, E.M. 1985 cannot be used to derive assessment end points, mainly due to the difficulty to guarantee that no losses occurred taking into account that no radiolabelled material is used and volatility of the substance and its potential metabolites.	RMS : Comment noted. Addressed	Addressed

section 4 – Environmental fate and behaviour

Route and rate of degradation in soil				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(5)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation. Hatton C, shepler K., Ruzo L. 1995.	EFSA: The determination of DegT50 in this study is a reasonably realistic worst case and usually the accepted method for DegT50 determined from laboratory studies in the case of volatile substances. Excluding the amount of chloropicrin in the volatile trap (foam plug) will result on a DissT50 not a DegT50. This study gives supporting indications that nitromethane and chloronitromethanol are likely to be metabolites down in the route of degradation of chloropicrin.	RMS: Comment noted. The RMS also notes that the study suggests the likely metabolites are dichloronitromethane, chloronitromethane, nitromethane, and carbon dioxide. Addressed Applicant: Due to the deficiencies identified in the study by the RMS, including the high levels of chloropicrin detected in the PUF trap, the Applicant agrees with the RMS that the derived degradation/dissipation values are not suitable for use in the risk assessment.	Addressed
4(6)	Vol. 3, B 8.1.1.1, study Völkel, 2004	DE: We believe that for an active substance as volatile as chloropicrin, an aerobic soil study without a total mass balance should not be considered acceptable. It is possible, that part of the active substance escaped from the system during incubation, besides, the amount of chloropicrin that vaporised from the soil into the headspace need to be considered before deriving DT ₅₀ endpoints. Otherwise, the derived DT ₅₀ endpoints are dissipation rates but not degradation rates.	RMS: It is agreed that the lack of a mass balance from this study is problematic, irrespective of whether chloropicrin is volatile or not. The RMS does note that the endpoints from this study have previously been accepted for use at community level and no requirement for a new aerobic soil degradation study was made in the EFSA conclusion. See also comment 4(7). Applicant: In the previous evaluation detailed in EFSA Journal 2011;9(3):2084	Experts' consultation MSs experts to examine the acceptability of the degradation in soil study Völkel (2004) in relation to the mass balance, the potential losses by volatility. If the study ist to be considered acceptable then the MSs need to consider if there is justification to exclude data of any particular soil in the study. See also 4(7) and the open point

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			<p>this study was not considered deficient and no further information on the route and rate of degradation of chloropicrin in soil was requested. In this system measures were taken to prevent losses via volatilisation. A closed system was used instead of continuous aeration and headspace was kept to a minimum with the test item injected into the bottom of the soil column and the vessel closed with a screw lid immediately afterwards. This differs to the conditions in Hatton <i>et al.</i> (1995) where 50 g soil samples were added to biometer flasks with a significant amount of headspace, therefore the potential for the generation of volatile losses in Hatton <i>et al.</i> (1995) was significantly greater. In the light of the measures taken to prevent such losses in Völkel (2004) the Applicant believes it appropriate to use the DT₅₀s from this study as DegT₅₀s. Further argumentation is included under Comment 4(8).</p>	<p>therein.</p> <p>See also data requirement in 4(34)</p> <p>See also 4(16), 4(17), 4(36), 4(50), 4(55).</p> <p>Note: since there are serious doubts on the acceptability of the values derived from study McLaughlin, S. 2013a, the exclusion of soil II in Voelkel (2004) may result in reducing the data set for the active substance to only three soils and the identification of a data gap (and the need to use DT50 = 8.8 d for the rest of the exposure assessment instead of the geometric mean).</p>
4(7)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation. Voekel, W. 2004.	EFSA: The aerobic degradation study in soil (Voekel, W. 2004) was already considered in the previous assessment of chloropicrin. It is noted that a slight different end point than the previous agreed is proposed for	<p>RM:</p> <p>Point (1): The conclusion by EFSA on the slight difference in endpoints is correct.</p> <p>Point (2): The soil with the longest DT₅₀ has</p>	<p>Open point</p> <p>RMS to provide in an amended DAR, within the B.8 summary of the study, the reason for discarding the results on</p>

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		<p>the soil IV Senozan (silty clay loam) probably due to the use of non-linear fitting vs previously derived values by linear regression.</p> <p>Also it is noted that for the exposure assessment the soil with longest DT₅₀ (soil II) has been discarded as an outlier. However, the reason does not seem to be fully justified in the evaluation of the study.</p> <p>In a more modern study (McLaughlin, S. 2013a, see comments below), important losses of volatiles (either parent or metabolites) are observed not being possible to close an acceptable mass balance. Since in this study material balance was not accounted, it cannot be excluded that a significant fraction of the losses observed are actually volatilization instead of degradation. Therefore, it is doubtful the DT₅₀ can be considered to represent pure degradation.</p>	<p>been discarded for higher tier assessment because the microbial biomass of the soil dropped below 1% during the study. This is stated in the overall summary of soil degradation (section B.8.1.1.4) but not explicitly in the study summary. A statement will be added in the study summary.</p> <p>Point (3): The RMS notes that despite the fact that chloropicrin is a highly volatile substance and no mass balance was presented, the study by Völkel was accepted for use at community level as part of the previous assessment. The DT₅₀ values were used to generate an endpoint for modelling and there was no requirement set to provide a new study.</p> <p>It is agreed that the data from the new study shows that there are losses from the system and that strictly speaking the DT₅₀ values generated are dissipation values for the system and not purely degradation values. The RMS also comments that the extraction procedure described is probably not conducive to achieving a good mass balance.</p> <p>The RMS has made the case that the losses are less at the start of the study when chloropicrin and DCNM are present and</p>	<p>soil (II) in study Voekel, W. 2004. If loss of microbial activity is considered for a particular soil, this loss should be compared with the loss of microbial activity in the other soils investigated in this study.</p> <p>See experts' consultation in 4(6)</p> <p>See also data requirement in 4(34)</p> <p>See also 4(16), 4(17), 4(36), 4(50), 4(55).</p>

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			<p>increase with time concurrent with DCNM degradation. The metabolites likely to be formed from DCNM are chloronitromethane and nitromethane. These are both highly volatile and could quite possibly escape the volatile trap, causing the trend of lower mass balance with time. The RMS does accept that this argument is debatable, given that chloropicrin and DCNM are also volatile.</p> <p>The RMS opinion from looking at all of the aerobic soil studies is that conducting a study that complies with the guideline may not be possible, in terms of maintaining a mass balance or keeping the components in contact with the soil for the duration of the study. Some consideration should be given to the fact that the active substance is a highly volatile soil fumigant and a pragmatic approach taken to interpreting the studies.</p> <p>For example, a case can be made for accepting the data from the study by McLaughlin (2013a) based on the following two points:</p> <p>(1) If kinetic assessment is made using the data where mass balance was approximately 80% or more (to day 7 for Speyer 2.2 and day 2 for the other soils),</p>	

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Route and rate of degradation in soil				
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			<p>the kinetic fittings gave very similar DT₅₀ values to those derived for the whole dataset. This suggests that the mass balance does not greatly influence the DT₅₀ value generated for chloropicrin.</p> <p>(2) Mass balances are poorer at the earlier timepoints of the study where DCNM is applied as parent (McLaughlin, 2013b) compared to the study where chloropicrin is applied. This suggests that the greater contribution to the poor mass balance in the chloropicrin study comes from losses of either DCNM itself or metabolites of DCNM. This argument is strengthened by the fact that mass balance generally declines most rapidly after formation of DCNM is first seen.</p> <p>Open point: Validity of the study by Völkel (2004).</p> <p>Applicant: It is confirmed that the difference in the end-point for soil IV Senozan soil is due to the method of calculation. Please refer to comment 4(6) regarding the potential for losses via volatilisation in Völkel (2004).</p> <p>The reason for excluding the outlier is not</p>	

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			<p>given in the study summary, however, it is discussed under B.8.1.1.4 where it is stated that the microbial biomass of the soil was below the minimum of 1% of total organic carbon stipulated in the OECD guideline (microbial activity at such low levels has been cited as a reason for discarding such soils in the evaluations of other active substances). In addition the DT₅₀ value in this soil is not in keeping with values from other studies (even that of Hatton 1995 where volatile residues were included in the calculation of the DT₅₀). Indeed when evaluated statistically (using Grubb's test) the DT₅₀ of 26.9 days is identified as an outlier (P <0.05).</p> <p>McLaughlin 2013a is addressed under Comment 4(8).</p>	
4(8)	Vol. 3, B 8.1.1.1, study McLaughlin, 2013a	DE: We believe that the DT ₅₀ values for chloropicrin from this study should not be used. Chloropicrin is extremely volatile and with a total mass balance of only 30- 56 % at the end of the study it is likely that a high amount of chloropicrin escaped from the system or during the extraction. Thus the DT ₅₀ values represent dissipation rates and not degradation rates. The RMS states that the lost radioactivity is due to loss of	<p>RMS :</p> <p>The RMS does not state anywhere in the dRR that 'the lost radioactivity is due to a volatile metabolite' as stated in this comment.</p> <p>The RMS does discuss the poor mass balance and sets out the possible reasons for this. The attention of the MS is drawn to the conclusion of this study. There it is</p>	<p>Open point</p> <p>RMS to clarify in an amended DAR the possible reasons for the low mass balance observed in study McLaughlin (2013a).</p> <p>Experts' consultation</p>

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No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		a volatile metabolite but there is no evidence provided for this and even if some of the loss is due to a volatile metabolite, additional loss of chloropicrin cannot be ruled out.	<p>stated that one possibility that explains increased losses with time is the production and then loss of a volatile metabolite, although this is not the only possible explanation.</p> <p>The RMS agrees that a strict interpretation of the guidance leads to the conclusion that the DT₅₀ values should be regarded as dissipation values. However, it is possible to make a case for acceptance of the chloropicrin values as degradation DT₅₀ values, made in response to comment 4(7). It is also noted that the DT₅₀ values from the study by Völkel (2004) were accepted at community level in the previous assessment (despite clear deficiencies) and these DT₅₀ values are not significantly different from those in the study by McLaughlin (2013a). Therefore the RMS is of the opinion that if the results from the study by Völkel continue to be accepted, then the DT₅₀ values from this study should also be added to the data set.</p> <p>See also point 4(12) Open point</p> <p>Applicant: In the DAR the RMS states that the mass balance was reasonable during</p>	<p>MSs experts to examine the acceptability of the degradation in soil study McLaughlin (2013a) in relation to the mass balance and losses by volatility.</p> <p>See also data requirement in 4(34)</p> <p>See also 4(9), 4(12), 4(50) and 4(55).</p>

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			<p>the timeframe of chloropicrin degradation in the study. Significant drops in the mass balance were observed at later time-points where the majority of chloropicrin degradation had already occurred indicating that any losses will likely be due to losses of a volatile metabolite. The volatility of chloropicrin and subsequent detection in foam traps in Hatton <i>et al</i>/1995, appears to be the main reason for the concerns about the low mass balance and possible losses of chloropicrin in Völkel (2004) and McLaughlin (2013); however, direct comparison of the results in this manner is not appropriate due to the differing methodologies used. In Hatton <i>et al</i> (1995) 50 g soil samples were incubated in flow through systems using biometer flasks with significant head space. This study design did not maximise contact of the test item with the soil and appears to have led to significant volatile losses with >30% identified as chloropicrin in the foam traps after 2-3 days incubation. Conversely in Völkel (2004) and McLaughlin (2013) the headspace was kept to a minimum to maximise contact with the soil and to minimise such</p>	

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			<p>losses. In McLaughlin (2013a) a flow through system with volatile traps including foam and Harvey's Cocktail traps for organic volatiles was used. Levels of radioactivity in the foam trap were negligible in stark contrast with the observation in Hatton <i>et al</i> (1995) indicating that indeed volatilisation of chloropicrin was minimised in these studies. The mass balances over the initial period of chloropicrin decline in McLaughlin (2013) support this view. For example in the Brierlow soil after 2 days levels of chloropicrin had declined to 12.1 to 15.8 %AR after 2 days when the mass balance is 80.6%AR. This clearly indicates that the primary process for chloropicrin loss is not volatilisation and loss from the system itself. Use of the derived DT_{50s} in these studies as DegT_{50s} is therefore justified.</p>	

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4(9)	Vol. 3.B.8. Study McLaughlin 2013B	NL: The NL has the opinion that this study is not acceptable because the mass balance are not sufficient. Since the mass balance are not correct the DT50 derived from this study are also not acceptable a part of the mass is missing, this can be DCNM that is not degraded and this will have an effect on the DT50 value that has been estimated.	<p>RMS :</p> <p>It is agreed that the mass balance values do not comply with the guideline. The RMS has made a case, that losses may be due to the formation and loss from the system of a volatile metabolite.</p> <p>The RMS comments that consideration should be given to the high volatility of the test substance and metabolites formed when interpreting the study data. The proposed metabolites formed from degradation of DCNM are chloronitromethane and nitromethane, both highly volatile substances.</p> <p>See also comment 4(14).</p> <p>Applicant: Please refer to the response to Comment 4(8).</p>	See experts consultation and open point in 4(8)
4(10)	Vol. 3.B.8.1.1 Table B8.1-37	NL: Typo at an A after McLaughlin (2013)	<p>RMS :</p> <p>Thank you for pointing this out. The missing 'a' will be added.</p> <p>Open point</p> <p>Applicant: Comment noted - RMS to address.</p>	Addressed RMS to consider typo identified in reporting table comment 4(10) in an updated DAR.

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4(11)	Vol. 3, B.8.1.1.1, McLaughlin, 2013a	FR (April, 2018): As reported for the active substance, the visual fits for the kinetic assessment performed for metabolite DCNM should be reported.	RMS : Noted. The plots will be added. Open point	
4(12)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation 4). McLaughlin, S. 2013a.	EFSA: In chloropicrin aerobic degradation study (McLaughlin, S. 2013a), recoveries significantly below of 90 % are the symptom of a failure on the experimental methodology. Without an adequate explanation of the losses the study should be discarded and not used for deriving kinetic end points. The presumed volatile metabolite would need to be identified. Despite to the losses metabolite DCNM can be confirmed as a major soil metabolite by the data in these experiments considering the amounts quantified should be taken as lower values in the actual range.	RMS : It is agreed that the study has deficiencies because recoveries are lower than 90% for most timepoints and decrease with time (discussed in the conclusion to the study). The opinion of the RMS is that a pragmatic approach should be taken to the interpretation of studies with a highly volatile test substance and metabolites. A case has been made for the acceptance of the study data for derivation of DT ₅₀ values for chloropicrin – see reply to comment 4(7). Open point: Validity of the study by McLaughlin (2013a). Applicant: Please refer to the response to Comment 4(8).	See experts consultation and open point in 4(8)
4(13)	Vol. 3, B 8.1.1.1, study McLaughlin, 2013b	DE: Also for the metabolite study with DCNM, we do not believe that the DT ₅₀ values from this study should be used. With a total mass balance of only 50-53 % at the	RMS : As with comment 4(8), the RMS would like to make it clear that the dRR does not state at any point in the dRR that 'the lost	Data requirement Applicant to provide data or studies to

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		end of the study it is likely that a high amount of DCNM escaped from the system or during extraction of the soil. Thus the derived DT ₅₀ values represent dissipation of DCNM and not degradation. Again, the RMS states that the lost radioactivity is due to loss of a volatile metabolite but there is no evidence provided for this and even if some of the loss is due to an additional volatile metabolite, additional loss of DCNM cannot be ruled out.	<p>radioactivity is due to loss of a volatile metabolite'. The attention of the MS is drawn to the conclusion of this study, where it clearly discusses the various possibilities concerning why losses have occurred. See also comment 4(14).</p> <p>Applicant: The results of the study do support the argument that the mass balance losses are due to the losses of an unknown volatile metabolite and due to the very rapid decline of DCNM in the study the mass balances at the end of the study are not best placed to draw conclusions on the route of losses of DCNM. As stated previously, all efforts were made to minimise volatile losses and increase contact of the test item with soil. In the Longwood and South Witham soils after 1 day levels of DCNM decline to 9.3 to 17.9% AR, yet mass balances at this time-point were 60-70% AR. In the soils where degradation is slower (Brierlow and Speyer), mass balances were maintained for longer and after 2 days levels of DCNM had declined to 19 to 30% AR after 2 days and mass balances were 77 to 83.8% AR. These results indicate that the rapid losses of</p>	<p>identify the presumed volatile metabolite formed by the aerobic degradation in soil of DCNM.</p> <p>Experts' consultation</p> <p>MSs experts to examine the acceptability of the degradation of metabolite DCNM in soil study McLaughlin (2013b) in relation to the mass balance and losses by volatility.</p> <p>See also 4(14)</p>

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No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			DCNM are not due to volatilisation of DCNM itself from the system. Indeed the better maintenance of the mass balances when the degradation of DCNM is slower indicates that the decline in mass balance is due to losses of a volatile metabolite.	
4(14)	Vol. 3. B.8. (AS), B.8.1.1. Route and rate of degradation in soil. Aerobic degradation. Metabolite DCNM McLaughlin, S. 2013b.	EFSA: In metabolite DCNM aerobic degradation study (McLaughlin, S. 2013b), recoveries significantly below of 90 % are the symptom of a failure on the experimental methodology. Without an adequate explanation of the losses the study should be discarded and not used for deriving kinetic end points. The presumed volatile metabolite would need to be identified.	<p>RMS :</p> <p>It is agreed that the recoveries are significantly below 90% because of a failure in the methodology of the study. The RMS has made a limited case that this could be due to the formation of a volatile metabolite based on the pattern of mass balance.</p> <p>It is agreed that if this argument were accepted, there would still be the need to identify and quantify the volatile metabolite(s) formed, either in this study or in the study where the test substance was chloropicrin (preferably both).</p> <p>Open point</p> <p>Validity of the study by McLaughlin (2013b).</p> <p>Applicant: Please refer to the response to Comment 4(13). The unknown metabolite is considered unlikely to be a halogenated metabolite of chloropicrin</p>	See data requirement and experts' consultation in 4(13).

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			(e.g chloronitromethane) or nitromethane due to their respective volatilities (comparable to chloropicrin) and their possible detections in the soil degradation studies. It is therefore likely that the metabolite is a more volatile potential degradation product such as methylamine.	
4(15)	Vol. 3.B.8.1.1 Table B8.1-39	NL: Could the RMS explain why are the values in this table different for Brierlow and Speyer 2.2 than the values in table B8.1-38	RMS : The values in Table B8.1-38 are trigger values, those in B8.1-39 are modelling values. Addressed. Applicant: Comment noted - RMS to address.	Addressed
4(16)	Vol. 3.B.8.1.1 conclusion page 23	NL: doesn't agree with the RMS that on basis of the microbial biomass the DT50 of Speyer 2.3 soil is an outlier. The biomass is within the range given in the OECD307 guidance and therefore should not be considered as an outlier. Also the refinements with the shorter DT50 without this soil DT50 should be taken out of the dossier.	RMS : The biomass is 1.03% at the start of the study but was 0.84% at day 10 and 0.77% at the end of the study. The guideline recommends that the microbial biomass should be greater than 1% and this is not the case throughout the study. The DT ₅₀ from this soil is also significantly longer than that from any other soil. Based on this evidence, the RMS therefore maintains the opinion that as a refinement	See experts' consultation in 4(6) and open point in 4(7).

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			<p>the DT₅₀ value from this soil could be removed from the data set as a refinement. An explanation of the reason for the potential to omit the data from this soil as a refinement is presented in the summary section B.8.1.1.4 (page 48) but a more complete explanation will be added to the study summary itself.</p> <p>Open point: The removal of the DT₅₀ for the soil Speyer 2.3 from the dataset if the study is accepted.</p> <p>Applicant: Please refer to the response to comment 4(7). Under paragraph 23 of OECD307 it is stated that "a microbial biomass of at least 1% of total organic carbon is recommended". The %oc content of the Speyer 2.3 soil was 1.02 g/100g soil and the microbial biomass at the end of the incubation was 7.7 mg C/100 g of soil. This equates to 0.76% of total organic carbon, which is below the minimum value specified in the guideline.</p>	

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4(17)	Vol. 3B.8.1.1 Table B.1-12 and B8.1-17	NL: the percentage of biomass at the end of the study seems unrealistic high	RMS : The RMS agrees - it appears to be a mistake in the study report. A footnote will be added to the table to point this out. Open point Applicant: In the study the following explanation is provided "Also, these values are higher than typically observed since they were determined with soils dosed with [¹⁴ C]chloropicrin containing a high amount of carbon and nitrogen which may have stimulated growth of certain segments of the microbial population."	See experts' consultation in 4(6) and open point in 4(7).
4(18)	Vol. 3, B.8.1.1.2, Photolysis in soil	FR (April, 2018): Agrees with RMS that a soil photolysis study may not be considered as required in the case of the very specific application method of chloropicrin. Weight of evidence may apply.	RMS : Comment noted. Addressed	Addressed
4(19)	Vol. 3, B.8.1.1.3, Field studies	FR (April, 2018): No storage stability data for chloropicrin are available for field dissipation studies. RMS should mention this point.	RMS : A comment will be added. Open points Applicant: Comment noted - RMS to address.	Open point RMS to highlight in an amended DAR that no storage stability data is available for the field studies.

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Adsorption, desorption and mobility in soil				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(20)	Vol. 3, B.8.1.1.4, Summary & assessment – Soil studies, Page 49	Applicant: Under "Aerobic soil (rate of degradation of DCNM)" in the first line McClaughlin should be amended to McLaughlin	RMS : Noted. The amendment will be made. Open point Applicant: noted - RMS to amend DAR	Addressed RMS to consider in an updated DAR the typo identified in the Reporting Table comment 4(20).
4(21)	Vol. 3, B.8.1.2.1, Adsorption in soil	FR (April, 2018): RMS should indicate for each adsorption study if a potential correlation between adsorption and soil characteristics is observed.	RMS : A statement has been made in the conclusion on the correlation between pH and Koc for chloropicrin. A statement on the correlation between pH and Koc will be added to the conclusion of the adsorption study for DCNM. Open point Applicant: noted - RMS to address	Open point RMS to add in an updated DAR the assessment of the potential correlation pH and Koc on the adsorption of chloropicrin and DCNM. See also 4(22)
4(22)	Vol. 3, B.8.1.2.1, Penketh, 2008	FR (April, 2018): As stated by RMS, only 4 soils are considered acceptable in order to determine chloropicrin adsorption behaviour. Based on these 4 soils, a potential correlation of Kfoc and soil pH has been pointed out by RMS. However, all soil pH values (in water) are not exceeding 6.9 according to table B8.2-2. Additional alkaline soils should be provided	RMS : Chloropicrin has no functional groups that would influence adsorption based on changes in pH. Any pH dependence would occur because of the properties of the soils themselves. The RMS therefore sees no reason to further investigate pH dependence. A statement will be added to clarify that any	See open point in 4(21)

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Adsorption, desorption and mobility in soil				
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		by applicant in order to clarify the possible pH dependence for Kfoc of the active substance.	<p>pH dependence is not due to the properties of the active substance.</p> <p>Open point</p> <p>Applicant: The same study was evaluated in the previous EFSA evaluation (EFSA Journal 2011;9(3):2084) and it was concluded that there were no indications that the adsorption of chloropicrin was pH dependent and no further data were requested. It is agreed that when the Kfoc is plotted against pH there is a correlation, however, this does not imply causation. Chloropicrin is not a dissociating substance and there is no mechanistic explanation for such a relationship. If there was pH dependence, or relationship with other soil properties, it would be expected that such relationships would be observed with the Kf; however, this is not the case, and there is no specific correlation with any soil property. It is suspected that the apparent correlation of the Kfoc with pH is actually an artefact of properties of the soils used in the study and the process of correction for %oc (there is some degree of correlation between the %oc and pH of the soils used). For example the</p>	

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Adsorption, desorption and mobility in soil				
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			soil with the lowest %oc by quite some margin (Warsop) and consequently with the highest Koc after correction is also the soil with the lowest pH.	

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Adsorption, desorption and mobility in soil				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(23)	Vol. 3, B.8.1.2 Adsorption, desorption and mobility in soil (IIA 7.1.3, IIA 7.1.4). Metabolite DCNM. Kang, S., 2013	EFSA: In the summary of study Kang, S., 2013 on the adsorption desorption of DCNM in soil it is stated that the tested substance was stable under the tests conditions. However, no evidence seems to have been provided. Evidences on the stability of the test substance under the test condition should be required to the applicant and summarized in the RAR.	<p>RMS :</p> <p>Evidence for stability was provided for two of the four soils for a 48 hour adsorption period.</p> <p>For the main experiment either 2 or 3 hours adsorption time was used. It is only possible to make the case that as the stability criteria were met for two soils for 48 hours adsorption time, it is likely that the other two soils would also meet the criteria when shaken for a much shorter period of time. This case will be added to the study summary.</p> <p>Open point DAR will be amended</p> <p>Applicant: Evidence of stability in the test system is provided in the study report. Preliminary tests were performed in accordance with the OECD106 guideline. The stability of the test item was determined and DCNM was stable in the test systems for the 2-3 hour equilibration time.</p>	<p>Open point</p> <p>RMs to update the DAR to summarize pre test experiments and, in particular, stability test data under the test system of the substance DCNM in the soil batch adsorption desorption study Kang, S., 2013. It needs to be clarified that stability refers to the substance in both phases (aqueous and soil) and not only on total radioactivity recovery.</p>

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Adsorption, desorption and mobility in soil				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(24)	Vol. 1 and 3.B.8 B.8.1.2.4.	NL: is not familiar with the SSLRC classification system, please included an reference where these can be found classification can be found	RMS : This is a classification system used in the UK and not specifically relevant at community level. The sentence will be removed. Applicant: noted - RMS to amend DAR to provide a reference.	Open point RMS to either remove or provide reference to the SSLRC classification system in Vol. 1 and 3.B.8 B.8.1.2.4.

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(25)	Vol. 3, B.8.3.3, General comment on water/sediment studies	FR (April, 2018): Agrees with RMS considering that the data are sufficiently robust, considered the volatility of chloropicrin, in order to characterize the AS behaviour in water-sediment systems despite low mass balances. Weight of evidence may apply.	RMS : Comment noted. The RMS has expanded on the case in answer to comment 4(26).	Addressed
4(26)	Vol. 3.B.8.3.3.3	NL: the mass balances in the study, especially towards the end, are not acceptable. This has been observed after 7-14 days however no discussion and explanation was given. NL doubts if this study is acceptable. Is it possible that	RMS : For all systems, chloropicrin was either not detected or was present only low %AR at a timepoint where mass balance was still greater than 90% (either 7 or 14 days). Therefore it can be concluded that the loss	Data requirement Due to the serious doubts on the acceptability of the water sediment study McLaughlin, 2013c, the applicant is given the opportunity to provide a

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		<p>volatiles are formed from the metabolite DCNM that are not are not trappable ?</p>	<p>of chloropicrin from the system is by degradation and a whole system degT₅₀ can be derived.</p> <p>For DCNM the same case could be made for one system (Weweantic River, no headspace). It is less clear for the other three systems as DCNM was still detected at the last timepoint with acceptable mass balance and a case needs to be made based on losses of a volatile metabolite from the formation of DCNM.</p> <p>The RMS agrees that the discussion of mass balance is inadequate and will add text, including making the case that a whole system degT₅₀ can be derived for DCNM. This is based on the fact that mass balance was acceptable when chloropicrin and DCNM were present in the system at relatively high concentrations.</p> <p>Open point. Validity of the water / sediment study (McLaughlin, 2013c).</p> <p>Applicant: Every effort was made to prevent loss of volatile radioactivity in the study. As stated by NL mass balances to day 7 to 14 were acceptable but they declined after this.</p>	<p>new fully reliable water sediment study.</p> <p>Open point.</p> <p>RMS to provide in an updated DAR further assessment on the validity of the water / sediment study (McLaughlin, 2013c) and / or summary and assessment of any new study presented by the applicant.</p> <p>Experts' consultation</p> <p>MSs experts to discuss the acceptability of end points derived form water sediment study McLaughlin, 2013c.</p> <p>See also 4(28) and 4(37).</p>

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Examination of the detections of chloropicrin and DCNM reveals that the entirety of the decline of chloropicrin and all the formation and majority of the decline of DCNM are covered by the period over which mass balances were acceptable. Any losses of radioactivity are therefore due to non-trappable volatile metabolites. As the losses are not attributable to losses of chloropicrin or DCNM the study is valid. The unknown metabolite is considered unlikely to be a halogenated metabolite of chloropicrin (e.g chloronitromethane) or nitromethane due to their respective volatilities (comparable to chloropicrin) and their possible detections in the soil degradation studies. It is therefore likely that the metabolite is a more volatile potential degradation product such as methylamine.	

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(27)	Vol. 3, B.8.3.3	DE: An OECD 309 study on aerobic mineralisation in surface water is missing.	RMS : The submission pre-dates the requirement for an aerobic mineralisation study. Addressed Applicant: This submission was made in 2013 and the applicable data requirements are those set out in Commission Regulations 544/2011 and 545/2011 for the active substance and products respectively. This study is therefore not required.	Addressed

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(28)	Vol. 3, B.8.3.3, McLaughlin, 2013c	DE: We believe that the DT ₅₀ values for chloropicrin and DCNM from this study should not be used. Chloropicrin is extremely volatile and with a total mass balance of only 62-63 % (with headspace) or 40 % (without headspace) at the end of the study it is likely that a high amount of chloropicrin escaped from the system or during the following extraction. Thus, the DT ₅₀ values represent dissipation rates and not degradation rates.	RMS : Whole system degT50 values can be derived for chloropicrin as mass balance was acceptable during the timeframe of chloropicrin degradation – see also comment 4(26). The RMS opinion is that a case can be made for derivation of whole system degradation values for DCNM – see reply to comment 4(26). Applicant: Please refer to the response to Comment 4(26). Acceptable mass balances are obtained over the entire decline of chloropicrin. Any decline in mass balance is therefore not due to loss of volatile chloropicrin. The degradation rates can therefore be considered to be DegT ₅₀ s.	See data requirement, open point and experts 'consultation in 4(26).
4(29)	Vol.3, B.8.3.5, Impact on water treatment procedures	DE: Since chloropicrin is very toxic and very prone to leaching into groundwater, the impact on water treatment procedures should really be addressed for this compound.	RMS : The impact has been addressed, although not directly for groundwater – the MS is referred to the statement in section B.8.3.5. See also comment 4(30). Applicant: Although the Koc indicates that chloropicrin is mobile, based on the other properties of chloropicrin (impersistence and	Data requirement Applicant to provide further data, or a more elaborated and substantiated case, on the possible impact of water treatment procedures on the residues of chloropicrin.

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>volatility) and its controlled use it is highly unlikely groundwater contamination arising from the proposed use would occur. The Applicant also does not believe that there is evidence of groundwater contamination from crop protection uses from groundwater monitoring programmes. The possible impact of water treatment procedures is however presented in response to Comment 4(30).</p>	<p>Open point</p> <p>RMS to update the DAR with further information and assessment of the data presented by the applicant on the possible impact of water treatment procedures on the residues of chloropicrin.</p> <p>Experts' consultation</p> <p>MSs to consider if the data provided in relation to the possible impact of water treatment procedures on the residues of chloropicrin are satisfactory in relation to what is required in Regulation (EC) No 1107/2009 under the approval criteria.</p> <p>See also 4(30) and 4(60)</p>
4(30)	Vol. 3, B.8.3.5. Impact on water treatment procedures.	EFSA: Regulation (EC) No 1107/2009 requires in its approval criteria that 'it shall have no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health,through drinking water (taking into	<p>RMS :</p> <p>It is agreed that the argument presented is not detailed enough. The Applicant has proposed a case (see previous comment and below). The RMS could also propose an alternative case based on the following:</p>	See data requirement, open point and experts consultation in 4(29).

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		account substances resulting from water treatment). Further data, or a more elaborate and detailed case, is needed on the impact of water treatment procedures may have on residues of chloropicrin.	<p>'Chloropicrin itself is recognised as a bi-product of disinfection of water systems by chlorination with some evidence that formation is enhanced by ozonation. The RMS therefore considers that the impact of chlorination / ozonation on residues of chloropicrin is not relevant to any risk assessment but that the relative potential concentrations of chloropicrin that reach a water treatment facility compared to reported concentrations of chloropicrin produced by the disinfection process should form the basis of any assessment.</p> <p>The regulatory acceptable concentration for chloropicrin in surface water is 0.016 µg/L. This is an order of magnitude below reported concentrations of chloropicrin formed in disinfection processes. This does not consider the considerable dilution that will occur before any contaminated surface water becomes a source for drinking water.</p> <p>The regulatory trigger for chloropicrin in groundwater is 0.10 µg/L. This is approximately the same order of magnitude as concentrations of chloropicrin reported to be formed in disinfection processes but does not consider the considerable dilution that will likely occur before any contaminated groundwater becomes a source for drinking</p>	

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>water.</p> <p>Overall it is highly likely that the presence of chloropicrin from use as a plant protection product in water treatment facilities will be lower than from its direct formation as a disinfection bi-product and therefore it is considered that the risk is acceptable'.</p> <p>Open point:</p> <p>Approach to assessment of impact on water treatment processes.</p> <p>Applicant: Due to the properties of chloropicrin and the highly controlled manner in which it is used it is highly unlikely to be present in groundwater or at surface water abstraction points. However, the possible effects of drinking water treatment on chloropicrin have been considered. In the EU the main processes of drinking water treatment are filtration (sand and activated carbon filters), ozonation, chlorination and UV treatment. Based on the properties of chloropicrin slow sand filtration will be an effective removal mechanism for both chloropicrin and its metabolites via degradation, and there will also be the potential for volatilisation in such systems.</p>	

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Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Activated carbon is also an effective removal mechanism for chloropicrin. Based on the structure chloropicrin is unlikely to be oxidised in the presence of ozone or the hypochlorite ion, however under reducing conditions it will be readily degraded via DCNM, NCM and chloroform. It is extensively degraded under UV light to terminal degradation products, such as chlorine and carbon dioxide (WHO/SDE/WSH/03.04/52). A more detailed consideration of this issue can be submitted as additional information on request.	

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Fate and behaviour in air				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(31)	Vol. 3.B.8.3.4 and 3.B.8.3.2 Aquous photolysis	NL: Quantum yield of 0.5699 and 0.87 are reported in the DAR, please explain the difference	RMS : The quantum yield of 0.5699 was determined from a study provided by the applicant conducted to GLP. The value of a 0.87 was reported in a literature paper. The RMS cannot provide an explanation based on the information provided in the literature paper. The value of 0.5699 should be relied upon as is the value reported in the list of endpoints. Addressed Applicant: no comment provided	Addressed

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Fate and behaviour in air				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(32)	Vol. 3.B.8.7	NL: According to the Atkinson calculations the active substance has the potential for long range transport. The photolytic half-life is much shorter. Can this be used instead?	RMS : This case has been made in the section on long range transport (page 140). Addressed Applicant: In their evaluation the RMS states the following "Overall, the RMS accepts that there is sufficient evidence to indicate that the photodegradation half-life in natural sunlight for chloropicrin is most likely to be less than 2 days, and no further exposure assessment for long-range transport is required."	Addressed

PEC in soil				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(33)	Vol. 3, B.8.2, PECsoil calculations	FR (April, 2018): Agrees with the approach proposed. It could be noticed that PECsoil values from deposition from the air can be considered negligible compared to PECsoil values from application to soil either by shank injection or drip irrigation.	RMS : Comment noted thanks. A comment on the relative likely contribution from deposition from the air will be added. Open point	Addressed Deposition from air to soil may still be relevant for non-target areas.

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PEC in soil				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(34)	Vol. 3, B 8.2	DE: No valid degradation $DegT_{50}$ for chloropicrin or DCNM in soil are available (see our comments on aerobic soil degradation). Thus reliable PEC_{soil} values can only be derived immediately after one application.	<p>RMS :</p> <p>The RMS comments that the study by Völkel has been previously accepted at community level and DT_{50} values from that study used in an assessment.</p> <p>The RMS has made the case that if the values from the study by Völkel continue to be accepted, then the values from the study by McLaughlin (2013a) should also be accepted – see comment 4(36) for a fuller discussion.</p> <p>Applicant: Please refer to the response to comments 4(8) and 4(13). The applicant is of the opinion that the derived DT_{50s} can be considered $DegT_{50s}$. However, the use of $DissT_{50s}$ for the calculation of soil PECs is perfectly valid, as evidenced by the use of the longest DT_{50} from field studies in soil PEC calculations when such data are available.</p>	<p>Data requirement</p> <p>Due to the serious doubts on the acceptability of the degradation studies in soil Völkel (2004) and McLaughlin (2013a), applicant is given the opportunity to provide new fully reliable degradation in soil studies under aerobic conditions.</p> <p>See also experts consultations in 4(6) and 4(8)</p> <p>See also open points in 4(7) and 4(8)</p> <p>See also 4(9), 4(120), 4(36), 4(37) and 4(55).</p>

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PEC in soil				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(35)	Vol. 3, B.8.2, PECsoil	EL: Please clarify if redeposition from volatilisation has been considered in the PECsoil calculations presented.	<p>RMS :</p> <p>Thank-you for pointing this out, re-deposition has not been considered. A comment will be added explaining that the contribution from re-deposition will be relatively small and was therefore not considered.</p> <p>Open point</p> <p>Applicant: Redeposition from volatilisation is not included in the calculation as such residues will be negligible in comparison with calculations arising from direct application to bare soil, as stated by FR in Comment 4(33).</p>	<p>Addressed</p> <p>Deposition from air to soil may still be relevant for non-target areas.</p>
4(36)	Vol.3. B.8.2 PEC soil.	EFSA: The DT ₅₀ of 8.8 d has been used to refine PEC soil arguing the worst case in Voelkel (2004) of 26.9 d was an outlier (due to low microbial activity). Independently of other issues identified with this study (as lack of mass balance determination) it does not seem that authors of the study found soil II had to be discarded. In addition, since there is serious doubts on the acceptability of the values derived from study McLaughlin, S. 2013a, the exclusion of soil II in Voelkel (2004) may result on reducing the data	<p>RMS :</p> <p>The author did not identify the soil as one to be discarded but the applicant in their study summary identified the low biomass as a cause for concern, specifically in the context of the much longer DT₅₀ value.</p> <p>The RMS has not reflected those concerns in the study summary and this will be added. The concerns are discussed in section B.8.1.1.4 (summary of the soil studies).</p> <p>EFSA have questioned the legitimacy of all</p>	See experts consultation in 4(6), open point in 4(7) and data requirement in 4(34).

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PEC in soil				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		set for the active substance to only three soils and the identification of a data gap (and the need to use DT ₅₀ = 8.8 d for the rest of the exposure assessment instead of the geometric mean).	<p>of the DT₅₀ values in the study by Völkel in comment 4(7). The RMS has argued that if the data in the study by Völkel is accepted, the data in the study by McLaughlin (2013a) should also be accepted in the reply to comment 4(7). Therefore it is the RMS view that there are either no acceptable DT₅₀ values or 7 acceptable values. The case that only the study by Völkel will be accepted and there could only be three DT₅₀ values is perhaps a more unlikely outcome of any discussions.</p> <p>Open point:</p> <p>The DT₅₀ value used to calculate PECsoil (if any of the aerobic soil degradation studies are considered acceptable).</p> <p>Applicant: Please refer to the response to Comments 4(7) and 4(8).</p> <p>It is not unusual for Study Directors to not comment on the suitability of soils used in their studies. It is frequently only on evaluation when compiling the dossier or DAR/RAR when such issues come to light.</p>	

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PEC in surface water and ground water				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(37)	Vol. 3, B 8.6, PEC _{SW} and PEC _{GW}	DE: No valid DegT ₅₀ values of chloropicrin or DCNM in soil, water and sediment representing real degradation are available (see our comments above). The DT ₅₀ values used for PEC _{SW} and PEC _{GW} calculation represent dissipation rather than degradation and are not sufficient for surface water and groundwater modelling.	<p>RMS :</p> <p>Endpoints for chloropicrin in soil were accepted at community level previously and there are suitable endpoints available for chloropicrin in water and sediment (see comment 4(26)). The RMS has made the case that the endpoints for DCNM are also acceptable, also in response to comment 4(26). It is freely acknowledged that the acceptability of the endpoints for chloropicrin in soil, and DCNM in soil, water, and sediment are contentious and open to discussion.</p> <p>See also comment 4(38) and 4(50).</p> <p>Applicant: Please refer to the response to Comments 4(6), 4(8), 4(13), 4(26) and 4(28).</p> <p>Although not currently recommended practice, it is possible to run the models assuming that the parameters are DissT_{50S} and disabling other dissipation processes (e.g. volatilisation). This was common practice in the past.</p>	See data requirements in 4(34) and 4(26)
4(38)	PEC _{sw} and PEC _{gw} calculations	NL: has doubts to use the load of chloropicrin and metabolite after 21 days of the VIF with the geometric mean DT50 of 4.2	<p>RMS</p> <p>The RMS accepts that there will be some movement, both lateral and vertical but</p>	See data requirement in 4(54)

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PEC in surface water and ground water				
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		<p>days. Since these first 21 not only degradation but also sorption, horizontal and vertical transfer will occur. Additionally the drip application will also result in further movement of the active. Groundwater flow might also have an influence on the active substance distribution. As a conservative and realistic worst case approach the initial load should be used input for the models. As higher tier the worst case DT₅₀ of the Speyer 2.3 soil can be used since this is also applied for the PECsoil calculations instead of the geometric mean DT₅₀ value.</p>	<p>lateral movement away from the tarped area is likely to be low in the timeframe considered. Vertical flow will be much reduced because of the protection against rainfall entering the soil. Overall the RMS does not think the approach taken to be unreasonable.</p> <p>The RMS understands the argument for using the worst case DT₅₀ value for refining the application rate. The RMS has used the geomean value as it is generally recommended that mean pesticide parameters should be used in the modelling. However the RMS recognises that the use of the DT₅₀ value is outside of the model itself and therefore whether a geomean or worst case DT₅₀ value is appropriate is open to discussion.</p> <p>The case has been made that the Speyer 2.3 soil can be discarded – see reply to comment 4(16). If this is accepted, then the longest unnormalised DT₅₀ value is then 8.8 days (Senozan IV).</p> <p>The RMS also would like to comment that in addition to concerns of MSs over the parameterisation of the models, there is a more fundamental question concerning the models themselves and their suitability for</p>	

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PEC in surface water and ground water				
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			<p>use with volatile substances.</p> <p>Open point</p> <p>Validity of the general approach and DT₅₀ values used for assessing the risk to groundwater.</p> <p>Applicant: The approach taken for the modelling is a pragmatic approach in the light of the limitations of the models used for simulating the highly controlled manner of application of a volatile substance. The FOCUS models are not designed to simulate either aspect. It is agreed that there is the potential for distribution throughout the soil column while the tarpaulin (VIF) is in place; however, even when applied in drip irrigation (in 14-18 mm water), the water volume applied is not that high and while the tarpaulin (VIF) is in place there will be no net downward movement of water in the soil column. This principle has been accepted in the evaluation of other fumigants (e.g. dazomet) as has the principle of a raised temperature under the tarp (VIF) (rejected by the RMS in this evaluation). In addition in the situations in which the product is used it is highly</p>	

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			unlikely that the water table would be shallow enough for groundwater flow to be an influence. The use of the initial load and running the FOCUS models normally does not represent realistic conditions and The Applicant would contend that the use of a 'worst case' DT ₅₀ (not in line with guidance to use the geometric mean) does not represent a 'higher tier'.	
4(39)	Vol. 3, B.8.4, PEC in groundwater and surface water	<p>EL: The available models are not designed to model such volatile substances, as well as do not take into consideration the application methods and practices used for chloropicrin. This can be also understood from the comparison of the PEARL and PELMO model results for shank application; as it is apparent that one of the two models over- or under- estimates the actual concentrations.</p> <p>Thus, from our point of view, the results of PEC_{gw} and PEC_{sw} calculations shall be taken into account with caution since the FOCUS models are not validated for volatile substances thus are also not appropriate for such calculations.</p>	<p>RMS :</p> <p>The RMS understands the point made by the MS and has discussed the validity of the models on page 126 of the dRR (vol 3).</p> <p>The practical experience of the RMS of running the groundwater models with a highly volatile substance is that the results should be treated with caution as pointed out by the MS.</p> <p>The models are extremely sensitive to small changes in vapour pressure input values for example.</p> <p>Addressed</p> <p>Applicant: We agree with the comment from Greece. The RMS identified this concern in their evaluation and we support the view that the FOCUS models are not designed to</p>	Addressed

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			model highly volatile substances and that predicted exposures are highly likely to be overestimates – see applicant comment at 4(49).	
4(40)	Vol. 3, B.8.4, PEC in groundwater	EL: For consistency reasons, we would propose to include in the non confidential part of the RAR (Volume 3) PECgw calculations for impurities, without though noting their names, structures, or any other confidential characteristic.	RMS : The RMS agrees that it would be better for the reader of the report if the groundwater assessment was all in one place. However, we consider the assessment of the impurities should remain in the confidential section. Addressed Applicant: RMS to consider.	See data requirement in 4(61)
4(41)	Vol. 3, B.8.4.1, PECsw and PECsed calculations	FR (April, 2018): Different vapour pressure values are given for chloropicrin between sections. For PECsw and PECsed calculations in Step 3 (p.99), a vapour pressure of 4226 Pa is reported whereas a value of 2666 Pa (at 20°C) in section B.8.6.1 (p. 139). RMS should harmonize the values reported in the different sections.	RMS : These are vapour pressures at different temperatures. The values will be harmonised as requested. Open point Applicant: The reason for the use of the differing vapour pressures in the different models is explained by the RMS within the DAR. Due to the limitation of the PRZM model in dealing with compounds with high vapour pressures, the vapour pressure	Open point RMS to updated the DAR with further consideration of the assumed vapour pressures on the result of the PEC GW and PEC SW calculations and to justify the values used in each case.

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			needed to be lowered in order to get the model to run. This will have led to an underestimation of the volatilisation loses and consequent overestimation of the PECsw.	
4(42)	Vol. 3, B.8.4.1, PECsw and PECsed calculations	FR (April, 2018): Although the EVA tool is not very suitable for fumigant as explained in FOCUS guidance document AIR (2008), Tier 1 calculations should have been performed with EVA in order to address the potential surface water contamination from atmospheric deposition with a common and harmonized EU tool (like GW simulations were proposed with FOCUS tools). Experimental data could be used as a Tier 2 if refined PECsw calculations are required.	<p>RMS :</p> <p>The RMS understands the point being made by the MS and agrees that for consistency a tier 1 assessment with EVA may have been appropriate.</p> <p>The RMS was guided by the statement in FOCUS AIR (2008) in the section on short range transport (section 5.4.4) that the proposed exposure assessment schemes are not suitable for very volatile pesticides ($V_p > 10^{-2}$ Pa at 20°C) and a study would be required to determine deposition.</p> <p>As experimental data was available (in contrast to groundwater where FOCUS modelling was the only option), the RMS took the view that the experimental data together with an assumed deposition velocity provided an adequate assessment.</p> <p>Addressed</p> <p>Applicant: As it is agreed by FOCUS AIR that the EVA tool is not appropriate for</p>	See data requirement in 4(52)

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			fumigants, the Applicant does not see any benefit in running calculations with a tool that is not suitable, even if it is a harmonised approach for non-volatile substances. Please also refer to Comment 4(45) made by DE.	
4(43)	Vol. 3, B.8.4.1, PECsw and PECsed calculations	FR (April, 2018): Agrees with RMS approach concerning the use of the experimental data for PECsw calculations.	RMS : Comment noted, thank-you. Addressed	Addressed
4(44)	Vol. 3, B.8.4.2, PECgw calculations	FR (April, 2018): Agrees with RMS approach and comments. Although the suitability of both FOCUS models PEARL 4.4.4 and PELMO 5.5.3 for fumigants can be questioned, they are the only European models available for now in order to fulfil the EU requirement for groundwater risk assessment.	RMS : The RMS has reservations about the models but agrees that the absence of an alternative assessment effectively necessitates their use. Addressed Applicant: please see applicant comment 4(49). It is recognised that, despite the contention that the models do not reliably estimate exposure for highly volatile substances, acceptable risk to aquatic life is identified for a majority of FOCUS surface water scenarios (in some cases with mitigation at FOCUS Step 4) allowing 'safe use' to be	Addressed

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			<p>demonstrated. It is noted that some reviewers have concerns about the parameterisation of the models. However, it should be noted that the parameterisation used in the DAR represents a pragmatic worst case approach and potentially overestimates the aquatic risk. The lack of an appropriate accepted validated tool to assess the exposure for highly volatile compounds should dictate a more pragmatic approach and recourse to unrealistic extreme worst case parameterisation should be avoided. The product is applied under an impermeable tarp and in the DAR the applicant contends that the evidence of a raised temperature under the impermeable tarp can be used to refine the degradation assumed under the tarp (one of the purposes of such a tarp is to increase soil temperature). The RMS is reluctant to accept this having concerns that the elevated soil temperature may lead to elevated levels in the gas phase, thus affecting the degradation rate; however, this principle has been accepted in the evaluation of other fumigants (e.g. dazomet). In addition data in the Dossier relating to the possible effect of temperature on degradation (Volkel (2004)</p>	

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			where degradation rates in a single soil were 9.8 and 3.9 days at 10 and 20°C respectively) give no indication of any retardation of degradation due to increased levels in the gas phase at the higher temperature. Daily soil temperature data are available from two of the sites from the monitoring studies, one in EU CZ and one in EU SZ. At both sites the average difference between covered and uncovered plots was ca 6°C. Application of such an adjustment to the soil temperature over the 21 day covered period results in a significant reduction in the residue available after removal of the membrane with the consequent potential to significantly reduce run-off losses. Additional information can be submitted on request in support of this contention and a more detailed case made in relation to the overestimation of exposure for highly volatile substances by the accepted models.	
4(45)	Vol. 3, B 8.6, PECsw	DE: The most volatile compound investigated for the tool EVA was lindane with a vapour pressure of 0.04 Pa (20°C). It is not suitable to calculate the deposition fluxes of a compound as volatile as chloropicrin.	RMS (17/05/2018): The difficulties of carrying out a risk assessment for a substance as volatile as chloropicrin are discussed in the dRR. The implication of the comment is that the assessment with the deposition flux used will be conservative. In the absence of any	See data requirement in 4(52)

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			<p>other justifiable deposition flux values, we consider the assessment should be considered acceptable.</p> <p>Addressed</p>	
4(46)	Vol. 3, B 8.6, PECsw	<p>DE: We believe that volatilisation and subsequent deposition of a compound as volatile as chloropicrin should be considered both in Step 3 (by running Step 4 with volatilisation and subsequent deposition but without risk mitigation measured) and Step 4.</p>	<p>RMS :</p> <p>Volatilisation and subsequent deposition has been considered. FOCUS AIR (2008) guidance recommends the use of experimental data and therefore the assessment was made using experimental data of air concentrations and an assumption about deposition flux. See also reply to comment 4(52).</p> <p>Addressed</p> <p>Applicant: We are unsure if there would be any benefit to be gained from running the FOCUS models including deposition as the deposition and run-off/drainage events will occur separately in time and thus there is unlikely to be any material effect on the risk assessment. It is therefore considered reasonable to assess the two processes separately as is currently done by the RMS in the DAR.</p>	See data requirement in 4(52)

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4(47)	Vol. 3, B 8.6, PEC _{sw}	DE: Please check if the PEC _{sw} value for the R4 stream after application for olive tree planting is correct (Table B.8.6-21). It is very different to the PEC _{sw} of citrus trees although the application scenarios for both crops are very similar.	RMS : Thank-you for pointing out this apparent anomaly. The values have been checked and are correct. Addressed	
4(48)	Vol. 3, B.4.2, groundwater	DE: We believe that the application scenario used for groundwater modelling is not sufficient to reflect the real possible exposure of groundwater with chloropicrin or its metabolite DCNM in the intended uses. While no major water movement is likely to occur while the area is tarpred of, both compounds are highly volatile and will mainly remain in the gas phase of the soil. In the gas phase, both compounds can be distributed throughout the soil column via diffusion. The available field dissipation study Ivancovich, 1987 investigated the concentration profile of chloropicrin under tarp after injection of the active substance into the soil to depths of 15 to 20 cm and found elevated chloropicrin concentrations up to a depth of 121 cm in the sandy and the clay loam soil immediately after removing the tarp after only 2 days of incubation! Although the study was performed in California and	RMS : The RMS acknowledges the points made about the study by Ivancovich (1987), in particular that there is evidence that chloropicrin will move to depth through diffusion. It is noted that this study is relatively short compared to the tarpred time and only considers two soils. As chloropicrin diffuses through air in the soil, the depth it reaches is very dependent on the nature of those soils and the subsoil. No information is provided on the soils beyond the description of the soil class (clay loam and sandy soil). There is other evidence not presented in the fate section that also suggests vertical movement but more limited and that rapid degradation also occurs such that chloropicrin is below limits of detection (LOD) after 7 days. Again information on the soils themselves is not provided or the LOD value.	See data requirement in 4(54)

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		<p>the requirements of an OECD field dissipation study are not fulfilled, it cannot be ruled out that similar distribution of chloropicrin would occur in European soils. This would need to be reflected in an acceptable groundwater modelling for this substance.</p>	<p>It is likely that the whole approach to the groundwater assessment will be a point for discussion and this experimental evidence may inform any assessment of the approach taken.</p> <p>See also comment 4(38).</p> <p>Applicant: It is accepted that there will be diffusion throughout the soil while the tarp (VIF) is in place, however the levels reaching the depths indicated in Ivancovich 1987, represent a very small proportion of the total applied. While the tarp (VIF) is in place there will be no net downward movement of water (a principle accepted for other similarly applied fumigants such as dazomet) and chloropicrin will be extensively degraded. Should residues reach the lower layers of the soil column, when the tarp (VIF) is lifted they will represent a very small proportion of the soil residues remaining. The approach taken for the modelling is a pragmatic approach in the light of the limitations of the models used for simulating the highly controlled manner of application of a volatile substance. The FOCUS models are not designed to simulate either aspect and</p>	

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			would not be able to model the complex distribution of a volatile substance through the soil column.	
4(49)	Vol. 3, B.8.4.1. Surface water and sediment	Applicant: It is our position that the FOCUS models do not reliably estimate exposure for highly volatile substances and will overestimate predicted surface water (and groundwater) exposure. The RMS recognises in the DAR that the models are "particularly sensitive to the vapour pressure value and associated temperature" and states that the use of the FOCUS models may not be appropriate for predicting exposures for highly volatile substances. The limitations are clearly illustrated by the need to enter a lower vapour pressure in order to get the models to run. This has been recognised for other similar volatile fumigants, and flux data from the air monitoring studies indicate a far more rapid decline than is being assumed in the models. It is considered that the peer review should specifically consider whether the model outputs can be relied on for estimating surface water and groundwater concentrations for highly volatile substances. The applicant can submit additional information making the case that the models overestimate	RMS : Comment noted. Addressed	Addressed

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		exposure including consideration of the influence of raised temperatures under the VIF ('tarp') using daily soil temperature data from the monitoring trials (in covered and uncovered plots). This can be submitted as additional information on request from EFSA.		
4(50)	Vol. 3, B.8.4.1 PEC SW	EFSA: The results of the PEC SW calculations are very dependent on the DT50 soil, since only the amounts remaining after the covered period contribute to the loads to surface water. Therefore, PEC SW may need to be recalculated once the issues identified during the peer review, with respect to the studies of degradation in soil, are clarified. Specially, in relation to the STEP 4 calculations for which the longest DT50 is proposed to be removed from the set used for geometric mean calculation as an outlier.	RMS : Comment noted. Open point: Validity of the FOCUS surface water assessment. Applicant: Please refer to the responses to Comments 4(6), 4(8), 4(13), 4(26) and 4(28).	See experts consultations in 4(6) and 4(8) See open points in 4(7) and 4(8) See data requirement in 4(54)
4(51)	Vol. 3, B.8.4.1 PEC SW Step 4. VBS	EFSA: 20 m vegetated buffer zones have been assumed in the Step 4 calculations. It should be noted that according FOCUS SW, efficacy of such risk mitigation measures is not demonstrated for substances with mobile as chloropicrin.	RMS : Comment noted. See also comment 4(50).	Addressed

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4(52)	Vol. 3, B.8.4.1 PEC SW Atmospheric deposition.	EFSA: Atmospheric deposition has been calculated on basis of data from operators and bystanders exposure on air concentration at 1m and 50 m. However, to be used for the environmental assessment values at other distances (eg. 10 m and 20 m) would be needed to be in line with possible mitigation buffer zones. Values obtained would need to be added to the loads by drainage and run off.	<p>RMS :</p> <p>Atmospheric deposition values have been calculated based on concentrations in air reported in operator and exposure studies. The distances from the site are not dictated by potential buffer distances. The air concentrations at 1 m could be used as a worst case assessment.</p> <p>It is assumed in the risk assessment that contamination of water bodies by run-off will not take place simultaneously with deposition from the air. This assumption was made based on the fact that maximum PEC values always occurred at least a week after tarp removal, some time after maximum air concentrations.</p> <p>The RMS opinion is that it is unrealistic and unnecessarily conservative to assume air deposition and run-off to occur simultaneously.</p> <p>Addressed</p> <p>Applicant: Further data have been generated on measured air concentrations at 15 and 25 m. These additional data can be provided on request.</p>	<p>Data requirement</p> <p>In the lack of adequate model to simulate volatilization / deposition of a substance with the properties of chloropicrin experimental data at 10 and 20 m is needed (in addition to the available data at 1m and 50 m) for the consideration of adequate risk management measures for the protection of surface water.</p> <p>See also 4(42), 4(45) and 4(46).</p>

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4(53)	Vol. 3, B.8.4.2. Groundwater	<p>Applicant: It is our position that the FOCUS models do not reliably estimate exposure for highly volatile substances and will overestimate predicted groundwater (and surface water) exposure. The RMS recognises in the DAR that the models are "particularly sensitive to the vapour pressure value and associated temperature" and states that the use of the FOCUS models may not be appropriate for predicting exposures for highly volatile substances. This has been recognised for other similar volatile fumigants, and flux data from the air monitoring studies indicate a far more rapid decline than is being assumed in the models. It is considered that the peer review should specifically consider whether the model outputs can be relied on for estimating surface water and groundwater concentrations for highly volatile substances. The applicant can submit additional information making the case that the models overestimate exposure including consideration of the influence of raised temperatures under the VIF ('tarp') using daily soil temperature data from the monitoring trials (in covered and uncovered plots). This is can be submitted</p>	<p>RMS : Additional information can be requested from the applicant and reviewed by the RMS in an updated DAR.</p> <p>Addressed</p>	See data requirement in 4(54)

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		as additional information on request from EFSA.		
4(54)	Vol. 3, B.8.4.2 PEC GW	EFSA: the presumption that there is not significant leaching or downwards movement of chloropicrin during the time the soil is covered is not realistic. By its nature chloropicrin may distribute to over the upper soil horizons even in the absence of leaching water. In addition the water entering laterally to the field can increase this effect and cannot be precluded without further data. For the drip irrigation applications, according GAP table, water is added in high amounts at the precise moment of application.	<p>RMS :</p> <p>The RMS does not disagree with the argument presented that there will be movement (vertical and to a lesser extent lateral). Although drip irrigation involves the addition of water, experimental evidence suggests the presence of chloropicrin is generally restricted to shallower depths than when it is introduced by shank injection.</p> <p>There are different options for parameterising the models, more so in PEARL than PELMO. The RMS used the option of incorporation to 20 cm as a refinement for shank injection. A refinement using a different depth of incorporation could be used.</p> <p>There are a number of issues considering the parameterisation and suitability of the models which are open to discussion and the parameterisation of injection could be part of that discussion.</p> <p>See also comment 4(38).</p> <p>Applicant: It is agreed that there is the</p>	<p>Data requirement</p> <p>Applicant to propose more realistic distribution of chloropicrin over the soil horizons during the time the soil is covered to be considered for the PEC GW calculations.</p> <p>In order to identify a realistic worst case for the distribution of chloropicrin over the soil horizons it is suggested that results of the study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox section are considered.</p> <p>Other studies produced by the applicant or found in the open peer</p>

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			<p>potential for diffusion throughout the soil column while the tarpaulin (VIF) is in place; however, the levels reaching the deeper depths, as indicated in the field study, will represent a very small proportion of the total applied. While the tarp (VIF) is in place chloropicrin will be extensively degraded there will be no net downward movement of water in the soil column (a principle accepted in the evaluation of other similarly applied fumigants, e.g. dazomet), even when applied in drip irrigation (in 14–18 mm water) as the water volume applied is not that high. In the situations in which the product is used it is highly unlikely that the water table would be shallow enough for lateral groundwater flow to be an influence. The comments on this issue have concentrated on potential downward movement of chloropicrin; however, there will also be upward movement in the soil column which the available models cannot simulate. The approach taken for the modelling is a pragmatic approach in the light of the limitations of the models used for simulating the highly controlled manner of application of a volatile substance.</p>	<p>reviewed scientific literature may also be considered.</p> <p>See open point in 4(58) and expert consultation in 4(57).</p> <p>See also 4(38), 4(48), 4(53) and 4(56)</p>

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			The FOCUS models are not designed to simulate either aspect.	
4(55)	Vol. 3, B.8.4.2 PEC GW	EFSA: The results of the PEC GW calculations are very dependent on the DT50 soil, since only the amounts remaining after the covered period contribute to the leaching to ground water. Therefore, PEC GW may need to be recalculated once the issues identified during the peer review, with respect to the studies of degradation in soil, are clarified.	RMS : Comment noted. The RMS also notes that the PECgw calculations are very sensitive to other parameters that call into question the suitability of the models. See also comment 4(38). Applicant: Applicant: Please refer to the response to Comments 4(6), 4(8), and 4(13).	See expert consultations in 4(6) and 4(8) See open points in 4(7) and 4(8) See data requirement in 4(34)

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4(56)	Vol. 3, B.8.4.2 PEC GW. Drip application. Refinement of injection depth to 5 cm	EFSA: For the reasons given in a comment above, assuming the application depth as 0 cm is not realistic even for the drip application. Movement of chloropicrin through the upper soil horizons during the time soil is covered cannot be excluded. Actually, it seems necessary in order the treatment is efficacious. For the same reasons the "refinement" by reducing the injection depth to 5 cm seems also not realistic, since even if the injection is produced at this depth chloropicrin will move deeper during the time the soil is covered.	RMS : Point (1): The RMS agrees that an application depth of 0 cm is not realistic for drip irrigation, given that the active substance will spread through the soil while the tarp is in place. The refinement used for the shank injection was incorporation to 20 cm. The RMS proposes that this parameterisation should form part of the general discussion on parameterisation and suitability of the models. Point (2): There was no refinement to an injection depth of 5 cm. This was proposed by the applicant and reported as such (page 122) but was rejected by the RMS. See also comment 4(38). Applicant: Please refer to the response to Comment 4(54).	See data requirement in 4(54), open point in 4(58) and expert consultation in 4(57).
4(57)	Vol. 3, B.8.4.2 PEC GW.	EFSA: considerations by the RMS in relation to the reliability or representativeness of the values obtained by FOCUS GW model for a substance of the characteristics of chloropicrin are agreed. Whether the values calculated can be considered representative worst cases for the respective scenarios may be subject to discussion.	RMS : Comment noted. Addressed Applicant: see applicant comment at 4(53). It is recognised that, despite the contention that the models do not reliably estimate exposure for highly volatile substances,	Experts' consultation MSs to consider the proposals of the applicant for the assumptions used in the calculation of PEC GW. In particular in relation to the fate of the substance in soil during the time it is covered.

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PEC in surface water and ground water				
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			<p>acceptable risk to groundwater is identified for half of the FOCUS groundwater scenarios modelled allowing 'safe use' to be demonstrated. It is noted that some reviewers have concerns about the parameterisation of the models. The lack of an appropriate accepted validated tool to assess the exposure for highly volatile compounds should dictate a more pragmatic approach and recourse to unrealistic extreme worst case parameterisation should be avoided. For example in the DAR the applicant proposed that the evidence of a raised temperature under the impermeable tarp could be used to refine the degradation assumed under the tarp (one of the purposes of such a tarp is to increase soil temperature). The RMS are reluctant to accept this having concerns that the elevated soil temperature may lead to elevated levels in the gas phase, thus affecting the degradation rate; however, this principle has been accepted in the evaluation of other fumigants (e.g. dazomet). Data in the Dossier relating to the possible effect of temperature on degradation (Volkel (2004) where degradation rates in a</p>	<p>See data requirement in 4(54) and open point in 4(58).</p> <p>See also 4(56)</p>

section 4 – Environmental fate and behaviour

PEC in surface water and ground water				
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			single soil were 9.8 and 3.9 days at 10 and 20°C) give no indication of any retardation of degradation due to increased levels in the gas phase at the higher temperature. Daily soil temperature data are available from two sites, one in EU CZ and one in EU SZ. At both sites the average difference between covered and uncovered plots was ca 6°C. Application of such an adjustment to the soil temperature over the 21 day covered period results in a significant reduction in the residue available after removal of the membrane with consequent improvements for the PECgw. Additional information can be submitted on request in support of this contention and a more detailed case made in relation to the overestimation of exposure for highly volatile substances by the accepted models.	

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PEC in surface water and ground water				
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4(58)	Vol. 3, B.8.4.2 PEC GW.	<p>EFSA:</p> <p>Study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004. (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions.) presented in the ecotox section needs to be summarized in fate chapter and be considered with respect to its implications for the soil and ground water assessment.</p>	<p>RMS :</p> <p>Thank you for pointing out this study. It will be summarised in the soil section with the other literature papers (page 50).</p> <p>Open point</p> <p>Applicant – RMS to consider amending DAR.</p>	<p>Open point</p> <p>RMS to summarize and assess in an updated DAR the study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox section of the dossier with respect to its implications for the soil and ground water assessment.</p> <p>See data requirement in 4(54), and expert consultation in 4(57).</p> <p>See also 4(56)</p> <p>When evaluating this study, care should be taken in assessing if residues measured for soil injection (Bartolome, 2009) can be extrapolated to the drip irrigation uses, see 5(16).</p>

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PEC in surface water and ground water				
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4(59)	Vol 4, PEC GW of relevant impurity [REDACTED]	EFSA: Most of the comments relevant to the PEC GW calculations for the parent and soil metabolite are also applicable to the calculations produced for main relevant impurity [REDACTED]. In addition, the fact that input parameters are modelled, add extra uncertainty to the results. As shown by the RMS, an increase in the DT50 will result on a number of scenarios exceeding 0.1 µg/L. the same is likely to happen if the Koc is reduced (for example by using the one of [REDACTED]).	RMS : Comment noted. Addressed Applicant: comment noted. See applicant comment at 4(53) and 4(57) regarding the appropriateness of the FOCUS models for predicting environmental exposure for highly volatile substances.	
4(60)	B.8.3.5 Impact on WTP	EL: Even if it is unlikely that the a.s. will occur in such facilities it is proposed to present the possible fate of chloropicrin in WTP, after a scientifically based theoretical assessment.	RMS : Please see comment 4(30). Applicant: It is considered reasonable to exclude consideration of the effects of WTP if it can be argued that the compound will not be present in groundwater or surface water abstraction points. However, the possible effect of drinking water treatment is addressed in the response to comment 4(30).	See data requirement, open point and experts consultation in 4(29).

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PEC in surface water and ground water				
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4(61)	Vol 4, PEC GW Impurities.	EFSA: It seems other impurities identified besides [REDACTED] may be considered toxicologically relevant and need to be assessed for groundwater exposure.	<p>RMS :</p> <p>A case was made that no further assessment was required. It is acknowledged that this may not be adequate for one or more of the impurities and an assessment may be required.</p> <p>Open point:</p> <p>Concerning which other impurities need a full risk assessment.</p> <p>Applicant: The impurities in the material based on the results of the five batch analysis were screened and it was concluded that no quantitative assessment of the risk to groundwater was required for the other three impurities based on their properties.</p>	<p>Data requirement</p> <p>Applicant to address potential GW contamination by relevant toxicological impurities.</p> <p>Open point</p> <p>RMS to present in an updated DAR the assessment of PEC GW for all the impurities considered to be toxicologically relevant.</p> <p>See also 4(40)</p>

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PEC from airborne transport and other routes of exposure				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(62)	Vol. 3, B.8.6.1. Chloropicrin, Table B8.8-1	Applicant: The values in this table differ to those given in B8.6-34 and 35, should they differ?	<p>RMS :</p> <p>The values in Table 8.8-1 are peak air emission values while those in the first row of Tables B.8.6-34 and 35 are worst case air concentrations over a 24 hour time period. In conclusion, they should differ.</p> <p>Addressed</p>	Addressed
4(63)	Vol. 3, B.8.5, Redeposition via air	EL: A more recent EVA model is available and should have been used for the estimation of volatilisation and redeposition.	<p>RMS :</p> <p>The estimation of deposition uses a default deposition velocity from the EU (TGD) guidance document. It was simply noted that the applicant calculated a similar value from use of EVA. They use EVA version 1.1 and that has been reported.</p> <p>Addressed</p> <p>Applicant: The FOCUS guidance document AIR (2008) states that the EVA tool is not entirely appropriate for fumigants. In addition the comment made by DE (Comment 4(45)) also casts doubt on the applicability of the EVA tool for calculating the deposition flux for chloropicrin.</p>	Addressed

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Definition of the residues				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

Other comments incl. available monitoring data				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
4(64)	General	DE: Please note that there is currently a complete ban of using PPPs containing chloropicrin in Germany.	RMS : Comment noted. Addressed Applicant – the historical position of Germany is noted. This is not considered relevant to the scientific consideration of the current assessment and the comment is not considered relevant to EFSA's remit. In any event it is not the intention of the ECG to seek authorisation in Germany (nor in the Northern Zone).	Addressed

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Other comments incl. available monitoring data				
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4(65)	Vol. 3, B.8, General	DE: An open literature review on chloropicrin is missing.	RMS : The attention of the MS is drawn to Appendix 2 where the open literature review is presented. Addressed Applicant: this is presented in Appendix 2 of Volume 3 B.8.	Addressed
4(66)	Vol. 3, B.8 Appendix 2. Literature search.	EFSA: Surface water metabolites chloronitromethane, nitromethane, iminodi-methanethiol thiocianic acid are not covered by the literature search.	RMS : Comment noted (see also Applicant response below). Addressed Applicant: An updated literature search can be performed and submitted if necessary and requested.	Data requirement Applicant to provide an updated review of peer reviewed open scientific literature in relation to the metabolites of chloropicrin identified in the environment. Especially surface water metabolites, chloronitromethane, nitromethane, iminodi-methanethiol thiocianic acid should be considered with respect to its fate and behaviour, toxicological and ecotoxicological properties. See also 4(2)

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Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(67)	Vol. 3, B.8 Appendix 2. Literature search.	EFSA: The five papers found relevant for the fate section, would need to be summarised and assessed in the RAR. Otherwise, there is no transparent support to the claim that the data in these studies does not supersede other experimental data in the dossier.	RMS : The papers are summarised on page 50-51 of the dRR. Addressed Applicant: RMS to consider.	Addressed
4(68)	Vol. 3 Monitoring studies data	EL: RMS to consider taking into account the available monitoring results from the US, after the appropriate evaluation of their representativeness in the geoclimatic conditions of the EU. Relevant approach has been followed for TFD studies from the US for several other active ingredients in the near past.	RMS : The monitoring study from the USA is summarised in the dRR. The results are presented and the limitations noted. The conclusion of the RMS, like that from the previous submission, was that the report as submitted, was not acceptable to make any conclusions on the risk to groundwater. Addressed Applicant: comment noted. Extensive groundwater monitoring has been conducted in the USA. As stated in the DAR, 16,561 wells were sampled in the states of California and Florida. In total only three of the 15,175 wells sampled over a period of 1971-1991 in the state of Florida had detectable limits of chloropicrin. The range of chloropicrin concentrations observed in the three	Addressed

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Other comments incl. available monitoring data				
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			wells monitored in Florida was 0.035 to 0.068 µg/L. In the 1386 wells sampled over a period from 1984 to 1989 in the state of California there were no detectable levels of chloropicrin. This information is considered supportive however the RMS notes that no information is recorded that determines the individual sampling regime nor methods used to collect the data. The RMS considers that differences in study design, laboratory procedures/equipment, sampling practices, or well use may affect the results. This information is not easily obtainable for historic monitoring information. Further efforts can be made to obtain information on the issues identified by the RMS and to consider the geoclimatic representativeness to the EU. This can be submitted as additional information if available.	
4(69)	[COMMENT COPIED FROM THE ECOTOX SECTION reporting table point 5(21)] Vol. 3, B.9.1.2, overall conclusion	DE: We disagree with the conclusion that no risk assessment is necessary for crops grown under permanent protection. This is due to the fact of the extreme volatility of chloropicrin. Permanent greenhouses or tunnels need to be aired sometime after application to allow personnel entering the	This needs to be taken into account and addressed in the risk assessment. This statement is valid as well for the risk assessment for birds. Applicant: The RMS has used maximum measured air concentrations of chloropicrin	Experts' consultation MSs to consider the need for a specific risk assessment for uses of chloropicrin in permanent glass houses, accounting for the emissions occurred at the time of the necessary ventilation.

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Other comments incl. available monitoring data				
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		greenhouse/tunnel. Since chloropicrin is a pulmonary agent, entering the greenhouse without protective clothing cannot take place before airing. Therefore, it is expected that once airing takes place high amounts of chloropicrin enter the surroundings and concentrations exiting the greenhouse/tunnel might even be higher than after lifting the VIF.	<p>following shank, drip and protected (outside the glasshouse) applications. The exemption for permanent and full protection reflects the usual physical exclusion of birds and mammals that applies for glasshouses of this type.</p> <p>RMS: It is acknowledged that airing of permanent greenhouses can result in chloropicrin being present in the air leaving such structures. However, it must be remembered that there will be significant reduction in the mass of chloropicrin present in the greenhouse by the time it is aired. It must also be remembered that air leaving greenhouses via windows will leave at height and will quickly mix with surrounding air, thus diluting chloropicrin concentrations.</p> <p>In the inhalation and deposition risk assessment for birds and mammals conducted by the RMS, the maximum air concentration at 1 m used in the assessment comes from a study involving a protected use drip irrigation application. This maximum value occurred on day 3 following treatment (see section B.6.4.2.2.1), with any subsequent peaks in the air concentration being below this value. Therefore it is considered that the risk assessment</p>	

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Other comments incl. available monitoring data				
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			performed will be protective of any emissions from glasshouses at later time points. This justification can be added to an updated DAR. Open point	

section 5 – Ecotoxicology

5. Ecotoxicology

Birds and other terrestrial vertebrates				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	Vol.3 B9. pp.4	FR: Could you please further define the term "Virtually Impermeable Plastic"? Is this meaning that the plastic is almost impermeable?	<p>Applicant: The meaning is correct the barrier films used are almost impermeable.</p> <p>Information is available for submission on the characteristics of the Virtually Impermeable Film (VIF or 'gas-tight'/'barrier film') and its standardisation.</p> <p>This additional information can be provided in response to a request from EFSA.</p> <p>RMS: Additional information on this point can be requested from the applicant and included in an updated DAR.</p> <p>Open point</p>	Data requirement Applicant please provide information on the term "Virtually Impermeable Plastic"
5(2)	Vol. 3, B.9, B9.1.1 p11	EFSA: No negative control is used in study [REDACTED] (2009a), please note that this is not in line with the test guideline OECD 223. While it is acknowledged that no mortality was seen for the lowest six doses (when combining stage 1, 2, and 3), this still represents a significant deviation from the guideline. Hence the use of the endpoints from this study for RA should be further discussed.	Applicant: This study was initiated in 2007 according to a then current draft proposal for a new OECD TG 223, which represented the direction of development of best practice at that time. We do not know what the TG proposal had to say on the matter of control groups in 2007, but we agree that they are required according to the wording of the current version of OECD TG 223 adopted some 9 years later on 29/07/2016.	Point addressed

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Birds and other terrestrial vertebrates				
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			<p>According to §11 of the current TG 223: "<i>Controls are required to monitor the health and husbandry of the test birds to ensure that the ability of the study to provide reliable results is not compromised</i>'. No mortalities occurred in this study at Stage 1 at 35 mg/kg (1 bird/treatment group), Stage 2 at 23, 29, 37, 46 or 60 mg/kg (1 bird/treatment group) or at Stage 3 at 42 mg/kg (2 birds/treatment group). In the absence of mortality at the low end of the applied dose ranges at each Stage, no ambiguity or uncertainty arises as to whether mortality should be attributed to underlying ill-health of the test population, poor husbandry, the dose administration procedure or to the test substance itself – questions that could otherwise only be answered by reference to background mortality in a parallel control group(s). The study report (Introduction, §3) additionally notes that no abnormal morbidity or mortality was observed in unused birds of the same population as those used in this test, that were maintained in acclimation through the duration of this study.</p> <p>While the absence of a control group represents a deviation from the current OECD TG 223, the absence of mortality in</p>	

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Birds and other terrestrial vertebrates				
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			<p>the low dose groups means the lack of a control group does not detract from the validity of the test outcome or the ability to reach an unambiguous conclusion on the effects of chloropicrin on the birds used in this study.</p> <p>Importantly it should be noted that this was considered in the earlier review of chloropicrin. The Reporting Table for that review [(rev 1-1 (09.08.2010)) considers this at point 5(30) and EFSA concludes as follows on this point:</p> <p><i>"EFSA agree to the concern about validity of the study due to lack of a control group. In this case however, the endpoint is considered to be 'on the safe side', i.e. if birds would have been in a bad condition (which would have been evident from the control group), it would result in a more conservative endpoint. Furthermore, the sensitivity [sic] of the study endpoint is confirmed by the dietary toxicity endpoint."</i></p> <p>RMS: It is agreed that the lack of a negative control group does warrant consideration. The view of the RMS is that the study can still be considered reliable though given the absence of mortality at the lowest test item</p>	

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Birds and other terrestrial vertebrates				
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			treatment doses, as discussed on page 57 of section B.9 of the Volume 3. These data are considered sufficient to demonstrate that test birds were maintained in good health during the study. It is not clear from the comment whether EFSA is supportive of this conclusion. Addressed	
5(3)	Vol. 3, B.9, B9.1.1 p11	EFSA: Only males were tested in study [REDACTED] (2009a). The RMS indicated equal sensitivity of sexes based on [REDACTED] (2009b). However, this is based on one dose only (for both formulation) and a rather restricted number of organisms (5x2 for each sex). As such, the hypothesis of equal sensitivity might be challenged.	Applicant: This question of comparable sensitivity between male and female birds was considered in the earlier review of chloropicrin and information was provided on this point (see published Final Addendum to the Draft Assessment Report and Additional Report of January 2011 p340-341). On the basis of the submitted information it was concluded in the Evaluation Table (14.02.2011) Point 5.3 Column E as follows: "Point of clarification closed. It was accepted that only males were used in the acute oral toxicity test with birds as there was no clear evidence from the human health section that there was no consistent difference in sensitivity between sexes for any toxicity endpoints." This consideration can be summarised and submitted as part of the current	Addressed

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Birds and other terrestrial vertebrates				
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			<p>application if required.</p> <p>RMS: It is agreed that the comparison between male and female acute sensitivity to chloropicrin is based on a data set of limited size. However, the RMS is of the opinion that there is sufficient information to support the use of the LD50 of 62 mg a.s./kg bw in the acute risk assessment. It is not clear from the comment whether EFSA is supportive of this conclusion.</p>	
5(4)	Vol.3, B9.1.1, study IIA 8.16.2./01 (Bartolomè, 2009)	EFSA: the RMS has stated that the application rate in the study (272 L/ha) exceeds the maximum proposed rate of 227 L/ha (equivalent to 376 kg a.s./ha). However, we were not able to find anywhere the proposed application rate in terms of L/ha. It would be more transparent to include how this value was obtained.	<p>Applicant: The expression of the 227 L/ha volumetric rate as a mass equivalent rate of 376 kg a.s./ha is consistent with a conversion using the relative density of chloropicrin (1.664), corrected for the a.s. purity (99.5%):</p> $227 \times 1.664 \times 0.995 = 376 \text{ kg a.s./ha.}$ <p>We agree with the figure presented by the RMS.</p> <p>RMS: The application rate in L/ha can be derived from the application rate in kg/ha, the purity and the density, as stated in section 2.2 of volume 1.</p> <p>Addressed</p>	<p>Open point</p> <p>RMS to include the derived application rate in terms of L/ha into DAR. While doing this, we would appreciate that the indication of the density is specified, as this information is not easily retrieved in Vol 3B9 of the RAR.</p>
5(5)	Vol. 3, B.9.1.1.1. Acute bird risk assessment, risk	EFSA: In the acute risk assessment for inhalation, the RMS chose to use the LC50	Applicant: The applicant supports the use of the LC ₅₀ value from the [REDACTED] study.	Experts' consultation

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Birds and other terrestrial vertebrates				
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	via inhalation	value from [REDACTED] (2008). While this seems logical, in lack of a specific risk assessment scheme for inhalation, further discussion on this approach might be needed. Please note that this comment is also applicable to mammals.	This is consistent with the conclusion reached following discussion at PRAPeR Expert Meeting 85 (24 – 26 November 2010) – which records: <i>"It was concluded that the acute risk should be assessed on the 5 d LC50 > 659 ppb and for mammals it should be based on the 4 h LC50 of 0.04 mg/L."</i> RMS: It is agreed that discussion of this novel area of ecotoxicology risk assessment may be beneficial. Open point	Experts to discuss the approach and the conclusion of the RMS for what concern the acute and chronic inhalation risk to birds and mammals. In order to properly discuss this, it would be appreciated if the RMS could include in the assessment any relevant information submitted by the applicant in response to the data requirement 5(8). See also points 5(8); 5(9); 5(12); 5(22); 5(23); 5(25).
5(6)	Vol. 3, B9.1.1, Summary of avian toxicity data	EFSA: In table 9.1.1-28, the RMS used a conversion from ppm to mg a.s./m ³ for the endpoint from [REDACTED] (2008). Please explain the conversion factor.	Applicant: The conversion is as stated in the footnote to the table and follows standard procedure for inhalation endpoints, in this case using the molecular mass of chloropicrin (164.35) and the molar volume at 1 atm and 25°C. See https://www.markes.com/Resources/Frequently-asked-questions/How-do-I-convert-units.aspx . We agree with the converted values presented by the RMS. Incidentally, we note the date of the [REDACTED] (2008) study is given incorrectly as 2009 in the table.	Open point RMS to specify in the footnote of table 9.1.1-28 the meaning of all values. In particular, "24.45" should be presented, as now explained by the RMS, as the gaseous/vapour molar volume [L] at 1 atm and 25°C.

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Birds and other terrestrial vertebrates				
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			<p>RMS: The conversion factor is described in the footnote to table 9.1.1-28. It should be noted that the number 24.45 in the equation is the volume (litres) of a mole (gram molecular weight) of a gas or vapour when the pressure is at 1 atmosphere (760 torr or 760 mm Hg) and at 25°C.</p> <p>Addressed</p>	
5(7)	Vol. 3, B.9, B9.1.1	EFSA: It was noted that the draft OECD Test Guideline for Avian Reproductive Toxicity Test in the Japanese Quail or Northern Bobwhite (2000) was used. It needs to be considered that this Guideline is not among those listed in the Commission Communication related to the data requirements. As the exposure in this guideline is considerably shorter than the more commonly used OECD 206 (6 vs. 20 weeks), its relevance for the present risk assessment needs to be further discussed.	<p>Applicant: Noted. The reliability and applicability of this study has been evaluated rigorously by the RMS. We agree with the RMS conclusion that the study is considered suitable for use in risk assessment.</p> <p>Relevance for the present risk assessment will also need to take account of the limited scope for long-term exposure following application of chloropicrin. Application of chloropicrin to any given site would only be once per year. In some use scenarios there is a longer interval between applications (for tree crops application is no more than 1 year in 15) and the areas treated are typically small, but within areas of intensive horticultural production (as set out in the</p>	<p>Experts' consultation</p> <p>Experts to discuss about the appropriateness of the dietary endpoint selected by the RMS for the reproductive long-long term dietary risk of birds.</p>

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Birds and other terrestrial vertebrates				
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			<p>example information on usage provided in the RMS evaluation in Appendix 3 of Volume 3CA-CP B.9).</p> <p>During preparation (clearance of vegetation, fine soil tillage and formation of planting beds) and during application there would be intense human and machine activity. The disturbance during application and loss of cover giving protection against predation may be expected to discourage birds or mammals from foraging on or near the treated and tarped soil before and during the application period. The VIF is laid immediately behind the applicator vehicle, primarily to minimise volatilisation loss of chloropicrin to the atmosphere, but it also presents a physical barrier to ground-foraging birds and mammals while it remains in place.</p> <p>Further disturbance occurs during crop-planting, with the VIF still in place. Once the VIF is lifted there remains little likelihood of birds or mammals actively foraging in the treated area until such time has passed to allow the restoration of protective ground cover vegetation and food sources. Similarly, when the VIF is removed human activity would</p>	

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Birds and other terrestrial vertebrates				
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			<p>again discourage foraging.</p> <p>RMS: The study was conducted to the draft OECD guideline "<i>Avian reproduction toxicity test in the Japanese Quail or Northern Bobwhite</i>" (April, 2000). It is noted that the draft guideline used is not referenced in <i>Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market</i>. However, the RMS considers that the study is fit for purpose and the design allows for a robust consideration of potential effects of the test item on bird reproduction. While the exposure duration is less than specified in OECD 206, this study design has the advantage that only known breeders are included. It is noted that no MS have questioned the reliability of this study in the comments provided. Additional wording can be added to the study summary to discuss the duration of exposure in this study and why the RMS considers the study to be reliable.</p>	

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			Open point	
5(8)	Vol. 3CA-CP, B.9, B.9.1.1.2, reproductive bird risk assessment, Risk via inhalation p72	<p>Applicant: The RMS has proposed that a data gap be set to consider the reproductive risk to birds via the inhalation exposure. The assessment proposed by the RMS is highly conservative given that long term exposure to chloropicrin will not occur following a single application.</p> <p>Overall the opportunities for inhalation exposure of birds from a single application are considered to be very limited, both in terms of concentration, duration and geographical scale, and are therefore unlikely to invoke long-term reprotoxic effects in birds. It is considered that inhalation exposure presents a low reproductive risk to populations of birds from a single application of chloropicrin. The applicant proposes to make a submission of additional information to address this uncertainty identified by the RMS. This will include information on the duration of exposure from the existing monitoring studies and the new monitoring study which is available for submission (see section 2 comment 6) and information on the scale of exposure. The additional information will also include, as proposed by the RMS, a consideration of the results from the avian</p>	<p>RMS – Further information to address this issue could be provided by the applicant and assessed by the RMS in an updated DAR.</p> <p>Data gap</p>	<p>Data requirement Applicant to provide further information to address the reproductive risk to birds and wild mammals via inhalation exposure.</p> <p>See points 5(22); 5(25).</p> <p>In addition, see expert discussion 5(5).</p>

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		dietary studies in the reproductive risk assessment for the inhalation exposure route (see applicant comment 3 below in this section). This additional information can be provided in response to a request from EFSA.		
5(9)	Vol.3 B9.1.1 pp.72-74	FR: The applicant proposal to use Haber's law would be an interesting approach but we agree with RMS that no enough data are available to support it and reminds that the reliability of Haber's law has been criticised in literature. Thus FR agrees also to not consider this approach in the risk assessment. Moreover, a dilution factor could have been derived with at least one or two more sampling point at different distance. FR agrees with the RMS conclusion regarding the impossibility to conclude for the long term risk of inhalation exposure for birds.	Applicant: Noted. Please also see the Applicant's comment 5(8) above. RMS: Noted. No further action needed. Addressed	See data requirement 5(8) and expert consultation 5(5).
5(10)	Vol. 3, B.9, Table B9.1.1-10	EFSA: LC50 value under Table 9.1.1-10 should be reported as a 'greater than' value (i.e. > 562 ppm a.s.)	Applicant: Agreed. RMS: Agreed. The table can be updated accordingly. Open point	Open point RMS to update the LC50 value under Table 9.1.1-10 (should be reported as a 'greater than' value).
5(11)	Vol. 3, B.9, Table 9.1.2-1	EFSA: NOAEC from study [REDACTED]	Applicant: We disagree. Table 9.1.2-1	Open point

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		(1993a) is < 0.3ppm (from B6) not =0.3ppm (in the table in part B9)	<p>clearly states that the endpoints presented are <u>systemic</u> NOAELs, along with the corresponding NOAECs. The systemic NOAECs concluded for rats and mice from this 90-day inhalation study (B.6.3.3.1) are both 0.3 ppm.</p> <p>RMS: Agreed. The table can be updated accordingly.</p> <p>Open point</p>	RMS to update Table 9.1.2-1, by specifying that the NOAEC from study [REDACTED] (1993a) is < 0.3ppm
5(12)	Vol. 3, B.9	EFSA: Inhalation studies for birds and mammals are generally not required. This substance has clearly peculiar characteristics, so the inhalation data and a risk assessment are appreciated. However, as no standard methods exist, the whole appropriateness of the approach needs to be discussed.	<p>Applicant: Noted – see also applicant comment at 5(7) and applicant response at 5(8) above.</p> <p>RMS: See 5(5)</p>	See expert discussion 5(5).
5(13)	Vol. 3, B.9.1.2.2., refinement of chronic endpoint	DE: In the text below Table 9.1.2-1 it is described that the long-term mammal endpoint comes from the 2-year rat study ([REDACTED] 1995) and not from the 1-year dog study ([REDACTED] 1994). The endpoint is not only based on decreased bodyweight but also on hyperplasia and hyperkeratosis which may in turn have led to the decreased food consumption and body	Applicant: Noted. We direct attention to the discussion and justification of the relevant mammalian reproductive NOAEL below the heading ' <u>Further consideration of the reproductive toxicity endpoint for ecotoxicology</u> ' on pp 92-94 (Volume 3. 3CA-CP, B9). This assessment notes that the effects on foetal bodyweight are likely to have been influenced by the marked	<p>Experts' consultation</p> <p>Experts to discuss about the appropriateness of the dietary endpoint selected by the RMS for the reproductive long-long term dietary risk of mammals.</p> <p>See points 5(14); 5(20).</p>

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		weight. There is no two generation reproduction study with the active substance from oral exposure via feed. Reproduction has not been assessed in the study by [REDACTED] therefore it is not possible to draw a conclusion on whether or not the observed effects affect reproduction or not.	maternal toxicity. RMS: Noted. The text below table 9.1.2-1 can be updated to reflect that the NOAEL of 0.1 mg a.s./kg bw/d is also relevant based on results from [REDACTED] (1994). It is proposed that further expert discussion of the relevant mammalian reproductive toxicity endpoint for chloropicrin would be beneficial, in light of this and other comments. Open point	
5(14)	Vol. 3, B.9, Table 9.1.2-1	EFSA: We have noted that the dataset does not include any 2-generation test for oral toxicity. As this is normally the most relevant study type for setting the reproductive dietary endpoint, the current setting of the endpoint can be challenged.	Applicant: Noted. We also note other comments that accept that standard approaches to the risk assessment are inappropriate in the case of chloropicrin. According to Vol. 3, B.6, p.158, Summary of reproductive and developmental toxicity , ' <i>testing has been via the most important route of exposure, inhalation, and conducted in sensitive species: rats and rabbits</i> ' and ' <i>the data are acceptable for addressing reproductive and developmental toxicity endpoints</i> '. It is clear that developmental and reproductive toxicity are unlikely at chloropicrin dose levels not causing general toxicity as a consequence of	See expert discussion 5(13).

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			local effects. Setting the endpoint based on these effects therefore represents a protective approach. RMS: See 5(13)	
5(15)	Vol. 3, B.9, B.9.1.2.	EFSA: It is noted, that Bartolome (2009) study was used for refinement in RA. Considering the specificity of the substance and its application techniques, we agree that it is appropriate to use specific residue data in the risk assessment. Nevertheless, the choice of the values to be used in both the acute and chronic dietary risk assessment should be further discussed.	Applicant: Noted. RMS: It isn't clear from the comment whether EFSA agree with the residue values used or not. The RMS has included discussion of why we consider the specific values selected to be appropriate for the risk assessment on pages 60 and 69 of section B.9 of the Volume 3. No MS have disagreed with the values used during commenting. Addressed	Addressed.
5(16)	Vol. 3, B.9,	EFSA: For drip irrigation, why were the two studies by Gao et al. (2004, 2008) only included in the appendix of the RAR? If these are providing relevant information, complete study summaries and RMS evaluations should be included in the main text. Also, please note that these studies were not presented in the environmental	Applicant: Noted. Summaries of these studies can be provided. RMS: Summaries of these studies can be added to section B.8 of Volume 3. Open point	See open point 4(58) When evaluating this study, care should be taken in assessing if residues measured for soil injection (Bartolome, 2009) can be extrapolated to the drip irrigation uses.

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		fate part. Only when this information is appropriately peer reviewed, there could be an agreement about the extrapolation of the Bartolome (2009) study for the drip irrigation uses.		
5(17)	Vol. 3, B.9, B9.1.1, drinking water risk assessment	EFSA: For the puddle scenario (risk via contaminated drinking water) where contamination was assumed via deposition, we believe that the performed calculations should be further justified. For example, why was deposition only calculated from protected uses? Why only over 24 hours? Please note that this comment is also relevant for mammals.	Applicant: Noted. RMS: The value for air concentration used was the geometric mean of the worst case air concentration values at 1 m from the application area over a 24 hour time period. This data is presented in Table B.8.6-34 (fate section of the dRR). The geometric mean for drip irrigation (protected) studies was the largest geometric mean value when compared to shank (field) and drip (field) studies and therefore the worst case. The shortest time period for measurement was 24 hours and therefore this is the worst case time period that can be considered. Addressed	Open point RMS to include in the DAR the justification presented in column 3 of the reporting table for what concern the calculation of the predicted exposure for drinking water risk assessment.
5(18)	Vol. 3, B.9.1.2.1, Toxicity to mammals, table 9.1.2-1	EFSA: The unit for the acute endpoint (from Pesticide Manual) is not correct (should be mg a.s./kg bw).	Applicant: Agreed. RMS: Agreed. The endpoint unit can be updated.	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1

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			Open point	
5(19)	Vol. 3, B.9.1.2.1, Acute mammal risk assessment	EFSA: In general, refining the DT ₅₀ of residues on food items is considered appropriate. We also consider appropriate to fit only the decrease part of the available dataset. However, we believe that when doing this operation, it is better to re-calculate time by fixing t=0 when the maximum residue was measured. It is acknowledged that this would not result in major inconsistencies when SFO is used (the largest difference is still very small in this case - for barley seeds we have calculated a DT ₅₀ of 1.27 days instead of 1.07 days), but it might be more relevant when the dissipation follows 2nd order kinetics.	Applicant: Noted. RMS: All DT50 values were calculated by fixing time t=0 to the maximum residue. A mistake has been made with the input data for barley seeds. The DT50 value quoted by EFSA (1.07 days) is agreed and the assessment can be updated (including the example plot) in a revised DAR. Open point	Addressed. However, for future assessments, we respectfully insist that the kinetic assessments was not done by fixing time t=0 to the maximum residue. This is very evident from the decline fitting plots, where the x-value of the first measurement points is never equal to 0. Anyway, as already acknowledged, this would not result in major inconsistencies when SFO is used.
5(20)	Vol. 3, B.9.1.2.1, Acute mammal risk assessment	EFSA: We disagree with the setting of different endpoints for different tiers of the assessment. Please note that during the ecotox general meeting (Pesticide Peer Review Meeting 133), it was decided that a unique ecotoxicologically relevant endpoint should be chosen and used consistently in the risk assessment. In addition, we are not fully convinced about the choice of the RMS to increase the previously agreed endpoint by one order of magnitude. This may need further	Applicant: This comment is referenced to the acute mammalian risk assessment, where a single endpoint has been used throughout, however we think the long-term mammalian risk assessment was intended. The long-term mammalian risk assessment follows the approach prescribed in the EFSA (2009) guidance document, which is the formally noted procedure in force at the time of submission of the dossier. The EFSA Technical Report reflecting the views	See expert discussion 5(13)

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		discussion.	<p>concluded at Pesticide Peer Review Meeting 133 was not published until 22 December 2015.</p> <p>Although the benefits of clarity and consistency in adopting a single endpoint throughout the assessment are not disputed, it is unclear from the Technical Report whether this approach was intended to cancel and supersede the relevant part of EFSA's 2009 B&M Guidance Document with immediate effect, or whether it was intended to do so after the then and still lacking further guidance on the derivation of ecotoxicologically relevant endpoints for mammals (mentioned in the last sentence on this theme in Chapter 2 of the Technical Report) has been developed.</p> <p>In our view the shift in the endpoint by one order of magnitude from a previous and more arbitrarily assigned value is of lesser importance than that the derivation of the ecotoxicologically relevant long-term mammalian endpoint for chloropicrin be justified transparently on a sound scientific footing. In this respect we agree with the rationale presented by the RMS in support of the properly considered NOAEL of 1 mg/kg bw/d, which addresses this aim.</p>	

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			<p>RMS: As noted by the applicant, the dossier was submitted before Pesticide Peer Review Meeting 133. It seems inconsistent that EFSA refer to the fact there was a previously agreed endpoint for the risk assessment, whilst at the same time questioning the reliability of other studies and endpoints, which were previously agreed to be acceptable.</p> <p>See 5(13) regarding the need for discussion on the reproductive toxicity endpoint for the mammal risk assessment.</p>	
5(21)	Vol. 3, B.9.1.2, overall conclusion	DE: We disagree with the conclusion that no risk assessment is necessary for crops grown under permanent protection. This is due to the fact of the extreme volatility of chloropicrin. Permanent greenhouses or tunnels need to be aired sometime after application to allow personnel entering the greenhouse/tunnel. Since chloropicrin is a pulmonary agent, entering the greenhouse without protective clothing cannot take place before airing. Therefore, it is expected that once airing takes place high amounts of chloropicrin enter the surroundings and concentrations exiting the greenhouse/tunnel might even be	<p>This needs to be taken into account and addressed in the risk assessment. This statement is valid as well for the risk assessment for birds.</p> <p>Applicant: The RMS has used maximum measured air concentrations of chloropicrin following shank, drip and protected (outside the glasshouse) applications. The exemption for permanent and full protection reflects the usual physical exclusion of birds and mammals that applies for glasshouses of this type.</p> <p>RMS: It is acknowledged that airing of</p>	<p>This comment was moved to the environmental fate section, as discussion on the issue raised by DE on emissions from permanent structures is to be chiefly discussed by fate experts.</p> <p>Open point</p> <p>Pending on the peer review from fate, the risk assessment to non-target organisms might need to be updated by considering using in permanent greenhouses.</p>

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		higher than after lifting the VIF.	<p>permanent greenhouses can result in chloropicrin being present in the air leaving such structures. However, it must be remembered that there will be significant reduction in the mass of chloropicrin present in the greenhouse by the time it is aired. It must also be remembered that air leaving greenhouses via windows will leave at height and will quickly mix with surrounding air, thus diluting chloropicrin concentrations.</p> <p>In the inhalation and deposition risk assessment for birds and mammals conducted by the RMS, the maximum air concentration at 1 m used in the assessment comes from a study involving a protected use drip irrigation application. This maximum value occurred on day 3 following treatment (see section B.6.4.2.2.1), with any subsequent peaks in the air concentration being below this value. Therefore it is considered that the risk assessment performed will be protective of any emissions from glasshouses at later time points. This justification can be added to an updated DAR.</p> <p>Open point</p>	
5(22)	Vol. 3CA-CP, B.9,	Applicant: We acknowledge the helpful	RMS: Noted. See 5(8)	See expert consultation 5(5) and data

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	B.9.1.1.2, reproductive bird risk assessment, Risk via inhalation (pp. 72-74)	suggestion offered by the RMS that it may be possible to consider results from dietary studies in the reproductive risk assessment for the inhalation exposure route. The RMS notes that this would require chloropicrin concentrations in air to be converted to equivalent internal doses and preferably such an approach would need to account for ADME processes. The applicant will prepare such an assessment as part of the overall additional information to address the uncertainty identified by the RMS about the risk posed by long-term inhalational exposure to birds (see application comment 1 above in this section). This additional information can be provided in response to a request from EFSA.		requirement 5(8).
5(23)	Vol.3 B9.1.2 pp.98	FR: FR agrees with the data gap proposed by RMS based on the lack of information regarding the toxicity for chronic exposure to inhalation pathway in the context of VIP removal and persistence of the active substance.	RMS: Noted. See 5(8)	See expert consultation 5(5).
5(24)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment	Public comment – French Chambers of Agriculture (AFCA) As mentioned previously, the specific use on apples will be made to limited areas of the overall cropped area where there is a specific	Applicant: comment noted. RMS: Noted. It is agreed these points are relevant but the RMS does not consider that	Addressed.

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		need to treat for replant disease. Use will not be on a large scale and limited to no more than 1 application in 15 years or longer. Effects on birds and mammals are expected to be minimised by such use. Long term exposure is not expected in such situations and this is indicated by the measured values which do not support a significant duration of exposure.	any modification of the assessment conducted is required on this basis. Addressed	
5(25)	Vol. 3CA-CP, B.9, B.9.1.2.2. Reproductive mammal risk assessment - Risk via inhalation p97	Applicant: The RMS has proposed that a data gap be set to consider the reproductive risk to mammals via the inhalation exposure. The assessment proposed by the RMS is highly conservative given that long term exposure to chloropicrin will not occur following a single application. Overall the opportunities for inhalation exposure of mammals from a single application are considered to be very limited, both in terms of concentration, duration and geographical scale, and are therefore unlikely to invoke long-term reprotoxic effects in mammals. It is considered that inhalation exposure presents a low reproductive risk to populations of mammals from a single application of chloropicrin. The applicant therefore proposes to make a submission of additional information to address this uncertainty identified by the	RMS: Noted. The proposed information could be submitted by the applicant and reviewed by the RMS in an addendum or updated DAR. Data gap	See expert consultation 5(5) and data requirement 5(8).

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		RMS. This will include information on the duration of exposure from the existing monitoring studies and the new monitoring study which is available for submission (see section 2 comment 6) and information on the scale of exposure taking into account the results of the available inhalation studies. This additional information can be provided in response to a request from EFSA.		

Aquatic organisms				
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5(26)	Vol. 3, B.9.2.2, Report: IIA 8.2.4/01	DE: EC ₁₀ values should be calculated for the chronic fish study.	<p>Applicant: The study was performed to OECD TG 210 (1992) and the ECX values were not required. The laboratory that conducted the study was asked to provide the recalculation. The response provided was that:</p> <p>"Based on the data set, we were not able to generate an LC10 or LC20 that were within guideline parameters for larval survival at termination. Every model available failed at</p>	<p>Data requirement Applicant to submit ECx calculations or an argumentation for not calculating ECx values.</p> <p>Open point RMS to include all relevant submitted information in the DAR.</p>

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			<p>least one of the following criteria: Lack of Fit, Normality or Homogeneity of Variance. While we currently run ELS testing with 4 replicates, this exposure was run under an older guideline which required only two. The reduced replication probably impacted the ability to determine these LC values."</p> <p>These can be calculated if necessary.</p> <p>RMS: EC10 values are specified where provided. Any additional information will need to be requested from the applicant.</p> <p>Open point</p>	
5(27)	Vol. 3, B.9.2.5, Report: IIA 8.3.2.1/01	DE: In our opinion the RMS should have requested the applicant to recalculate the mean measured concentrations based on the provisions given in the OECD GD 23 on difficult substances.	<p>Applicant: The RMS stated the following in the DAR:</p> <p><i>Actual measured concentrations are reported for the two highest concentrations (4.27 and 28.3 µg/L), at renewal. As true measured values are used to establish the geometric mean for the NOEC this value can be considered an acceptably accurate estimate for risk assessment.</i></p> <p>Therefore it is not considered necessary to re-calculate the analytical endpoints.</p> <p>RMS: The view of the RMS is that given this</p>	Addressed.

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			<p>issue does not impact the reliability of the study or the critical endpoint derived (since measured concentrations adequately characterise the NOEC and are above the LOQ), we don't consider this recalculation to be necessary. Additionally, an alternative calculation method would not address the unknown rate of decline seen at lower test concentrations.</p> <p>Addressed</p>	
5(28)	Vol. 3, B.9, B.9.2.5	EFSA: in the chronic study with daphnids (Jenkins , 2009) geometric mean measured concentrations were calculated to estimate the exposure. There was, as expected, a clear issue with the concentration maintenance. In addition, only few measurements in time were performed, often resulting below the detection limit. On the other hand, for the concentration representing the NOEC the analysis were always resulting in a quantifiable level of the substance.	<p>Applicant: The RMS stated the following in the DAR:</p> <p><i>Actual measured concentrations are reported for the two highest concentrations (4.27 and 28.3 µg/L), at renewal. As true measured values are used to establish the geometric mean for the NOEC this value can be considered an acceptably accurate estimate for risk assessment.</i></p> <p>RMS: See 5(27)</p>	Addressed, see 5(27).
5(29)	Vol. 3, B.9, Table B.9.2.9-1	EFSA: Jenkins study is from 2009	<p>Applicant: Noted – RMS to amend DAR.</p> <p>RMS: Agreed. This typo can be corrected in an updated DAR.</p>	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1

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			Open point	
5(30)	Vol. 3, B.9.2.6, Report: IIA 8.4/01	<p>DE: The study needs to meet the validity criteria set out in the GD in force at time of application, since this reflects the current state of the art in science and technology. Please elaborate on this. It is scientifically not justifiable to reject one study because of non-compliance with the validity criteria set out whereas it has not been checked for the second study if the same validity criteria are met.</p> <p>Additionally, in our opinion the RMS should have requested the applicant to recalculate the mean measured concentrations based on the provisions given in the OECD GD 23 on difficult substances.</p>	<p>Applicant: The Flatman (2004) study was considered by the RMS to meet the necessary validity when the study was conducted. As noted by the RMS <i>the initial exposures are greater than or equal to the nominal treatment concentrations, and the decline observed in the study is broadly in-line with expected losses following application of the formulations under field conditions.</i></p> <p>The Flatman (2004) was considered to be the key algal endpoint in the EFSA 2001 conclusion.</p> <p>RMS: The coefficient of variation in the overall 0-72 h growth rate is 2.63% for the negative control and 5.54% for the solvent control (meeting the validity criterion). The coefficient of variation for the mean section-by-section growth rate is 66.4% for the negative control and 72.1% for the solvent control (therefore not meeting the validity criterion). On this basis the study would not be considered reliable and further consideration of analytical measurements would not seem productive. This information can be added to an updated Volume 3.</p>	Open point RMS to update the DAR by invalidating the study from Flatman (2004).

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			Open point	
5(31)	Vol.3, B.9.2.6. Effects on algal growth, study IIA 8.4/01 (Flatman, 2004d)	EFSA: It is not clear whether all validity criteria listed in the new version of OECD 201(2011) guideline were respected in the study. In the study summary only reference to the criteria of the previous version of the guideline (1984) are mentioned.	<p>Applicant: The study was conducted in 2004 and therefore the validity criteria reported where those that applied at the time the study was conducted.</p> <p>Please also see comments at 5(30).</p> <p>RMS: See 5(30)</p>	See open point 5(30).
5(32)	Vol.3, B.9.2.6. Effects on algal growth, study IIA 8.4/01 (Flatman, 2004d)	EFSA: Analytical measurements are too scattered for a reliable definition of the actual concentrations tested. Nevertheless, we don't believe that using nominal concentrations is by any means better in this situation. The actual suitability of this study for risk assessment purposes should be questioned.	<p>Applicant: The study was deemed to be acceptable by both the RMS and Co-RMS and a detailed consideration of the study was provided by the RMS. The initial exposure concentrations were greater than or equal to the nominal treatment concentrations, and the decline observed in the study is broadly in-line with expected losses following application of the formulations under field conditions.</p> <p>RMS: See 5(30)</p>	See open point 5(30).
5(33)	Vol. 3, B.9.2.6, Report: IIA 8.4/02	DE: Chloropicrin is to be notified as a herbicide. Therefore a valid study on a second taxonomic group is required according to the data requirements.	<p>Applicant: As described in the introduction to Section B.9 chloropicrin is a soil fumigant applied to bare soil prior to crop planting to combat a variety of pests and diseases. The commercial target</p>	Data requirement Applicant to provide a valid study with algae for chloropicrin. We agree that a study on a second species is not needed. Nevertheless,

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			<p>organisms are fungi and nematodes. As with other soil fumigants chloropicrin has some effect on insect pests and germinating weed seeds. Chloropicrin is not commercially used or recommended for specific use as a herbicide on grounds of cost and limited activity (specific herbicides would be applied to the commercial crops grown following chloropicrin treatment). The inclusion of weeds was in the pests controlled section of the GAP table was solely to indicate this activity but chloropicrin should not be regarded as a herbicide. Chloropicrin has the product type soil fumigant. No additional algal testing is required.</p> <p>RMS: Agreed. Given the Wilby (2009a) study is not considered suitable for use in regulatory risk assessment, a data gap should be set for a study on a second algal species, given the herbicidal activity of chloropicrin.</p> <p>Data gap</p>	<p>following the information provided by the RMS under point 5(30), none of the two available studies (Wilby, 2009a; Flatman 2004) is considered sufficiently reliable for the risk assessment. Hence, a new valid study is needed.</p>
5(34)	Vol. 3, B.9.2.9, Table B.9.2.9-1	DE: Please also add NOEC values for all studies.	Applicant: RMS to consider revision of the DAR.	Open point RMS to include NOEC values for all studies.

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			RMS: See 5(26)	
5(35)	Vol. 3, B.9.2.9, Risk assessment for algae	DE: The endpoint ErC ₅₀ is selected but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: "... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future". Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended in the central zone to address this uncertainty at the level of each Member State.	Applicant: Noted. RMS: It is agreed that MS may wish to consider this issue further at MS level but given the ErC ₅₀ is the recommended endpoint for use in aquatic risk assessment in EFSA (2013) guidance, it is considered appropriate to use this endpoint in the DAR. Addressed	Addressed.
5(36)	Vol. 3, B.9.2, general	DE: Since it is very likely that chloropicrin migrates to the groundwater in relevant concentrations the route of exposure of groundwater becoming surface water again needs to be considered.	Applicant: Although the Koc indicates that chloropicrin is mobile, based on the other properties of chloropicrin (impersistence and volatility) and its controlled use it is highly unlikely groundwater contamination arising from the proposed use would occur. The PECgw calculated by the FOCUS groundwater models cannot be considered reliable estimates of the	Addressed. Consideration of groundwater becoming surface water is not relevant for the parent compound.

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			<p>potential exposure of groundwater due to their inherent inability to simulate the fate of volatile substances or the way fumigants are applied. The Applicant also does not believe that there is evidence of groundwater contamination from crop protection uses from groundwater monitoring programmes.</p> <p>RMS: It is accepted that for certain FOCUS scenarios chloropicrin can reach >0.1 µg/L in groundwater. However, there are also scenarios where the predicted concentration is less than the trigger of 0.1 µg/L. For these scenarios the risk to aquatic organisms via groundwater is acceptable. Where the concentration in groundwater is >0.1 µg/L, the risk is considered to be unacceptable and hence use should not be permitted in situations comparable to these scenarios.</p> <p>Addressed</p>	
5(37)	Vol. 3CA-CP, B.9, B.9.2, Conclusion on the aquatic risk assessment	<p>Applicant: The RMS has noted that the risk assessment for aquatic organisms, driven by toxicity to algae and based on FOCUS Step 4 exposure estimates, is unresolved for a limited number of scenarios.</p> <p>It is recognised in the DAR, and in the</p>	RMS: See 4(41)	Addressed.

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		evaluations of a number of other fumigants, that the use of the FOCUS models may not be appropriate for volatile substances such as fumigants and are likely to overestimate exposure. The limitations are further illustrated by the need to enter a lower vapour pressure to get the models to run, which will further overestimate the PECsw. Further information on this aspect is provided in the Applicant's comment (1) in response to Vol. 3, B.8.4.1; Surface water and sediment.		
5(38)	Vol 3 – B.9.2.5, p. 139	IE: Section 2 describes the preparation of stock solution. This paragraph reads as 5.93 µg was dissolved in 1L to make a 10mg/L stock solution. Please change the unit µg to µL .	Applicant: Noted – RMS to revise DAR. RMS: Agreed. The Volume 3 can be updated accordingly. Open point	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1
5(39)	Vol.3, B.9.2.7. Effects on aquatic macrophytes, study IIA 8.6/01 (Wilby 2009b).	EFSA: Analytical measurements are scattered and often below the LOD. The reliability of the calculated geometric mean measured concentrations for establishing the experiment endpoint should be further considered.	Applicant: The RMS notes that whilst there was some variation in the analytical results the biological results indicated that exposure was maintained. Therefore the use of geometric mean was appropriate.	Point addressed, no further action required.

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			RMS: At 1.49 and 4.77 µg a.s./L concentrations were generally below the LOD but at higher concentrations the test item was generally detected and quantifiable. The critical ErC50 from this study is 24 µg/L, i.e. around concentrations where exposure to the test item was better characterised. While not an ideal dataset, the RMS considers that noting the difficulties working with this substance, the endpoints derived from this study based on mean measured concentrations are sufficiently robust to use in regulatory risk assessment. Addressed	
5(40)	Vol. 3, B.9, B.9.2.10.5	EFSA: Pending on the discussion in the environmental fate section, some refinement of PEC values in FOCUS Step 4 with buffer strip may not be considered appropriate.	Applicant: The comment is noted. The applicant considers the RMS/co-RMS assessment to be appropriate – see also comments and responses in the environmental fate section. RMS: Noted, the DAR can be updated accordingly, if required. Open point	Open point Pending on the discussion in the fate area, the risk assessment for aquatic organisms might need to be updated for what concern consideration of buffer strips.
5(41)	Vol. 3, B.9, B.9.2.9	EFSA: Some of the endpoint estimation for some metabolites are based on extremely small dataset, for which a proper	Applicant: As the dossier was prepared and submitted at the end of 2013 so it was	Data requirement Applicant to include additional QSAR

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		<p>regression is either very unreliable (e.g. DCNM toxicity to algae, based on a halonitrite dataset of 2 points) or even impossible (toxicity of isothiocyanic acid to daphnids and algae, based on a imides dataset consisting of one data point?). Furthermore, the EFSA (2013) guidance recommends to follow a scheme for the application of QSAR estimation which encompasses several steps, including an analysis of the validity of the model (e.g. predictive capacity), whether the modelled substance is within the domain of the model, etc.</p> <p>In this case, the QSAR were used in a kind of weight of evidence approach, which is also foreseen in the EFSA guidance document. Nevertheless, in such case, the guidance recommends to provide estimations from different models. Use of other models to confirm the prediction obtained with ECOSAR would increase the confidence of the present estimations, particularly for those based on very small data sets.</p>	<p>not possible or relevant at that time to follow the new EFSA (2013) guidance (the 2013 EFSA guidance has an implementation date for all applications from 1 January 2015 onwards). The RMS conclusion was whilst the data may not be sufficiently reliable to be used in a quantitative risk assessment for isothiocyanic/thiocyanic acid and iminodimethanethiol it was reasonable to conclude that the risk to aquatic organisms was adequately covered by the active substance risk assessment. Additional estimates can be provided if requested.</p> <p>RMS: Additional QSAR calculations could be requested from the applicant and reviewed by the RMS in an addendum or updated DAR. The view of the RMS is that the existing weight-of-evidence argument is sufficient.</p> <p>Addressed</p>	<p>calculations.</p> <p>Open point RMS to review the outcome of these additional QSARs.</p>
5(42)	Vol. 3, B.9, p 207	EFSA: for some scenarios/crop combinations, a high risk is still predicted despite the application of mitigation measures.	<p>Applicant: There are a number of scenarios where safe has been demonstrated using appropriate mitigation.</p> <p>RMS: Agreed. It can be considered at MS</p>	<p>Data requirement The applicant is being given the opportunity to submit further data to address the risk for scenarios/crop combinations for which a high risk is</p>

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			level whether available mitigation options are sufficient to address the risks identified for relevant scenarios. Addressed	still predicted despite the application of mitigation measures.
5(43)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to aquatic organisms	Public comment – French Chambers of Agriculture (AFCA) As mentioned above, the specific use on apples will be made to limited areas of the overall cropped area where there is a specific need to treat for replant disease. Use will not be on a large scale and limited to no more than 1 application in 15 years or longer. Long-term effects on aquatic are expected to be minimised by such use. Long term exposure is not expected in such situations.	Applicant: Noted RMS: Noted. It is agreed these points are relevant but the RMS does not consider that any modification of the assessment conducted is required on this basis. Addressed	Addressed.

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5(44)	Vol. 3, B.9, Bees	AT: The risk to honey bees should have been assessed based on the EFSA GD on honey bees (2013).	Applicant: It is noted that the Bee Guidance Document (2013) has not yet been implemented. In line with Article 12 of Regulation 1107/2009 it is a legislative requirement that "...the Authority shall adopt	Addressed. As the old data requirements apply, the use of the EFSA GD cannot be made.

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			<p>a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application". The application was made in 2013. The implementation of the EFSA bee GD has not yet been agreed by Member States, neither has an implementation date been set. The applicant considers that the RMS has conducted an appropriate risk assessment for bees.</p> <p>RMS: The assessment was conducted in line with noted guidance available at the time of submission. Therefore the RMS does not agree with the need to include an assessment for bees to EFSA (2013) guidance.</p> <p>Addressed</p>	
5(45)	Vol. 3, B.9.3.2.1	DE: Since an exposure not only for ground dwelling arthropod species is possible (due to volatilisation and deposition), we consider studies with foliar dwelling species necessary. Since those are not provided this should be set as a data gap.	<p>Applicant: Chloropicrin is applied to bare soil by either a drip system or injected into soil and the treated area is then covered to reduce loss of chloropicrin by volatilisation. It is not practical to conduct glass plate studies using the standard test organisms. In addition, this was considered in the EFSA peer review in 2011. The EFSA conclusion states: "Standard tests were not considered appropriate for a risk assessment to non-</p>	<p>Data requirement Applicant to provide toxicity data on foliar dwelling arthropods.</p> <p>See also points 5(54); 5(55).</p>

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			<p>target arthropods. Tests with <i>Pardosa spp</i> and <i>Poecilus cupreus</i> on artificial substrate resulted in mortality up to 100% for both species. Chloropicrin applied at field rate of 272 L/ha had severe effects after initial exposure in extended laboratory tests with <i>Poecilus cupreus</i>, <i>Pardosa spp</i>, <i>Folsomia candida</i> and <i>Aleochara bilineata</i>. However, no major effects on survival, prey consumption or reproduction were observed on the 4 non-target arthropod species 18 days after treatment. Overall, the in-field and off-field risk to non-target arthropods was considered to be low (also covering soil non-target macro-organisms), based on the mode of application and the potential for recolonisation within an acceptable period. Additionally, the risk to non-target arthropods from inhalation was considered to be addressed by the assessment for bees."</p> <p>In the agreed list of endpoints following that review it is stated under the heading 'Laboratory tests with standard sensitive species' that this is "No [sic] relevant species for application to bare soil by injection".</p> <p>On the above basis, no data gap was identified in the EFSA Conclusion 2011 for</p>	

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			<p>studies with the standard species. There has been no change in requirements or applicable guidance relevant to the current application since that time.</p> <p>RMS: The RMS agrees that there is a need for data on the toxicity of chloropicrin to foliar-dwelling arthropod species. It is suggested that such information can be requested from the applicant and reviewed by the RMS in an addendum or updated DAR.</p> <p>Data gap</p>	
5(46)	Vol.3 B9.3.1 pp.231-232	FR: The inhalation toxicity study is a reliable option for bees in the case of chloropicrin, especially regarding the persistence in air of the active substance after the VIF removal (as observed in operator study). The available endpoint covered the acute risk for inhalation for bees. It is FR opinion that without other data with longer exposure or with other development stage of bees, it would not be possible to have a robust conclusion of the effects of chloropicrin on bee colonies.	Applicant: The inhalation study was considered by the RMS to have provided a NOEC (82 mg a.s./m ³) that exceeded the maximum measured peak concentration (0.2937 mg a.s./m ³) by a factor of 279 times. Bees are unlikely to visit the treated area as there will be no suitable food for them to forage on. It is noted that the RMS proposes, as an additional precaution, that any bee hives in the vicinity of treated areas will be removed during application and during tarp removal to minimise any potential risk to bees. This reflects the precautionary measure agreed at the PRAPeR	See expert discussion 5(47).

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			<p>Expert Meeting 85 (24 – 26 November 2010) and recorded in the EFSA Conclusion 2011 to minimise the risk to bees.</p> <p>It should be noted that, as application is made by a limited number of trained specialist operators, a high degree of compliance can be expected from any such additional mitigation requirements.</p> <p>RMS: Treated areas are initially covered and then after removal of the VIF, it would be expected to be some time before flowering plants are present. On this basis treated areas would not be expected to be attractive foraging areas for bees for a substantial period following application, noting the presence of an irritant gas would further discourage foraging bees from remaining in the treated area. As such, some exposure of foraging bees may occur (to a limited extent and for a short duration) but exposure of other bee life stages would be expected to be minimal. However a risk to bees (adults or other life stages) cannot be excluded if hives are present during application or VIF removal. It is suggested that risk mitigation labelling can be adopted to prevent this from occurring.</p>	

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			Addressed	
5(47)	Vol. 3, B.9.3.1. Effects on bees, study IIA 8.7/01 (Porch, 2009)	EFSA: Vapour exposure studies are generally not requested. This substance is highly volatile, so the vapour exposure study is appreciated. However, as no standard methods exist, the setup of the study and its use in the risk assessment need to be further discussed.	<p>Applicant: The RMS provided a detailed review of the study and its subsequent use in the risk assessment.</p> <p>In addition, this study was considered in the earlier review of chloropicrin. The EFSA Conclusion of 2011 states: "<i>An inhalation exposure study was submitted by the applicant. Bees were exposed for one hour without any treatment related mortality. TER based on the LC50 and peak exposure from field exposure measurements indicated a low inhalation risk to bees. Member State experts in PRAPeR 85 agreed with this assessment.</i>"</p> <p>The endpoint concluded by the RMS in the current assessment is the same as that agreed in 2011. The extensive dataset of measured chloropicrin values from the monitoring studies submitted in the current application provides a robust basis underpinning the RMS risk assessment.</p> <p>RMS: It is agreed that given the novel nature of the study/risk assessment expert discussion may be beneficial.</p>	<p>Experts' consultation</p> <p>Experts to discuss the approach and the outcome of the risk assessment to bees carried out in the DAR.</p> <p>In carrying out this task, the experts should consider</p> <ol style="list-style-type: none"> 1) vapour exposure and possible effects of chloropicrin on bee colonies 2) relevance of dietary and contact exposure and suitability of the available ecotoxicological data (Patnaude 2010, Patnaude 2011). <p>See also points 5(46); 5(48); 5(50); 5(51); 5(61); 5(62); 5(63).</p>

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			Open point	
5(48)	Vol. 3, B.9.3.1. Effects on bees, study IIA 8.7.1/01 (Patnaude, 2010)	<p>EFSA: This study presents several shortcomings. First of all, the solvent control showed high mortality, more than the allowed 10%. This might be due to an amount of acetone larger than the recommended. The positive control also showed a higher effect than expected. This means that validity criteria were not entirely met.</p> <p>However, the biggest issue is that the exposure to the test item was not confirmed. Due to the volatility of the a.s., it is not clear whether the authors took sufficient measures to ensure that the bees were actually exposed to the nominal doses. The lack of visible effect at all concentration tested is odd, when considering the toxicity shown by this chemical to other invertebrates (e.g. other NTAs, aquatic invertebrates, etc.).</p> <p>The final assessment of this study from the RMS is not clear: in vol.3 B9 it was stated that "the reliability of this study is considered to be limited". However, the study endpoint does not appear in the LoEP. If the RMS considers the study to be</p>	<p>Applicant: the comment is noted and the RMS can consider and clarify their position. The applicant agrees with the position of the RMS/co-RMS assessment that the exposure of bees via oral consumption and contact exposure is minimal given the nature of the active substance and application method - see also response at 5(51) below.</p> <p>RMS: It is agreed that not all validity criteria were met and that uncertainty over the level of exposure in this study means that it cannot be fully relied upon in regulatory risk assessment. The RMS has communicated in section B.9.3.1.2 that this study is not considered to be sufficiently reliable to assess the oral risk to bees but that further consideration of this route of exposure is not necessary. It is not that the study is considered invalid, more that the study design is likely to overestimate exposure and hence underestimate the oral sensitivity of bees to chloropicrin.</p>	Addressed See expert discussion 5(47).

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		invalid, this should be clearly mentioned in the assessment.		
5(49)	Vol. 3, B.9.3.1, Acute oral toxicity, Table 9.3.1-4.	EFSA: In the Patnaude (2010) study, there are inconsistencies between the replicates and the average mortality after 24 and 48h exposure to 50 µg a.s./bee. Please align.	Applicant: the comment is noted and the RMS can amend the DAR. RMS: Agreed. The average mortality values are correct in this case and the replicate values incorrect. The replicate values can be updated accordingly in a revised Volume 3. Open point	Open point RMS to adjust the summary of the Patnaude (2010) study, by correcting the inconsistencies between the replicates and the average mortality after 24 and 48h exposure to 50 µg a.s./bee
5(50)	Vol. 3, B.9.3.1. Effects on bees, study IIA 8.7.2/01 (Patnaude, 2011)	EFSA: This study presents several shortcomings. First of all, the solvent control showed high mortality, more than the allowed 10%. This might be due to an amount of acetone larger than the recommended. The positive control also showed a higher effect than expected. This means that validity criteria were not entirely met. It should be pointed out that this test might not be fully relevant for highly volatile substances, as the test item is likely to dissipate before being taken up by the bees.	Applicant: the comment is noted. The RMS considers the deficiencies in their evaluation and concludes that the study is acceptable. The applicant agrees with the RMS. The applicant agrees with the overall position of the RMS/co-RMS assessment that the exposure of bees via oral consumption and contact exposure is minimal given the nature of the active substance and application method - see also response at 5(51) below. RMS: The deviations from the guideline validity criteria are minor in magnitude. It can be added to the study summary and risk assessment that there is uncertainty as to whether exposure in this study represents a worst-case, given residues may have	See expert discussion 5(47).

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			<p>dissipated before being taken up by bees. However, the RMS considers that at the stage at which exposure to bees can first occur, concentrations in soil will have declined to the extent that subsequent volatilisation and deposition to plants and hence exposure to bees can be considered minimal. This is supported by the fact that no residues were detected above the LOQ in plants in the residue trials and in the Bartolome (2009) study residues in pea and barley seedlings were below the limit of detection 7 days after treatment. On this basis exposure via the contact route is expected to be minimal.</p> <p>Open point</p>	
5(51)	Vol. 3, B.9.3.1. Effects on bees, Risk via oral consumption and contact exposure	EFSA: The calculated HQ for acute contact is above the trigger value, indicating a potential risk. Although the conclusion of the RMS that 'an acceptable risk to bees via contact exposure can be concluded based on minimal exposure' seems reasonable, there might be the need to discuss this further. Note that the same comment applies to the risk assessment for oral exposure.	<p>Applicant: The conclusion reached by in the RMS/co-RMS DAR is supported and this is in line with the consideration at PRAPeR Expert Meeting 85 (24 – 26 November 2010) during the earlier review. The exposure of bees via oral consumption and contact exposure is minimal given the nature of the active substance and application method. The rationale for the conclusion of acceptable risk, based on minimal exposure, is very clearly set out by the RMS in the DAR (Section B9 p 230-231) and the applicant agrees with this</p>	See expert discussion 5(47).

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			assessment which is consistent with the conclusion reached in 2011. RMS: See 5(47)	
5(52)	Vol. 3, B.9.3.1. Effects on bees, p. 231	EFSA: It is unclear how the conversion factor of 24.45 to convert ppm concentrations to mg/m ³ was derived. Please provide explanation	Applicant: 24.45 is the molar volume for a reference condition of 25°C at one atmosphere RMS: See 5(6)	See open point 5(6)
5(53)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to bees	Public comment – French Chambers of Agriculture (AFCA) We acknowledge the importance of ensuring protection of bees. This is essential. The application is made to limited situations when no crop is present. We support the assessment conducted and note that the risk is considered acceptable. We note the possible need to remove bee hives during application and tarp removal. Bee hives are very unlikely to be present during this period however any necessary mitigation measures will be adhered to ensure safety to bees.	Applicant: Noted RMS: Noted. It is agreed these points are relevant but the RMS does not consider that any modification of the assessment conducted is required on this basis. Addressed	Point addressed, no further action required.
5(54)	Vol.3 B9.3.1 pp.231-232	FR: FR agrees with the conclusion of RMS regarding the non-target arthropods assessment. It is FR opinion that the off-field assessment exclusively performed for soil arthropods is not complete and addresses an acceptable risk only for bare	Applicant: See the response at 5 (42) above. Additional information considering the off-field risk to foliage-dwelling arthropod species can be submitted if requested by EFSA.	See data requirement 5(45).

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No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		soil off-field. FR suggests that further data or justifications should be provided to support that the existing data package would be sufficient to support a robust conclusion also for vegetated off-field considering also that no toxicity data are available for the representative species (<i>Typhlodromus pyri</i> and <i>Aphidius rhopalosiphi</i>).	RMS: See 5(45)	
5(55)	Vol. 3, B.9.3.2. Effects on non-target arthropods	EFSA: No standard tests for tier 1 testing with <i>Aphidius rhopalosiphi</i> and <i>Typhlodromus pyri</i> are performed, HQ calculation for tier 1 tests is therefore not possible.	Applicant: see response to 5 (42) above RMS: See 5(45)	See data requirement 5(45).
5(56)	Vol. 3, B.9.3.2. Effects on non-target arthropods	EFSA: Application of chloropicrin is non-standard as it is injected in bare soil. It is noted that the application methods for the reference materials used in all NTA studies are not comparable to the application method for chloropicrin. The study design and use of reference material should therefore be further discussed. This comment applies to all NTA studies performed.	Applicant: Application of chloropicrin is by soil injection and also by drip irrigation. The design and use of the reference material is considered appropriate and relevant to the studies conducted. It should be noted that the majority of these studies were considered in the earlier review and accepted in that review. RMS: Noted. While the reference item results do not fully inform on the sensitivity of test organisms exposed via soil injection, they do at least inform on the sensitivity of the test organisms themselves. This point is raised	Point is addressed, no further action needed.

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Bees and non-target arthropods				
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			<p>already in the RMS comments and it is difficult to see what further action could be taken given a suitable reference item for application via soil injection is not available. It is also noted that very high levels of mortality occurred in test organisms when exposed to fresh residues of the active substance from applications at in-field rates. The view of the RMS is that while non-standard in design, the available studies are suitable for assessing effects on soil-dwelling non-target arthropods. It is noted that the same point regarding the difference in application methods for the test and reference items applied for the recently assessed substance 1-MCP and this point was not considered to invalidate the non-target arthropod studies.</p> <p>Addressed</p>	
5(57)	Vol. 3, B.9.3.2. Effects on non-target arthropods, IIA 8.8.1.3/04 (Gray, 2004a)	EFSA: There is inconsistency in the reporting of the reference item. Both dimethoate and decis (deltamethrin) are mentioned in different parts of the study summary.	<p>Applicant: dimethoate is not mentioned in the report, therefore its inclusion in the report summary is an error.</p> <p>RMS: The correct reference item was Decis (deltamethrin). This typo in the Volume 3 can be corrected.</p>	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1

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			Open point	
5(58)	Vol. 3, B.9.3.2. Effects on non-target arthropods, IIA 8.8.2.3/01 (Sharples, 2004b)	EFSA: It is noted that in the Sharples 2004b study spiders were used that were collected in autumn. Based on the application time of chloropicrin (june-september) over-wintered spiders should be used, as described in ESCORT2. As over-wintered species are more sensitive, endpoints used in RA may underestimate risks. The use of this endpoint should be further discussed.	<p>Applicant: the use of autumn collected spiders was detailed as a guideline deviation in the report summary and has been specifically considered by the RMS in the DAR. The RMS concluded that there was a consistent pattern in the results seen across all 3 ground-dwelling species tested and that therefore use of autumn collected spiders was acceptable. The applicant agrees with the RMS conclusion.</p> <p>RMS: This point has been noted by the RMS in the study summary and risk assessment. The RMS considers that the study still provides useful information on how quickly soil residues may decline to levels which do not affect the health of <i>Pardosa Sp</i>. While over-wintered spiders may be more sensitive to chloropicrin, the study results are considered sufficiently clear to demonstrate the potential for recolonisation of this species to occur within a 1 year period.</p> <p>Addressed</p>	Point addressed, no further action required.
5(59)	Vol. 3, B.9.3.2. Effects on non-target arthropods, IIA 8.8.2.3/01	EFSA: It is noted that data on reproduction effects is missing in the aged residue studies from Sharples (2004b) and Gray	Applicant: there is no missing data to provide.	Point addressed, no further action needed.

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	(Sharples, 2004b) and IIA 8.8.2.3/02 (Gray, 2004b)	(2004b). The ESCORT2 guidance states that reproduction assessments should be included in aged residue studies. Please provide the missing data.	RMS: Reproduction was not assessed in these studies as is the normal practice. These studies were conducted to standard guidelines (Candolfi et al., 2000), which do not require reproductive assessments for these species (<i>Pardosa sp.</i> and <i>P. cupreus</i>). Addressed	
5(60)	Vol. 3, B.9.3.2.2, Effects on non-target terrestrial arthropods in extended laboratory/semi –field tests	EFSA: For all the three available aged residue studies, it is not clear when the animals were inserted in the test system. Was that when the tarp was removed?	Applicant: animals were added immediately after the removal or the tarp (4 DAT) or 11 days after tarp removal (18 DAT) RMS: Soil samples were taken for these bioassays 4 and 18 days after treatment. At this point test organisms were added to the test system. The tarp was removed 4 days after treatment. Therefore the 4 DAT results represent arthropods exposed to chloropicrin in soil immediately after tarp removal and the 18 DAT represent arthropods exposed to chloropicrin in soil 14 days after tarp removal. Addressed	Open point RMS to clarify in the study summaries when the animals were added to the test system in relationship with the removal of the tarp.
5(61)	Vol. 3, B.9.3.2.3, in field risk	DE: In our opinion the argumentation concerning the potential for recolonisation is insufficient. For the active substance	Applicant: The German comment does not appear to provide a full picture of the position in relation to the equivalent aged	Addressed. However, pending on the data requirement 5(47), potential for

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		<p>1,3-dichloropropene no effects on <i>Poecilus cupreus</i>, <i>Aleochara bilineata</i>, and <i>Pardosa spp.</i> were observed in an aged residue study. However, in the presented field studies no recovery could be concluded even after two years.</p> <p>Therefore in our opinion a full field study is needed in order to conclude on the recovery potential after chloropicrin application.</p>	<p>residue studies conducted with 1,3-dichloropropene. Our understanding is that, for the studies conducted with 1,3-dichloropropene, no effects were seen in the positive controls in these studies. The RMS evaluation for 1,3-dichloropropenes states: “ <i>In addition to these [Folsomia and Hypoaspis], three further crop relevant species were tested, Poecilus cupreus (carabid beetle), Aleochara bilineata (staphylinid beetle) and Pardosa spp. (wolf spider), but these studies were considered as supplementary data due to the absence of effects in the positive control (please refer to Vol 3 CP B.9.5.2 for details).</i> ” The studies are not listed in the LOEP for 1,3-D and we consider that they cannot be relied-on and that the parallel with chloropicrin suggested by Germany is invalid.</p> <p>The assessment of the RMS, of acceptable in- and off-field risk for soil dwelling arthropods, is supported and this is also in line with the conclusion reached in the EFSA Conclusion on the earlier review in 2011 (see also point 5(45) above.</p> <p>RMS: Given that the potential for</p>	<p>recolonization can be concluded if a low off-field risk is concluded also for foliar dweller arthropods.</p>

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			<p>recolonisation to occur within an acceptable time frame based on aged residue studies and in line with ESCORT II guidance is indicated, the RMS considers that an acceptable in-field risk has been demonstrated. The point is noted but it would not seem appropriate to reach a different conclusion based on field study results for another active substance.</p> <p>Addressed</p>	
5(62)	LoEP, bees risk assessment	EFSA: the final risk assessment for oral and contact exposure is not included in the LoEP, while being qualitatively presented in vol. 3 B9. This should be aligned.	<p>Applicant: noted – for RMS to revise the DAR</p> <p>RMS: Given the oral toxicity study is not considered fully reliable the RMS does not agree with adding this to the LoEP. The contact and oral risk assessments rely on reasoned arguments, which can be added to the LoEP.</p> <p>Open point</p>	See expert discussion 5(47).
5(63)	LoEP, bees risk assessment	EFSA: the final conclusion of the risk assessment for inhalation should be briefly reported in the LoEP.	<p>Applicant: noted – for RMS to revise the DAR</p> <p>RMS: This information can be added to the LoEP.</p> <p>Open point</p>	See expert discussion 5(47).

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No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
5(64)	LoEP, NTAs risk assessment	EFSA: The outcome of the risk assessment considering the aged residue tests is not clear in the LoEP. It might be useful to add a short conclusion also there.	Applicant: noted– for RMS to revise the DAR RMS: This information can be added to the LoEP. Open point	Open point RMS to amend the LoEP by clarifying the outcome of the risk assessment considering the aged residue tests.

Earthworms and other non-target soil macro- and mesofauna				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
5(65)	Vol.3 B9.4.4 pp. 326	FR: Regarding the acute toxicity study on earthworms, FR agrees with conclusion of RMS.	Applicant: noted RMS: Noted. No action needed. Addressed	Addressed
5(66)	Vol. 3CA-CP, B.9, B.9.4	Applicant: The RMS has identified a data gap for further consideration of the risk to earthworms on the basis that recovery of earthworm populations within the treated area has not been fully demonstrated within an acceptable period. The RMS noted that the size of the overall area treated and the presence of any untreated areas within the field would be important factors in recolonisation.	RMS: Noted. Additional information regarding the risk to earthworms could be requested from the applicant and reviewed by the RMS in an addendum or updated DAR. The view of the RMS is that it may be difficult to sufficiently demonstrate an acceptable risk to earthworms without a suitable field study (covering reproductive effects) but the points made by the applicant regarding the difficulty of conducting such a study for chloropicrin are noted.	Data requirement Applicant to provide further information to address the risk to earthworms

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		<p>Chloropicrin is a high-cost treatment and is generally only applied on limited areas e.g. under strawberry or tomato cultivation, and in some situations at intervals of many years, for example on land bearing tree crops (<i>e.g.</i> citrus, top fruit, olives), where applications are made no more than on 1 year in 15 (as specified in the GAP). In some circumstances strip applications are made thus providing reservoirs for recolonisation. It should also be noted that populations of earthworms in fields that are suitable for chloropicrin treatment are likely to be low – irrespective of chloropicrin exposure - due to other unfavourable factors <i>e.g.</i> the characteristics of the soil (typically sandy with low organic matter content) and agronomic practices that entail removal of surface cover vegetation, causing the upper soil horizon to remain predominantly inhospitably dry – especially in S-EU MS. It is intended that further information to address the uncertainty about earthworm population recovery and recolonization can be provided as additional information in the peer review process. This will include information from the public domain and other sources and will take into account agronomic information. This can be</p>	Data gap	

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No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		provided in response to a request from EFSA for consideration in the peer review.		
5(67)	Vol. 3, B.9.4.1 Earthworm – acute effects, study IIA 8.9.1/01, Rogers (2004)	EFSA: In table 9.4.1-2, header of columns "Percentage (%)" and "Number of mortalities" seem to be swapped.	Applicant: noted– for RMS to revise the DAR RMS: Agreed. The RMS can update the column headings in a revised Volume 3. Open point	Addressed. RMS to correct in an amended RAR, this action is needed according to SANCO/10180/2013-rev.1
5(68)	Vol. 3, B.9.4.2, Report: IIA 8.9.2/01	DE: EC ₁₀ and EC ₂₀ values should have been reported. These values should be requested from the applicant.	Applicant: these can be provided if necessary. RMS: See 5(26)	Data requirement Applicant to submit EC _x calculations or an argumentation for not calculating EC _x values. Open point RMS to include all relevant submitted information in the DAR.
5(69)	Vol. 3, B.9.4.2 Earthworm – acute effects, study IIA 8.9.2/01, Patnaude (2013)	EFSA: The setting on the NOEC at 11 mg a.s./kg is questionable, as the number of surviving offspring was considerably reduced at all concentrations (even if not significantly in statistical terms at 11 mg a.s./kg). When assessing this, it should also be considered that the lack of dose-response for the three lowest nominal concentrations might be driven by an	Applicant: the RMS set the NOEC at 11 mg a.s./kg soil based on the nominal exposure concentration. This was then further reviewed and changed to 0.253 mg a.s./kg soil based on the initial measured concentration. The 0.253 mg a.s./kg soil endpoint is consistent with the endpoint obtained from the Rodgers 2009b study. RMS: The reproductive data is variable, with	Experts' consultation Experts to discuss the chronic risk assessment for soil macro-organisms. In particular experts should discuss: - the suitability for the tier 1 endpoint for earthworms (Patnaude, 2013). - the potential for recovery/recolonization of earthworms and other soil macro-organisms based

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Earthworms and other non-target soil macro- and mesofauna				
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		<p>overlap in terms of actual exposure. Indeed, at those levels, all measured soil concentrations were either below or slightly above the LOQ at the beginning of the exposure phase. Particularly, at 3.6 mg a.s./kg, all analytical verifications resulted in concentrations below the LOQ and at 11 mg a.s./kg, values below the LOQ were recorded for two out of three samples. In the RAR, averages concentrations were calculated using LOQ/2, when values were below the LOQ. In principle, this approach is considered correct, nevertheless, the observed lack of dose-response should be carefully considered in this case, as there are serious limitations to a reliable quantification of the exposure.</p> <p>We suggest that no reliable NOEC (nor ECx) could be derived from the present study.</p>	<p>high standard deviations, meaning that setting the NOEC for this parameter is not straightforward. There is also a high degree of uncertainty regarding what chloropicrin concentrations earthworms were actually exposed to in this study and how accurately the measured concentrations reflect this. When interpreting the study results though it must also be remembered the practical difficulties of working with a volatile substance and what is technically achievable. Given there are a number of comments regarding the interpretation of the earthworm toxicity data and its use in the risk assessment, it is suggested that further expert discussion on these points may be helpful.</p> <p>Open point</p>	<p>on the available data.</p> <p>See also points 5(70); 5(72); 5(74); 5(77); 5(80); 5(81); 5(82).</p>
5(70)	Vol. 3, B.9.4.4, Risk assessment for earthworms	DE: The endpoints appear inappropriate for addressing the risk adequately due to the missing analytical verification/maintenance of active substance and initial exposure especially in the study by Paternaude (2013).	<p>Applicant: as noted by the RMS the Paternaude (2013) study was considered to be suitable to use in the risk assessment.</p> <p>RMS: See 5(69)</p>	See expert discussion 5(69)
5(71)	Vol. 3, B.9.4.4, Risk assessment for	DE: In our opinion it is not appropriate comparing the results of the study by	Applicant: as noted by the RMS the two studies give consistent results regardless	Addressed.

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Earthworms and other non-target soil macro- and mesofauna				
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	earthworms	Paternaude (2013) with the results of the study by Rodgers (2009b). This is due to the fact, that the latter study has been performed with aged natural soil residues instead of artificial soil and the application method and tarping is not documented.	<p>of the soil type used and therefore this is scientifically justified.</p> <p>RMS: It is agreed that the study designs are not comparable but the view of the RMS is that the lack of effects on survival and reproduction in field soil at similar concentrations provides support for the proposed NOEC from the Paternaude (2013) study. See also 5(69).</p>	
5(72)	Vol. 3, B.9.4.4, Potential for recovery	<p>DE: The term "Potential for recovery" is misleading, since an application of chloropicrin at the rate applied for will lead to 100 % mortality – at 53 mg as/kg soil dw 100 % mortality occurred in the Paternaude 2013 study, the calculated PEC_{Soil} values for either application type are > 100 mg as/kg soil. Therefore, the term of recolonisation should rather be used.</p> <p>Additionally, we would like to point out that 100 % effect on non-target species like soil organisms is not acceptable. A recovery is not possible since no reproduction can take place when there are no earthworms left to reproduce.</p>	<p>Applicant: Use of chloropicrin, in common with other soil fumigants, is expected to have an impact on earthworm populations in the treated areas. Recovery will happen from outside the treated areas (migration and also transfer of cocoons on farm machinery and via other agronomic activity) and the studies with aged soils demonstrate that once chloropicrin concentrations have declined earthworms will be able to migrate/be transported into treated areas and survive. See the also applicant comment at 5(66).</p> <p>In relation to the citation of the 2017 Scientific Opinion on soil organisms, in Column 3 of the commenting table, the dossier was submitted at the end of 2013. The 2017 Opinion presents proposals that are not yet agreed or implemented.</p>	See expert discussion 5(69).

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			<p>RMS: The RMS does not consider it appropriate to utilise decision criteria defined in the soil organism risk assessment scientific opinion (EFSA Journal 2017) in this instance. The document referenced is not noted guidance and was not available at the time of submission for this application, so it would be procedurally inappropriate to use it in the manner indicated.</p> <p>As part of the risk assessment of the potential for recovery to occur, the RMS considered that in the absence of demonstrating that in-field populations in isolation are able to recover within an acceptable timeframe, it would need to be demonstrated that immigration of earthworms from surrounding areas would be sufficient to recolonise treated areas within an acceptable timeframe. The view of the RMS is that this point was not sufficiently demonstrated and given the speed at which recolonisation may occur, this line of evidence is unlikely to be productive for earthworms. See also 5(69).</p>	
5(73)	Vol.3 B9.4.4 pp. 327	FR: A criticism could be made regarding the airtightness of "food grade transparent film" used in Patnaude (2013). Indeed,	Applicant: the report states the following: each test vessel was covered with food grade transparent plastic wrap (low	Data requirement Applicant to provide information about the permeability of film used in

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		this type of plastic film could be permeable to gas and this would explain the lack of recovery of chloropicrin at the beginning of the test. Could please RMS precise the grade of transparent film used in the study and if the food grade film used in this test can be considered impermeable to gas)? Is it similar to those uses in field, with a similar impermeability? This should be considered before using the Patnaude (2013) study in the risk assessment	<p>density polyethylene). There are no other details available. We can follow this up with the laboratory that conducted the test to provide more detail on the film used. If available this can be provided as additional information in response to a request from EFSA.</p> <p>RMS: Agreed. This information is not provided in the study report and would therefore need to be requested from the applicant.</p> <p>Open point</p>	Patnaude (2013).
5(74)	Vol.3 B9.4.4 pp. 327	FR: FR agrees with the endpoint value based on initial mean measured concentration and the RMS conclusion regarding the absence of knowledge regarding the potential recovery of the earthworm, especially depending of the extent of treated area and the proposal of data gap for field uses.	<p>Applicant: noted see applicant comment at 5(66) above.</p> <p>RMS: Noted. See 5(69).</p>	See expert discussion 5(69).
5(75)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to earthworms and other soil macro-organisms	<p>Public comment – French Chambers of Agriculture (AFCA)</p> <p>We note there is a concern about earthworm populations recovering following treatment. It appears that the effects of treatment do not persist more than 100 days but more</p>	<p>Applicant: Noted</p> <p>RMS: Noted. It is agreed these points are relevant but the RMS does not consider that any modification of the assessment conducted is required on this basis.</p>	Addressed.

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		information is required to demonstrate full recovery. This is a factor for all soil fumigants which by their nature will reduce populations in treated areas. In line with other fumigants we consider this can be demonstrated with further data to support product registration. The treated areas are limited and as stated treatment to tree crops will not exceed 1 year in 15 – long-term effects are not expected and can be demonstrated with further information. It should also be noted that in some circumstances strip application in fields may be applied to treat the specific areas to be planted therefore providing in-field untreated areas which will aid recovery.	Addressed	
5(76)	Vol. 3, B.9.4.4, Consideration of recovery from outside the treated area	DE: A relevant route of exposure for off field environments can also be run-off. This should be considered, too due to the high application rate and the high toxicity of chloropicrin.	Applicant: the RMS consideration of appropriate off-field routes of exposure is supported i.e. that there is sufficient evidence to conclude acceptable risks to earthworms outside of treated areas, whether exposure occurs via aerial deposition or lateral movement. RMS: The RMS has currently considered the risk to earthworms and other soil macro-organisms in surrounding areas via aerial deposition and via lateral movement through soil. While movement of chloropicrin to surrounding fields via runoff is possible, this	Open point RMS to update the DAR by including consideration of contamination for off field environments via run-off. This is relevant for the assessment of effects off-field impacting on the analysis of possible re-colonisation.

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			would be likely to only affect the edges of surrounding areas, with concentrations of chloropicrin declining rapidly with distance from the treated area. The presence of vegetation in field boundaries or neighbouring fields would further restrict movement of chloropicrin via runoff. For example, a 10 m vegetated strip is typically assumed to reduce runoff exposures by 90%. Overall, the RMS considers that for off-field areas runoff exposure can be expected to be a less significant exposure pathway than aerial deposition but it is appreciated that this is based on a qualitative consideration rather than a quantitative risk assessment. The DAR volume 3 can be updated accordingly. Open point	
5(77)	Vol. 3, B.9.4.4, RA for other soil macro-organisms, potential for recovery	DE: Due to the nature of the active substance it is expected that at the application rate of the representative use 100 % effects on mortality will be observed. Therefore the same applies as for earthworms.	Applicant: The laboratory that conducted the study was asked to provide the recalculation. The response provided was that: "Based on the data set, we were not able to generate an LC10 or LC20 that were within guideline parameters for larval survival at termination. Every model available failed at least one of the following criteria: Lack of Fit, Normality or Homogeneity of Variance. While we currently run ELS testing with 4	See expert discussion 5(69).

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Earthworms and other non-target soil macro- and mesofauna				
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			<p>replicates, this exposure was run under an older guideline which required only two. The reduced replication probably impacted the ability to determine these LC values."</p> <p>Use of chloropicrin, a fumigant, in common with other soil fumigants, is expected to have an impact on collembolan populations in the treated areas. Recovery will happen from outside the treated areas and the studies with aged soils demonstrate that once chloropicrin concentrations have declined collembolans will be able to migrate into treated areas and survive. We therefore agree with the RMS conclusion that the risk to soil macro-organisms (other than earthworms) can be concluded as acceptable on the basis of the potential for recolonisation. This is consistent with conclusions of the 2011 review in relation to non-target arthropods other than earthworms – also see comment at 5(45) above.</p> <p>In relation to the citation by Germany of the 2017 Scientific Opinion on soil organisms, in Column 3 of the commenting table, the dossier was submitted at the end of 2013. The 2017 Opinion presents proposals that are not yet agreed or implemented.</p>	

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Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>RMS: The RMS does not consider it appropriate to utilise decision criteria defined in the soil organism risk assessment scientific opinion (EFSA Journal 2017) in this instance. The document referenced is not noted guidance and was not available at the time of submission for this application, so it would be procedurally inappropriate to use it in the manner indicated.</p> <p>Given there are multiple comments regarding the use of the soil macro-organism toxicity data and the outcome of the risk assessment for soil macro-organisms (other than earthworms), it is suggested that further expert discussion on this point would be beneficial. It is also noted that there is a lack of agreed criteria in current guidance for establishing whether recovery can occur for soil macro-organism populations.</p> <p>Open point</p>	
5(78)	Vol. 3, B.9.4.2, Report: IIA 8.9.2/03	DE: EC ₁₀ and EC ₂₀ values should have been reported. These values should be requested from the applicant.	<p>Applicant: these can be provided if necessary.</p> <p>RMS: See 5(26)</p>	See data requirement and open point 5(68).
5(79)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other	EFSA: It is not clear why the RMS has decided not to apply the correction factor of 2 despite the LogP of chloropicrin being	<p>RMS: For earthworms this point is explained on page 322 of Volume 3, section B.9: '<i>Since the NOEC is expressed in terms of a</i></p>	<p>Open point</p> <p>RMS please amend the risk assessment</p>

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Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	soil macro-organisms	higher than 2.	<p><i>measured concentration, which is considered representative of the active substance available to earthworms in soil, the NOEC has not been corrected by the standard factor of 2 (triggered on the basis of log Pow = 2.5 for chloropicrin and used to assess differences in bioavailability between soils with different organic matter contents).'</i> It is also questionable whether the decision to correct the toxicity endpoint or not should be based alone on the log Pow for a volatile active substance. The log Poa would seem more relevant (i.e. the partition coefficient between octanol and air).</p> <p>For other soil macro-organisms the NOAEL for <i>Folsomia candida</i> is based on nominal rather than measured concentrations. However, whether this endpoint is corrected or not will not impact the outcome of the risk assessment and as discussed above it is questionable whether a correction factor based on the log Pow is relevant in this case.</p> <p>Addressed</p>	by correcting the endpoint with the appropriate factor of 2. While the scientific limitations of this approach are well known to EFSA, we would like to note that this has been consistently applied. The assumption of the RMS that what is measured equals what is bioavailable is questionable.
5(80)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other soil macro-organisms	EFSA: The approach presented in the RAR to demonstrate the potential for recovery of earthworms is not agreed upon. First of all, there are serious concerns about the	<p>Applicant: see applicant comment at 5(66) above.</p> <p>RMS: The RMS does not agree with the need</p>	See expert discussion 5(69).

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Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		<p>selection of the NOEC from the Patnaude (2015) study, which was not corrected despite the LogP of the substance, and was then compared to the foreseen PEC until 100 days after the application.</p> <p>In addition, as already highlighted by the RMS, such comparison would anyway be not sufficient to demonstrate a recovery potential, as earthworms are characterised by extremely slow movements, and as there are also still uncertainty regarding possible contaminations (particularly due to lateral movements) of areas surrounding the treated field.</p> <p>Without more appropriate data, we don't believe that a low risk is demonstrated.</p>	<p>to correct the NOEC from the Patnaude (2013) study (see 5(79)). It is agreed that an acceptable risk to earthworms has not been sufficiently demonstrated. See 5(66) and 5(69).</p>	
5(81)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other soil macro-organisms	<p>EFSA: The approach presented in the RAR to demonstrate the potential for recovery of other soil organisms is not agreed upon. No NOEC is available for Hypoaspis, and it is noted that the endpoint for Folsomia was not corrected despite the LogP of the substance.</p> <p>Most importantly, the available studies can only be used to derive a suitable (with some uncertainty) time frame to determine when a potential recovery can start. This is not equivalent to</p>	<p>Applicant: The RMS considered that a NOEC of 227 L a.s./ha could be used from the Hypoaspis study. Use of chloropicrin, a fumigant, is expected to have an impact on collembolan populations in the treated areas. Recovery will happen from outside the treated areas and the studies with aged soils demonstrate that once chloropicrin concentrations have declined collembolans will be able to migrate into treated areas and survive. We therefore agree with the RMS conclusion that the risk to soil macro-</p>	See expert discussion 5(69).

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Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		demonstrate a recovery. With the available data, we don't believe that a low risk to other soil organisms has been demonstrated.	organisms (other than earthworms) can be concluded as acceptable on the basis of the potential for recolonisation. This is consistent with conclusions of the 2011 review in relation to non-target arthropods other than earthworms – also see comment at 5(45) above. RMS: See 5(77)	
5(82)	Vol. 3, B.9.4, Risk assessment for soil organisms in general	DE: Resulting from the intended use of chloropicrin as nematicide against harmful organisms in soil, effects of the pesticide on soil organisms, especially beneficial nematodes, should be assessed at higher tier level in order to ensure a sufficient protection level for these organisms.	Applicant: Use of chloropicrin, a fumigant, is expected to have an impact on nematode populations. There is the potential for recovery from outside the treated areas and the studies with aged soils demonstrate that chloropicrin concentrations decline rapidly. We are not aware that there has been a requirement to address the impact on beneficial nematodes for any other nematicide (nor any other active substance) considered in the EU process under either Directive 91/414/EEC or Regulation 1107/2009. There is no established risk assessment scheme for beneficial nematodes. We do not therefore consider that this represents a data gap. This may be a generic issue that German wishes to pursue in relation to the development of guidance.	See expert discussion 5(69).

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Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS: The concern of the MS is appreciated but the RMS doesn't consider it appropriate to introduce additional data requirements for this active substance that are not stipulated in the relevant legislation. Addressed	
5(83)	Vol. 3 B.9.4.4. Risk assessment for earthworms and other soil macro-organisms	EFSA: As a high risk is concluded for the parent, the risk assessment for chloropicrin cannot "cover" for the metabolite DCNM	Applicant: RMS to clarify. RMS: The RMS considers that the risk from the metabolite DCNM is less critical than the risk from the active substance but agrees that without an acceptable risk to soil organisms being demonstrated for the active substance, an acceptable risk from DCNM cannot be concluded. See 5(66) & 5(81)	Data requirement The Applicant is given the possibility to submit further data to address the risk to soil macro-organisms due to exposure to the metabolite DCNM. Open point Pending on the submitted information, the RMS is requested to update the DAR by highlighting that a low risk from DCNM cannot be concluded if relevant data are missing.
5(84)	LoEP	EFSA: the time scale for all earthworm chronic studies is reported to be 28 days, while it should be 56 days.	Applicant: noted – RMS to amend LoEP RMS: 28 days refers to the duration of the adult exposure phase of the study. Given adult worms were not exposed for 56 days, the RMS considers it could be misleading to specify a 56 day duration. A footnote can be	Open point RMS to update LoEP by clarifying the duration of the test and of the exposure for the earthworm chronic studies.

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Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			added to the LoEP to indicate that 28 days refers to adult exposure. Open point	
5(85)	LoEP	EFSA: the endpoints reported for the third line of the table have a wrong unit (676 kg a.s./kg should be 676 mg a.s./kg)	Applicant: noted – RMS to amend LoEP RMS: Agreed. The LoEP can be corrected accordingly. Open point	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10180/2013-rev.1

Soil nitrogen transformation				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(86)	Vol. 3CA-CP, B.9, B.9.5	Applicant: The RMS considers that recovery of soil microflora within the treated area has not been fully demonstrated within an acceptable period. Chloropicrin is a high-cost treatment and is generally only applied on limited areas e.g. under strawberry or tomato cultivation, and in some situations at intervals of many years, for example on land bearing tree crops (e.g. citrus, top fruit, olives),	RMS: Further information can be requested from the applicant and reviewed by the RMS in an updated DAR. Data gap	Data requirement Applicant to provide further information to address the risk to soil microflora.

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Soil nitrogen transformation				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		where applications are made no more than on 1 year in 15 (as specified in the GAP). Further information drawn from the public literature to address the uncertainty about soil microorganisms can be provided as additional information in the peer review process in response to a request from EFSA.		
5(87)	Vol. 3, B.9.5, Risk assessment for soil micro-organisms	<p>EFSA: We agree with the conclusion of the RMS that the study from Carter (2009) is not sufficient to demonstrate a low risk for soil micro-organisms.</p> <p>In addition to the uncertainties already discussed by the RMS in the RAR, it should be noted that the soil aged in the field has been strongly manipulated (sieved) before the start of the lab test. This has the potential to have a significant effect on the residues in the soil.</p> <p>Furthermore, the test itself can be considered a laboratory one, as only the treatment and the aging was performed in the field, while the quantification of C and N transformation was done under controlled conditions, and after 3-6 days of acclimatisation. As such, we don't see particular justification for the variability observed among control replicates.</p>	<p>Applicant: see response at 5(86).</p> <p>RMS: The RMS agrees with the points raised by EFSA. These can be added to the study summary/discussion in the risk assessment in an updated Volume 3.</p> <p>Open point</p>	<p>Open point</p> <p>RMS to add discussion on the uncertainty in study summary from Carter (2009).</p>

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Soil nitrogen transformation				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(88)	Vol. 3, B.9.5, Risk assessment for soil micro-organisms	EFSA: As a high risk is concluded for the parent, the risk assessment for chloropicrin cannot "cover" for the metabolite DCNM	<p>Applicant: RMS to clarify 'cover' - see also response at 5(86) in relation to soil-micro-organisms.</p> <p>RMS: The RMS considers that the risk from the metabolite DCNM is less critical than the risk from the active substance but agrees that without an acceptable risk to soil organisms being demonstrated for the active substance, an acceptable risk from DCNM cannot be concluded. See 5(82).</p>	<p>Data requirement The Applicant is given the possibility to submit further data to address the risk to soil micro-organisms due to exposure to the metabolite DCNM.</p> <p>Open point Pending on the submitted information, the RMS is requested to update the DAR by highlighting that a low risk from DCNM cannot be concluded if relevant data are missing.</p>
5(89)	Vol. 3, B.9.5, Report: IIA 8.10.1/03	DE: It appears questionable how an application of chloropicrin can be "commercial" as stated in the study title, when this active substance is not approved in the EU. This seems illegal.	<p>Applicant: The comment from Germany intimating illegal use is incorrect. It should be noted that chloropicrin was authorised for use in several Member States prior to the 2011 review (UK, Belgium, Greece, Italy, Spain and Malta). A non-inclusion decision was taken in December 2011 with the 23 June 2012 set as the deadline for withdrawal of chloropicrin containing plant protection products. A period of grace was allowed for disposal, storage and use to expire no later than 12 months after the withdrawal deadline. In addition, since that time, several Member States have granted emergency authorisations under Article 53 of Regulation</p>	Addressed.

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Soil nitrogen transformation				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>1107/2009 (UK, Italy, Spain, Portugal, Belgium, Greece, Hungary and Malta. Therefore, commercial applications of chloropicrin are authorised in the EU under Regulation 1107/2009 and previously under Directive 91/414/EEC. The particular national position of Germany stated in comment 5(101) has not been the position of other Member States and therefore there has been legal use in the EU.</p> <p>RMS: Chloropicrin had been authorised prior to the first EU review in some countries and emergency use of chloropicrin has been authorised in some MS under Regulation 1107/2009.</p> <p>Addressed</p>	

Terrestrial non-target higher plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(90)	Vol. 3CA-CP, B.9, B.9.6 Effect on non-target terrestrial higher plants	Applicant: It is noted that the RMS assessment used the maximum air concentration determined at 1 m from the	RMS: Further information can be requested from the applicant and reviewed by the RMS in an addendum or updated DAR.	Data requirement Applicant to provide further

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Terrestrial non-target higher plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Risk to non-target terrestrial plants from representative uses of chloropicrin p381	treated area in the monitoring trials (0.2937 mg a.s./m ³) which results in a TER of 22.9 when compared to the ≤ 50% effects concentration. (6.72 mg a.s./m ³). This is in excess of the conventional SANCO/10329/2002 risk assessment trigger value of 5 and indicates safe use. The RMS indicates uncertainty in relation to longer term risk as the [REDACTED] (2009) study on which the effect concentration was based was limited to 2 daily periods of 6 h, which the RMS considers may underestimate the duration of exposure of non-target plants in the field. The RMS acknowledges that concentrations in air following application are not maintained at the same peak concentration for a prolonged period of time and decline relatively rapidly. It should also be noted that chloropicrin is used in areas of intensive horticulture and in many years of usage there is no evidence of unacceptable effects on surrounding commercial crops. The applicant can submit additional information taking into account information on the concentration and duration of exposure from the existing monitoring data and the new monitoring study as well agronomic information to address this point. This additional information can be provided on	Data gap	information to address the risk to NTTPs.

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Terrestrial non-target higher plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		request from EFSA for consideration in the peer review.		
5(91)	Vol. 3, B.9.6, Risk to non-target terrestrial plants from representative uses of chloropicrin	EFSA: we agree with the conclusion of the RMS that the available data are not sufficient to demonstrate a low risk to NTTPs from the intended uses of chloropicrin, particularly concerning the mismatch between the length of the exposure used in the effect study and the potential length of the exposure in the field.	Applicant: Please see comment provided at 5 (90). RMS: Noted. See 5(90).	Addressed.
5(92)	Vol. 3, B.9.6.2, Risk to non-target terrestrial plants from representative uses of chloropicrin	DE: A relevant route of exposure for off field environments can also be run-off. This should be considered, too, and is not covered by the adjusted exposure study presented. Since chloropicrin is applied for as a herbicide, also seedling emergence should be tested according to the respective OECD GD with concentrations to be expected from run-off.	Applicant: As described in the introduction to Section B.9, chloropicrin is a soil fumigant applied to bare soil prior to crop planting to combat a variety of pests and diseases. The commercial target organisms are fungi and nematodes. As with other soil fumigants chloropicrin has some effect on insect pests and germinating weed seeds. Chloropicrin is not commercially used or recommended for specific use as a herbicide on grounds of cost and limited activity (specific herbicides would be applied to the commercial crops grown following chloropicrin treatment). The inclusion of weeds was in the pests controlled section of the GAP table was solely to indicate this activity but	Data requirement Applicant to provide information to address effects of chloropicrin to seedling emergence when this reaches off-field areas via runoff. Open point RMS to consider providing a risk assessment addressing effects of chloropicrin to seedling emergence when this reaches off-field areas via runoff.

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Terrestrial non-target higher plants				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>chloropicrin should not be regarded as a herbicide. Chloropicrin has the product type soil fumigant. No additional testing on seedling emergence is considered necessary.</p> <p>RMS: See comment response 5(76) regarding runoff exposure. It is agreed that given the herbicidal activity of chloropicrin a seedling emergence study is triggered.</p> <p>Data gap</p>	
5(93)	Vol. 3, B.9.6.2, Risk to non-target terrestrial plants from representative uses of chloropicrin	DE: Please present the risk assessment in a tabular manner for better clarity.	<p>Applicant: RMS to consider revision of DAR.</p> <p>RMS: The risk assessment in tabular format can be added in an updated Volume 3.</p> <p>Open point</p>	Open point RMS to make clear table with RA results for NTPPs.

Other non-target terrestrial organisms (flora and fauna)				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(94)	Vol.3 B9.6.2 pp. 381	FR: FR agrees the RMS conclusion regarding the non-target plant risk assessment. Based	Applicant: see response at 5(90) in relation to the non-target plant assessment (additionally	Addressed.

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Other non-target terrestrial organisms (flora and fauna)				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		on the specific behaviour and exposure pattern (chronic exposure in field) to non-target plants (NTP) to this substance, the provided study would not cover the exposure of NTP to this gas. Moreover, an explanation on the different opinions of RMS regarding the exposure of tested organisms via the air would be welcome. Indeed, it is not clear why the 1h inhalation exposure of bees is considered sufficient whereas the 2 x 6h exposure pattern for NTP is not.	<p>see response at 5(46) in relation to bees. In relation to duration of exposure – the RMS considers that foraging bees would not stay where irritant gases are present for an extended period, which would justify the 1 h duration adopted – the applicant agrees with this conclusion which is consistent with the EFSA 2011 review. For non-target plants the RMS assessment considers that the exposure periods in the plant study may underestimate the duration of exposure of non-target plants in the field (given their static nature) - the applicant does not agree with this for the reasons given at 5(86) and additional information is proposed for submission on this point.</p> <p>RMS: Noted. See 5(90) regarding exposure to terrestrial non-target plants via air. The different approaches taken by the RMS for bees and non-target plants with respect to study duration are a result of different exposure situations. There is no standard duration specified for a bee study involving exposure via air. The RMS considers the 1 h duration in the bee inhalation study to be reasonable for assessing acute effects on individual adult bees (given it seems unlikely that foraging bees would spend longer than</p>	

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Other non-target terrestrial organisms (flora and fauna)				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>this within a treated field). However, the 1 h duration does not cover the length of the exposure period which adult bees may experience if colonies are present on site during application or during removal of the VIF. The air exposure study also does not cover other life stages that may be more sensitive to chloropicrin than adults (e.g. larvae). Therefore it is recommended that labelling is stipulated to specify that bee hives must be removed during application and during VIF removal.</p> <p>Addressed</p>	
5(95)	Volume 1 Section 2.9.9 Summary of product exposure and risk assessment – risk to non-target plants	<p>Public comment – French Chambers of Agriculture (AFCA)</p> <p>We note it is concluded there is uncertainty about exposure of non-target plants. Chloropicrin has been used for many years in areas of intensive horticulture and our understanding is that damage to surrounding horticultural crops following treatment is not seen. Given the potential value of surrounding crops this would have been noted. We consider any concern can be addressed with additional information but there is no evidence from practical usage situations of damage or adverse effects on neighbouring plants.</p>	<p>Applicant: Noted – see applicant comment at 5(90) above.</p> <p>RMS: Noted. It is agreed these points are relevant but the RMS does not consider that any modification of the assessment conducted is required on this basis.</p> <p>Addressed</p>	Addressed.

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Biological methods for sewage treatment				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)

Other comments incl. available monitoring data				
No.	<u>Column 1</u> Reference to Assessment Report (vol., point, page)	<u>Column 2</u> Comments from Member States, EFSA, applicant or public	<u>Column 3</u> Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	<u>Column 4</u> Data requirement or Open point (if data point not addressed or fulfilled)
5(96)	Vol. 3, B.9	AT: The studies were evaluated by the RMS taking into account the test guidelines used at the time of testing. However, for the validation of the studies the current valid test guidelines should have been considered.	<p>Applicant – this is noted as an outcome of the EFSA pesticides peer review meeting on recurring issues in ecotoxicology. RMS to respond.</p> <p>RMS: This point is only considered significant regarding the algal toxicity studies. Further information on the validity criteria for the algal study previously considered acceptable are described under point 5(30).</p> <p>Addressed</p>	Addressed.

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Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(97)	Vol. 4, C.1.4.2. Consideration of Impurities in the active substance material	EFSA: As the RMS specified in the RAR: "The high application rate of chloropicrin means that impurities in the active substance material may be applied to the soil in significant amounts". Indeed, at least 4 impurities were found to be applied in several grams per hectare (up to >300 g/ha - see table C.1.5.1.3-2). Why this issue was not considered for the environmental risk assessment?	<p>Applicant – the representativeness of the ecotoxicology batches tested is considered in Volume 4. The RMS concludes that batches tested are representative of the technical specification. Volume 4 also contains information on the nature of the impurities. The RMS may wish to consider inserting some further information in relation to environmental risk assessment.</p> <p>RMS: Consideration of the toxicity of impurities in the active substance should focus on the hazard. The levels of impurities present in the technical specification and the tested batches are such that the batches tested are considered representative of the technical specification. As such, the risk assessment performed for the active substance using data generated for the tested batches will address the risk from the active substance, including any impurities present. See also comment response 4(61).</p> <p>Addressed</p>	Open point It would be appreciated if the RMS could discuss the issues of the environmental risk assessment of the impurities in a more extensive form in the DAR.

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Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(98)	Vol. 3, B.9.11, Literature review	DE: Please elaborate on why chloropicrin has not been searched for in the RTECS database. This appears to be a relevant data base for literature on toxic effects.	<p>Applicant – an additional updated search can be conducted if required.</p> <p>RMS: The RMS has considered the literature search provided by the applicant. Consideration of additional databases could be requested from the applicant.</p> <p>Open point</p>	<p>Data requirement</p> <p>Applicant to provide an updated literature search by including the RTECS database.</p>

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Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(99)	Vol. 3, B.9.11, Literature review – summary of search results	DE: Why are the 13 studies that were not excluded for relevance not further discussed to have a transparent reasoning for the non-inclusion in the risk assessment?	<p>Applicant – RMS to consider. The laboratory that conducted the study was asked to provide the recalculation. The response provided was that:</p> <p>"Based on the data set, we were not able to generate an LC10 or LC20 that were within guideline parameters for larval survival at termination. Every model available failed at least one of the following criteria: Lack of Fit, Normality or Homogeneity of Variance. While we currently run ELS testing with 4 replicates, this exposure was run under an older guideline which required only two. The reduced replication probably impacted the ability to determine these LC values."</p> <p>RMS: Of the 13 studies not excluded based on relevance, none of these related to ecotoxicology, as explained on page 400 of Volume 3, section B.9.11. It must be remembered that a single literature search was performed across all areas of the evaluation.</p> <p>Addressed</p>	Addressed.

section 5 – Ecotoxicology

Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(100)	Vol. 3, Appendix 3: UK Pesticide Usage Survey	DE: How can chloropicrin have been used in UK as a soil sterilant when this substance was not approved in the EU neither under Directive 91/414/EEC nor under Regulation (EC) No 1107/2009? This seems rather illegal.	Applicant: The comment from Germany intimating illegal use is incorrect see response at 5(89) above. RMS: See 5(89) Addressed	Addressed.
5(101)	Vol. 1, Level 2, 2.10. C&L	DE: The proposal for aquatic environment (4.1) appears to be missing. Please add.	Applicant – RMS to amend the DAR. RMS: Agreed. This information will be added to an updated Volume 1. Open point	Open point RMS to update the DAR by including a proposal for the classification See also point 5(107)
5(102)	Vol. 1, Level 3, 3.1.1.1	DE: We disagree that approval is possible as the risks could be refined with further data at MS level. The purpose of a common active substance assessment is that safe uses have been demonstrated for the intended use. As this is not the case the risk should be first refined at EU level i.e. in the active substance assessment.	Applicant – chloropicrin is a niche product with important uses in commercial horticulture in several Member States. It is only used on limited areas of the total cropped area for horticultural crops (as exemplified by the table on pages 410-411 of Volume 3 B.9). The applicant agrees with the RMS and co-RMS assessment that approval can be recommended on the basis of the submitted dossier (and the applicant considers that some of the identified uncertainties can be resolved with additional information in the peer review process). Remaining uncertainties can be appropriately	Open point RMS please amend Vol.1 pending on the outcome of the peer-review.

section 5 – Ecotoxicology

Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			<p>refined with further data at Member State level. National circumstances, conditions, horticultural practises and mitigation measures are particularly important in relation to such a specialised use substance and more appropriately refined at Member State level.</p> <p>RMS: The RMS considers that an acceptable risk can be concluded for applications made under conditions of full and permanent protection. See 5(21) regarding concern relating to the risks to birds and mammals from uses made under full and permanent protection.</p> <p>Addressed</p>	
5(103)	Vol. 1, Level 3, 3.1.4.9	DE: We are of the opinion that further studies need to be generated in order to refine the risk (e.g. earthworm and arthropod field studies).	<p>Applicant: see comments in relation to non-target arthropods at 5(45) and earthworms at 5(66) above.</p> <p>RMS: See 5(45) and 5(66)</p>	See expert consultation 5(69).

section 5 – Ecotoxicology

Other comments incl. available monitoring data				
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5(104)	Vol. 1, Level 3, 3.1.5	<p>DE: Additional issues that could not be finalised are in our opinion: risk to earthworms, risk to non-target arthropods, risk to beneficial nematodes, and risk to aquatic organisms due to the simultaneous exposure via run-off/drainage and volatilisation/deposition.</p> <p>Alternatively, these issues could also be added to Section 3.1.6 "Critical areas of concern".</p>	<p>Applicant: the view of Germany is noted. See comment at 5(102) above and also the applicant comments and responses in this section relevant to the issues listed.</p> <p>RMS: The RMS does not agree that these are issues that could not be finalised, since sufficient information has been provided in all of these areas in order to conduct a risk assessment (except for nematodes, for which there are no data requirements). Additionally they are not considered to be critical areas of concern given that in the view of the RMS, acceptable risks can be concluded for applications made under full and permanent protection.</p> <p>Addressed</p>	Open point RMS please amend the DAR pending on the outcome of the peer-review.

section 5 – Ecotoxicology

Other comments incl. available monitoring data				
No.	Column 1 Reference to Assessment Report (vol., point, page)	Column 2 Comments from Member States, EFSA, applicant or public	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(105)	Vol. 1, Level 3, 3.2	DE: We disagree with the RMS' conclusion that chloropicrin can be approved under Regulation (EC) No 1107/2009.	<p>Applicant: see response at 5(102) above and also 5(106) below.</p> <p>RMS: Noted. The RMS considers that an acceptable risk to non-target organisms can be concluded for applications made under conditions of full and permanent protection. See 5(21) regarding concern relating to the risks to birds and mammals from uses made under full and permanent protection.</p> <p>Addressed</p>	<p>Addressed.</p> <p>Please note that this comment is not related to the risk assessment.</p>
5(106)	General	DE: We would like to point out that no uses of chloropicrin in Germany are allowed since 1980, due to its high toxicity to warm-blooded species and for the protection of groundwater.	<p>Applicant – the historical position of Germany is noted. This is not considered relevant to the scientific consideration of the current assessment and the comment is not considered relevant to EFSA's remit. In any event it is not the intention of the ECG to seek authorisation in Germany (nor in the Northern Zone).</p> <p>RMS: Noted. Addressed. No action needed.</p>	Addressed. No action needed.
5(107)	Vol. 1, 2.10, Classification and Labelling	IE: Please include Aquatic Acute 1 (M 1000) and Aquatic Chronic 1 (M 100) in the proposed classifications in section 4.1 Hazardous to the aquatic environment.	<p>Applicant – RMS to amend the DAR.</p> <p>RMS: See 5(101).</p>	See open point 5(101)

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List of all reports from Pesticides Peer Review Meetings

Date	Document	Section
12.09.2019	<u>Pesticide Peer Review expert meeting TC 08</u>	Residues
13.09.2019	<u>Pesticide Peer Review expert meeting 12</u>	Ecotoxicology
20.09.2019	<u>Pesticide Peer Review expert meeting 13</u>	Mammalian Toxicology
20.09.2019	<u>Pesticide Peer Review expert meeting 15</u>	Environmental Fate and Behaviour

REPORT OF PESTICIDE PEER REVIEW MEETING TC 08

CHLOROPICRIN

Rapporteur Member State: IT

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
September 2019	IT, DE, FR, NL, UK	Preliminary comments from MSs submitted before the meeting are entered in the discussion table below.

2. Documents submitted for meeting:

Date	Supplier	File Name
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.docx
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.pdf
March 2019	IT	Chloropicrin_DAR_02_Volume_2_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_02_Volume_2_2019_03_19.pdf
March 2019	IT	Chloropicrin_DAR_09_Volume_3CA_B-7_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_09_Volume_3CA_B-7_2019_03_19.pdf
March 2019	IT	Chloropicrin_evaluation table_section 3_2019-03-19.doc
July 2019	IT	Chloropicrin_List of endpoints_all sections_July_2019.doc
March 2019	IT, EFSA	Chloropicrin_reporting table_2018_06_14.doc

3. Documents tabled at the meeting: None

Appendix 1: Discussion table: CHLOROPICRIN

Appendix 1: Discussion Table, Chloropicrin (Fu, In, Ne, Hb)

3. Residues

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
Experts' consultation 3.1 Experts to discuss the storage stability of all compounds covered by the residue definition in the studies on strawberries and tomatoes and if possible conclude on the maximum storage stability for both crop groups and whether it is possible to extrapolate to other water- and acid matrices by default. See also 3(1) – 3(4) See reporting table 3(5)	<p>Preliminary comments submitted by MSs before the meeting:</p> <p>RMS IT: Comments available in PPT: https://dms.efsa.europa.eu/otcs/llisapi.dll?func=ll&objaction=overview&objid=21807987</p> <p>DE: Parent: The data indicates a clear decline over all samples – instability of chloropicrin is unquestionable. In view of the very simple chemical structure, it seems likely that physico-chemical effects (like pH dependent hydrolysis) are the key driver for degradation and not plant specific enzymatic processes. Thus, the conclusion to extrapolate tomato results also to other high water crops is generally supported. However; extrapolating the decline between 2 and 7 days based on a single study is an assumption too weak to make. Without additional information, 2 days should be the highest interval supported by data. DCNM: Again, extrapolation seems reasonable with the same argumentation as for parent in tomatoes. In this case, the assumption by the RMS to consider day 0 samples and procedural recoveries is supported to conclude on a 7 days interval. The compound seems to be susceptible to degradation, but slower than parent in tomato. Therefore; the process of fortification before freezing may have an impact on the initial residue, as shown by constant losses around 20% in the day 0 samples and in the procedural recoveries. Compensation of this effect, which is a systemic deviation and not related to the stability of residues during freezer storage itself, is required and suggests stability for 7 days.</p>	<p>It was concluded that the results on the stability of the parent and DCNM can be extrapolated to other high water- and acid content matrices as the instability is most likely independent of the food matrix but an inherent characteristics of the molecule.</p> <p>Regarding DCNM metabolite, since the recoveries of this compound accounted for only 83% at day 0, the DCNM residues can be considered as stable for up to 7 days, although the recoveries at this storage time interval accounted for only 59.8%.</p> <p>Data gap: A storage stability study on chloropicrin in a crop representative of the high water content commodities (preferably fruiting vegetables) and covering the maximum storage time interval of the residue samples in the trials on fruit crops in order to conclude on the validity of these trials is required.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>FR: FR agrees that the stability studies show that chloropicrin and DCNM are not stable after four days of storage. Since the (in)stability of the substance and its metabolite is not related to the matrix, this storage time can be applied to water- and acid matrices. Therefore the number of storage stability studies is considered sufficient and the samples must be analysed within 4 days.</p> <p>NL: Storage stability clearly is a problem for both chloropicrin and its metabolite dichloronitromethane. Only limited data is available (2 crops representing 2 crop groups with different analytes), and more studies could have been required. On the other hand, the available data show that chloropicrin and dichloronitromethane are instable, and to extrapolate these findings to other crops could be considered acceptable as a worst-case approach. Furthermore, analysis of samples within maximally 4 days after sampling is already a practical hurdle, and therefore, it is hardly possible to do this analysis any faster. NL agrees with the RMS that chloropicrin can be considered stable for 4 days in tomatoes, based on interpolation of the results. NL also agrees with the RMS that dichloronitromethane can be considered stable for 7 days in strawberries based on the comparison with day 0, showing <30% decline.</p> <p>UK: Based on the available data, UK concludes that the stability of chloropicrin can be shown for up to 4 days in high water crops. For dichloronitromethane, UK is of the view that stability can be demonstrated for up to 7 days in high acid crops. It is understood that generally individual results should not be corrected, however given that 0 day and fresh recovery samples all show results of ~80% it was considered more realistic to consider degradation from this level as 100% recovery is never expected even where samples are analysed immediately.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>Uncorrected recoveries show fairly constant levels on day 1(71%), day 2 (68%) and day 4 (69%). Therefore UK considers that at a minimum based on the uncorrected values the data can be considered to support frozen storage of up to four days.</p> <p>The residues trials were all analysed within 4 days (with the exception of 3 trials), for the majority of trials, it would not be possible to undertake analysis of the samples in a shorter timeframe.</p> <p>Given the demonstrated instability of chloropicrin and dichloronitromethane in high water and high acid commodities respectively, it is considered that they would also be unstable in other commodity groups, and hence it is reasonable to surmise that the compounds will only be stable for the same length of time in other commodity groups.</p> <p>The UK concludes that the instability of the compounds is inherent to the molecular structure. Therefore, the stability is not matrix-dependent and the UK considers studies in other commodity groups not to be necessary. Additionally, the UK considers that 4 days represents the minimum time period between harvest and analysis which would usually be achievable in practice.</p> <p><u>PREV TC 08:</u></p> <p>Storage stability data were submitted for chloropicrin in tomatoes and for dichloronitromethane (DCNM) in strawberries. Significant residue degradation (>30%) occurred for chloropicrin in tomatoes after 2 days (50.3% at 7 days storage time interval) and for DCNM in strawberries after 4 days (63.6% at 5 days) with a faster degradation observed specifically for the parent compound compared to DCNM. It was assumed that the instability is inherent property of the molecule and most likely instability would occur regardless of the food matrix. The experts therefore concluded that the results on the stability of the parent and DCNM can be extrapolated to other high water- and acid content matrices.</p> <p>For chloropicrin recoveries were available for day 2 (85 %), day 7 (50%) and day 15 (11%). Assuming a linear trend in degradation, stability could be assumed up to day 4 (ca 70 %) for which however no measured recovery data is available. Therefore, the experts</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>of the meeting were of the opinion to request an additional storage stability study on chloropicrin in a crop representative of the high water content commodities (preferably fruiting vegetables), covering the maximum storage time interval of the residue samples in the trials on fruit crops in order to conclude on the validity of these trials (data gap). Based on the available data, storage stability of chloropicrin has been demonstrated for 2 days. Pending upon the finalisation of the risk assessment residue definition in plants, further storage stability data on relevant compounds might be needed (See expert consultation 3.2).</p> <p>Regarding DCNM metabolite, since the recoveries of this compound accounted for only 83% at day 0, and the procedural recovery was similar at each time point (79-83%), the DCNM residues can be considered as stable for up to 7 days (decline <30%) although the recoveries at this storage time interval accounted for only 59.8%.</p>	
<p>Experts' consultation 3.2</p> <p>Experts to discuss the suitability of the metabolism studies on strawberries, green beans, and red beets for risk assessment in the light of</p> <ul style="list-style-type: none"> a) the suitability to cover the representative uses (see 3(6)) b) shortcoming (lacking intermediate samplings, the inadequate extraction and identification of terminal harvest samples and the proven instability of parent and DCNM over 	<p>Preliminary comments submitted by MSs before the meeting:</p> <p>RMS IT: Comments available in PPT: https://dms.efsa.europa.eu/otcs/lisapi.dll?func=ll&objaction=overview&objid=21807987</p> <p>DE:</p> <ul style="list-style-type: none"> a) First of all, it is supported that the metabolism study is vastly overdosed compared to the cGAP. The applied rate itself was already 1.5N, but additionally the planting interval was only 14 days instead of 28 days. The geoMean DT₅₀ is around 4 days, the max. DT₉₀ 29 days (Note to the RMS: the highest DT₉₀ of 89.3 days given in Vol1. 2.7.3 – Succeeding crops was flagged as outlier in the E-Fate part due to missing soil microbial activity). Therefore, it is safe to assume that during the longer interval in the field at least 75-90% of the amount applied would have degraded in soil before planting/sowing, introducing an additional factor of 4-10. In principle, the study addresses the representative use pattern, but is strongly overdosed (far more than 1.5N) b) Without even considering the metabolism study, it can already be concluded that a nil-residue situation (or very low residue situation) may be present. 1) Both the parent and its main metabolite are quickly degraded in soil down to CO₂ and 	<p>Data gap: Applicant to make a case that based on the chemical structure of chloropicrin and the overall available data on the metabolism in plants, residue trials, the degradation pathway of chloropicrin in soil (as the representative uses consist of a soil application) (see section 4), the potential toxicological relevance of the metabolites identified in soil (see section 2) and any relevant literature search on the parent and metabolites, the metabolism of chloropicrin in plants is sufficiently investigated.</p> <p>Residue definition for monitoring is set as chloropicrin. For risk assessment, the residue</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
<p>much shorter storage intervals than applied in the metabolism study)</p> <p>c) the need for a new metabolism study to address the data requirement.</p> <p>If possible experts should discuss and agree on a residue definition.</p> <p>See also 3(6) - 3(7), 3(9), 3(11), 3(30), 3(28bis), 3(33)</p> <p>See reporting table 3(8)</p>	<p>therefore likely to be incorporated into natural products 2) residues can only be taken up via roots and are consequently subject to growth dilution and 3) both compounds already degrade in freezer storage in contact with plant matrix and probably even quicker under field ambient conditions – so in summary accumulation in plants seems very unlikely. The study itself is poor and supplemental information (at maximum), maybe even invalid. The long storage intervals render all measured results apart from TRRs useless. All other deficiencies (no intermediate samples, extraction etc.) add to this.</p> <p>c) The main question should be, what answers a new metabolism study could provide. The parent substance is a simple molecule with very limited options for transformation. Most likely, subsequent losses of chlorine or the nitro group are connected to incorporation steps into natural products. It seems very unlikely that a kind of metabolic pattern will be present like for more complex compounds. In summary, parent and DCNM are probably the predominant components related to chloropicrin before natural incorporation occurs. Since both components are already addressed in all field trials to conclude on their quantity in foods, the request for a new metabolism study solely for the purpose to confirm the degradation steps already assumed seems unreasonable. In case of doubt, a literature read-across on the behaviour of potential degradation products (dichloromethane, mono-chloro-nitromethane) in plants could be provided by the applicant instead of a full OECD 501 metabolism study. Both of them are high tonnage chemicals with a good probability for further data.</p> <p>RD In view of the absence of detected residues, the RD "Chloropicrin" is supported by default.</p> <p>FR:</p> <p>FR agrees that the agricultural practices applied in the metabolism study cover the intended uses.</p> <p>In addition, since the plastic was removed more quickly than claimed, the time between application and planting of the crops was shortened and therefore a worst-case scenario can be considered.</p>	<p>definition is provisionally set as chloropicrin and should be revisited pending upon the requested additional information to confidently address the metabolism pathway of chloropicrin in plants (see data gap). The proposed residue definitions are set for all categories of crops following soil treatment.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>Nevertheless, the study is not sustainable because the storage time is much too long to observe the complete behaviour of chloropicrin knowing its validated storage time. In addition, the low extraction percentages for each matrix do not allow a robust conclusion on the fate of the active substance.</p> <p>However, the numerous residue trials submitted were all analysed within 4 days and confirm the no-residue situation in all crops. Therefore, even if the metabolism study is deficient, the whole data package seems sufficient to conclude on the residue definition (chloropicrin alone).</p> <p>NL: If the treatment protocol in the metabolism studies indeed can be considered worst-case compared to the cGAP of the defended use, then the metabolism studies can be considered suitable with regard to the application parameters, covering the intended uses. Indeed, the metabolism studies can be considered deficient, mainly with regard to the storage period of the samples in combination with the known instability of parent and dichloronitromethane. However, the available supervised residue trials, with fast analysis of samples, show that no chloropicrin and dichloronitromethane have to be expected. Therefore, an additional plant metabolism study is not expected to provide any useful new information.</p> <p>UK: In the metabolism studies, the time between treatment and removal of the plastic is shorter in the study compared to the proposed GAP (2 days compared to 21 days) and the time between plastic removal and planting (14 days) is in line with the proposed GAP. A shorter interval between treatment and plastic removal indicates less time for the parent compound to break down in the soil (the DT50 for chloropicrin is 8.8 days), indicating more chloropicrin will be present in the soil at the point of plastic removal, and hence potentially be present at harvest. However, at the point of plastic removal the chloropicrin can volatilize from the soil. The time period for this is the same in the metabolism study and the cGAP, hence there is the same time for this process to occur. The overall time between treatment and planting in the study is 16 days, compared to</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>28-35 days in the cGAP, making the study more worst case in terms of the time between treatment and planting, with less time for the chloropicrin to break down and become incorporated in the soil prior to treatment, but the same amount of time for the chloropicrin to volatilize. Therefore considering these factors and the higher dose rate in the metabolism study, it is considered that overall the study is slightly more worst case than the cGAP.</p> <p>UK considers that while the metabolism study has inadequacies as listed in the DAR, when considered alongside all of the available residues trials data, it can be considered that no residues of chloropicrin or metabolites would be expected in food commodities. This is in line with the conclusion reached in the previous peer review, in which the metabolism study was considered adequate given the other available data.</p> <p>Based on the metabolism study and extensive residues trials indicating the absence of chloropicrin or any metabolites or impurities in the representative uses, UK considers that a residue definition of parent only for plant commodities is appropriate.</p> <p>Further consideration of the residue definition may be needed if uses are considered on other crops in future.</p> <p><u>PREV TC 08:</u></p> <p>A metabolism study was provided on strawberries, red beet and green beans. The soil was covered in plastic sheeting prior to injection of the test substance ¹⁴C chloropicrin into the soil. The study design is compliant with the critical GAP and employs more severe conditions, i.e. 1.5 N rate for application, 2 days instead of 21 days after treatment the plastic was removed and 14 days instead of 28 days after treatment crops were planted.</p> <p>Several shortcomings were identified in this study, i.e. the samples were analysed at intervals > 300 days after sampling which is not covered by the available storage stability data on chloropicrin, no metabolites could be characterised or identified in the extracted fractions whilst the unextracted radioactivity was shown to be incorporated into natural plant components (starch, protein, pectin, lignin, hemicellulose and cellulose). It is also noted that from the residue trials on fruiting vegetables where the samples were analysed within an acceptable storage time interval, chloropicrin was never quantified (<LOQ). Although the study cannot be considered as guideline-compliant and therefore not suitable to establish the metabolic pathway of chloropicrin in plants, the experts were of</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>the opinion that a new metabolism study in plants is not needed as it will not bring any additional relevant information but agreed to request the applicant to make a case that based on the chemical structure of chloropicrin and the overall available data on the metabolism in plants, the degradation pathway of chloropicrin in soil (as the representative uses consist of a soil application) (see section 4), the potential toxicological relevance of the metabolites identified in soil (see section 2) and any relevant literature search on the parent and the soil metabolites, the metabolism of chloropicrin in plants is sufficiently investigated (data gap).</p> <p>In the meanwhile, the plant residue definition for monitoring is set as chloropicrin. For risk assessment, the residue definition is provisionally set as chloropicrin and should be revisited pending upon the requested additional information to confidently address the metabolism pathway of chloropicrin in plants (see data gap). The proposed residue definitions are set for all categories of crops following soil treatment.</p> <p>RMS assumption: The degradation products of chloropicrin (DCNM, aminomethane) are more volatile. Therefore, when the plastic is removed, these metabolites are expected to be volatilized. When the crops are planted it cannot be excluded that the metabolites could be present in soil with further uptake by the plants whilst chloropicrin residues are expected to be low and the major part of the radioactivity is expected to be incorporated into natural constituents of the plants. Co-RMS-IT assumption is based on literature data, and further include chloronitromethane and nitromethane in addition to DCNM and methylamine. Volatility of these compounds is:</p> <p>chloropicrin < DCNM < chloronitromethane < nitromethane < methylamine</p>	
<p>Experts' consultation 3.3</p> <p>Experts to discuss and conclude on the independency of the residue trials with respect to distance between the trial</p>	<p>Preliminary comments submitted by MSs before the meeting:</p> <p>RMS IT: Comments available in PPT: https://dms.efsa.europa.eu/otcs/llisapi.dll?func=ll&objaction=overview&objid=21807987</p> <p>DE:</p>	<p>Open point for RMS: The RMS is asked to check the validity of the residue trials in terms of compliance with the representative uses and covering "scenario 1": plastic film not removed and punctured at transplanting and "scenario 2": transplanting after the</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
<p>locations (tomato) and other factors and whether a sufficient number of valid residue trials is available. Experts should also address the Limit of Quantification of the various methods used and the question which limit should be chosen to establish a MRL.</p> <p>The finding of residues in one strawberry trial should be discussed and a conclusion drawn whether a non-residue situation can be established.</p> <p>See also 3(12), 3(13), 3(16) – 3(19), 3(26), 3(28), 1(12), 1(13)</p> <p>See reporting table 3(15)</p>	<ul style="list-style-type: none"> - Independence: The locations and possible non-independent trials were sufficiently reported. - MRLs should be based on the LOQ of the monitoring method evaluated in B.5 (0.005* mg/kg) <p>The one "finding" in strawberries is of no concern. Although the peak was present at the RT of chloropicrin, it was far below the LOQ and also smaller than the LOD. Identification itself is therefore doubtful and robust quantitation nearly impossible. This results in no true indication for the presence of chloropicrin and does not contradict a zero-residue assumption. The wording in Vol.1+3 should be amended accordingly, because on the basis of common analytical standard, no true detection of chloropicrin has occurred.</p> <p>FR:</p> <p>Residue trials on tomatoes in trials S26/2015-14 and 15 are indeed replicates with similar application rates, dates and locations of experimentation. Similarly, pepper trials S26/2015-16 and 17 are not independent for the same reasons.</p> <p>The number of greenhouse trials seems sufficient but additional open field trials, with lower limits of quantification (0.005 mg/kg), would be desirable. Indeed with the highest LOQ of 0.01 mg/kg an acute risk cannot be excluded (for oranges). Therefore an LOQ of 0.005 mg/kg would be necessary not to increase artificially the risk for consumers.</p> <p>Given the toxicity of the active substance, MRLs set with the lowest analytical method (0.005 mg/kg) appear to be the most appropriate choice to protect consumer health.</p> <p>Despite the strawberry trial, a non-residue situation can be validated with additional residue trials performed with LOQs at 0.005 mg/kg. In the absence of reliable metabolism data, more robust trials are needed.</p> <p>NL:</p> <p><i>Tomatoes:</i> since trials S26/2015-14 and 15 were conducted in the same greenhouse, and treatment occurred at the same date, these trials could indeed be considered replicates.</p>	<p>plastic is removed.</p> <p>Open point for RMS:</p> <p>RMS to re-assess the validity of the residue trials on fruiting vegetables and strawberries with regard to the independency of the trials and acceptable storage stability conditions (see also data gap under expert consultation 3.1) as there is indication that in some trials the samples were stored in cool (stored on ice), dark conditions within 24 hours of harvest and there is no information on whether the samples were stored in freezer or frozen conditions at <-18°C.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>Because the other trials were conducted in different greenhouses, having their own 'controlled environment', these trials could be considered independent. Distance is in this latter case considered of less importance. Variety is not considered as a differentiating factor.</p> <p><i>Peppers:</i> similar considerations as for tomatoes apply; treatment in the same greenhouse at the same date is considered as replicate trials. Therefore, trials S26/2015-16 and 17 are considered replicates.</p> <p><i>Strawberries, courgettes, melons:</i> all trials could be regarded as independent, since conducted in different greenhouses.</p> <p>In conclusion, only two trials could be regarded as replicates. Without these two trials, still sufficient trials are considered available to conclude on the zero-residues situation.</p> <p>If analytically feasible and validated, for consistency, all MRLs could be set at 0.005* mg/kg, since no residues are expected >0.005 mg/kg. Furthermore, the substance is considered toxicologically relevant, which could be a reason to set such a low MRL.</p> <p>With regard to the finding that a possible trace of chloropicrin was detected in 1 strawberry sample, NL agrees with the RMS that a zero-residues situation can be concluded on, also for this particular sample.</p> <p>UK:</p> <p>Following further consideration of the trial location UK considers all except two of the residues trials to be independent (see open point 3.3).</p> <p>Based on the number available trials and that the residues in the trials are <LOQ UK considers the data set sufficient to support the proposed uses (even where the replicate trials are discounted).</p> <p>The applicant has provided 26 further trials which have been evaluated by the UK. Whilst these trials demonstrate some deficiencies such that they cannot be fully relied upon, they provide additional evidence of the 'no residue' situation, irrespective of treatment method, trial location, and indoor and outdoor trials.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>In the DAR the UK did not propose any changes to the EU MRLs as they were sufficient to support the representative uses. The available data would indicate that no residues are expected above 0.005 mg/kg across all commodities and therefore this level could be chosen to propose a consistent MRL if required. An MRL of 0.005 mg/kg would lead to no exceedances of the ADI or ARfD.</p> <p>With respect the proposed 'no residue' situation, UK considers that sufficient data is available to demonstrate this. In all except one trial no residues were observed, and the one strawberry trial where a peak with the same retention time as chloropicrin was identified, this indicated levels of 0.2 µg/kg (25 x lower than the LOQ and below the LOD). This peak was barely distinguishable from the baselined noise and due to its low level, no further analysis could be undertaken to confirm identity. It is possible this peak could be attributable to a different compound, but this cannot be confirmed.</p> <p><u>PREV TC 08:</u></p> <p>Residue trials were submitted on different fruiting vegetables (tomatoes, peppers, courgettes, cucumbers, melon) and in strawberries.</p> <p>Open point for RMS: RMS is asked to check the validity of the residue trials in terms of compliance with the representative uses and covering "scenario 1": plastic film not removed and punctured at transplanting and "scenario 2": transplanting after the plastic is removed.</p> <p>Open point for RMS: To re-assess the validity of the residue trials on fruiting vegetables and on strawberries with regard to the independency of the trials and acceptable storage stability conditions (see also data gap under expert consultation 3.1) as there is indication that in some trials (new study from 2016) the samples were stored in cool (stored on ice), dark conditions within 24 hours of harvest and there is no information on whether the samples were stored in freezer or frozen conditions at <-18°C.</p> <p>Regarding the Limit of Quantification of the various methods the experts supported to use the lowest LOQ of 0.005 mg/kg for the purpose of MRL setting.</p> <p>The experts noted that a signal at the retention time of chloropicrin was reported in one</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>strawberry trial. Given the fact that the signal was far below LOQ (the submitted chromatograms indicated levels of 0.2 µg/kg (i.e. ~4% of the LOQ of 0.005 mg/kg)) and below the LOD, the experts agreed that this signal cannot be unanimously be attributed to chloropicrin and given the very low estimated concentration the finding is not of relevance.</p>	

REPORT OF PESTICIDE PEER REVIEW MEETING 12

CHLOROPICRIN

Rapporteur Member State: IT

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
September 2019	DE, FR, SI	Preliminary comments from MSs submitted before the meeting are entered in the discussion table below.

2. Documents submitted for meeting:

Date	Supplier	File Name
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.docx
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.pdf
August 2019	IT	Chloropicrin_DAR_08_Volume_3CA_B-6_APPENDIX_ED assessment_2019_03_19.doc
July 2019	IT	Chloropicrin_DAR_11_Volume_3CA_B-9_2019-07-30.docx
July 2019	IT	Chloropicrin_DAR_11_Volume_3CA_B-9_2019-07-30.pdf
July 2019	IT	Chloropicrin_evaluation table_section 5_2019-07-30.doc
July 2019	IT	Chloropicrin_List of endpoints_all sections_July_2019.doc
July 2019	IT, EFSA	Chloropicrin_reporting table_2018_06_14.doc
March 2019	APPL	ED assessment provided by APPL

3. Documents tabled at the meeting: None

Appendix 1: Discussion table: CHLOROPICRIN

Appendix 1: Discussion Table, Chloropicrin (Fu, In, Ne, Hb)

5. Ecotoxicology

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1	<p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>Experts to discuss the approach and the conclusion of the RMS for what concern the acute and chronic inhalation risk to birds and mammals.</p> <p>In order to properly discuss this, it would be appreciated if the RMS could include in the assessment any relevant information submitted by the applicant in response to the data requirement 5(8).</p> <p>See also points 5(8); 5(9); 5(12); 5(22); 5(23); 5(25).</p> <p>See reporting table 5(5)</p> <p>DE: In the view of the properties of the a.s., we are in the opinion that the exposure of mammals via the inhalation route cannot be disregarded. The potential risk via inhalation must part of the RA.</p> <p>However, based on the current guidance for B&M (EFSA 2019) it is difficult to conduct a robust risk assessment. Therefore, we agree with the RMS to conclude that the long-term risk for birds and mammals via the inhalation exposure can not be finalised. No safe use can be demonstrated.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>FR: The EFSA Bird and Mammal Guidance Document (2009) does not contain any specific methodology to assess the risk to birds and mammals from the inhalation route. Therefore, no relevant indicator species are defined for such use. It is FR opinion that there is a need for more robust data to better apprehend the potential exposure of birds and mammals during and following the application of chloropicrin in soil in the field.</p> <p>In addition, some concerns arise about how the endpoints are derived from inhalation studies (amount of breath air by animals during the experiments known?). Indeed, inhalation exposure is dependent on the activity of the animals and the species considered.</p> <p>FR agrees with the RMS regarding the impossibility to conclude for the long-term risk of inhalation exposure for birds and mammals.</p>	<p>Open point RMS (IT) to check and clarify in the RAR whether the air concentrations used for the risk assessment refer to the application or to other moments (e.g. when the film is cut or removed removed).</p> <p>Open point RMS to reflect the outcome of the discussion for the risk assessment for birds via inhalation exposure in an updated DAR.</p> <p>Open point RMS to reflect the outcome of the discussion in the DAR and to indicate that the majority of the experts considered that a low chronic risk to mammals was indicated.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>SI: We agree with RMS that the study is fit for purpose in case of chloropicrin. In our view the available data regarding physical chemical properties and toxicity of chloropicrin support that exposure via inhalation is the primary concern and not exposure via diet. The risk assessment for exposure via inhalation is considered to cover the risk from exposure via the diet.</p> <p><u>Meeting discussion</u></p> <p>Birds The acute risk to birds was assessed using an endpoint from a 5-day study where the birds were exposed only to 4 hours per day. It was questioned whether it was appropriate to perform the risk assessment for when the film is removed. The exposure values used in the risk assessment are taken from measured air concentrations determined for the operator exposure. Initially, it was not clear whether these values refer to measurements performed shortly after application or when the film is removed. However, after checking the fate and the operator exposure section, it seems that these measurements represent the worst-case conditions among the different operator activities (application, film cutting, film removal, etc.). As the information in the DAR was not very clear on this point, it was agreed that the new RMS (IT) will check whether the worst case air concentration was used for the risk assessment (and also whether it was worse during the application or when the film removed). It was noted that the RMS had took the maximum value (acute) or geometric mean (long-term) air concentration from all scenarios which were investigated (e.g. cutting of plastic, removal etc. – to be verified by the RMS). It was suggested that this was a reasonable assumption, provided that the worst-case had been captured. The experts at the meeting agreed with the exposure assessment performed.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>Open point</p> <p>RMS (IT) to check and clarify in the DAR whether the air concentrations used for the risk assessment refer to the application or to other moments (e.g. when the film is cut or removed removed).</p> <p>No concerns were raised regarding the acute risk assessment for birds (performed with the LD₅₀ of the 5-day study).</p> <p>The experts at the meeting agreed that the acute risk assessment performed was reasonable and consequently a low acute risk to birds from exposure via inhalation was concluded.</p> <p>For the long-term, the proposal from the initial RMS (UK) was to use the NOEC from the same 5-day study. It was noted that the acute LD₅₀/10 gave a similar endpoint to the 5-day NOEC value.</p> <p>It was also noted that, after a request suggested by the RMS (UK), the Applicant provided an estimate of an inhalation-type NOEL by attempting a conversion from the NOEL in the dietary reproduction study. This attempt resulted in a NOEL considerably higher than the one obtained in the inhalation study, hence it was not considered further.</p> <p>It was noted that for other similar substances (e.g. dimethyl disulfide) previously evaluated, the inhalation risk assessment was not considered acceptable owing to uncertainties about possible mismatches between the inhalation rates in the field and those in the lab. The RMS acknowledged the uncertainties.</p> <p>It was noted that the toxicity studies were performed with only 4 hours per day and whether this would be sufficient relative to the likely exposure in the wild.</p> <p>Particularly the RMS (UK) noted that the available assessment may not be sufficiently protective of birds nesting in the vicinity of the treated area, as in this case the daily exposure could potentially be longer than 4 hours.</p> <p>It was noted that low levels of chloropicrin were still detected – in some of the available operator exposure studies - 28 days after the substance application.</p> <p>A concern was raised regarding whether birds would damage the plastic film causing exposure. However, the experts agreed that this would be more a matter for acute</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>exposure. Some experts considered that the acute effects (e.g. irritation) due to inhalation are likely to be more relevant than other effects concerning reproduction. However, the experts still raised the concern that the toxicity studies only used 4 hours exposure per day. Furthermore, a concern was raised with the use of a 5-day endpoint for the assessment of reproductive effects given that there were detectable air chloropicrin concentrations (in some cases) up to 28 days after the substance application.</p> <p>The experts raised a concern that the length of exposure in the study is not realistic for a long-term risk assessment. The RMS (UK) originally concluded that, for this reason, the long-term risk to birds via inhalation exposure was not resolved.</p> <p>Overall, the expert agreed with the evaluation of the RMS that there are insufficient data to perform an assessment. Consequently, the long-term inhalation risk assessment for birds cannot be finalised.</p> <p>Open point</p> <p>RMS to reflect the outcome of the discussion for the risk assessment for birds via inhalation exposure in an updated DAR.</p> <p><u>Mammals</u></p> <p>The RMS performed the acute exposure assessment for mammals in the same manner as for birds. No concerns were raised. The resulting risk assessment indicated a low acute risk to mammals via inhalation. The experts at the meeting agreed with the assessment of the RMS.</p> <p>The long term risk assessment for mammals used the lowest of the available chronic endpoints for mammals via inhalation exposure. It is noted that in the available inhalation dataset, some were generational studies. Hence, this lowest endpoint should cover for reproduction effects.</p> <p>The resulting TERs were greater than the trigger value of 5. Nevertheless, the RMS (UK) concluded that the long-term risk to mammals was not resolved as the toxicity endpoint was from a study where the animals were only exposed for 6 hours a day albeit for 2 years.</p> <p>Some experts noted that the substance is likely to act more on an acute basis rather</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>than a long-term on mammals. The majority of the experts considered that the exposure in the long-term study (6 hours per day for 2 years) was sufficient, relative to that expected for wild mammals and therefore a low long-term risk could be concluded. It is noted that not all experts agreed and considered that the 6 hours of exposure per day was not sufficient.</p> <p>Open point RMS to reflect the outcome of the discussion in the DAR and to indicate that the majority of the experts considered that a low chronic risk to mammals was indicated.</p>	
Experts' consultation 5.2 Experts to discuss about the appropriateness of the dietary endpoint selected by the RMS for the reproductive long-long term dietary risk of birds. See reporting table 5(7)	<p>Preliminary comments submitted by MSs before the meeting:</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>FR: It is stated in the OECD 2006 guideline: 'this test guideline cannot be used for highly volatile or unstable substances'. However, in the [REDACTED] et al., 2009 study birds were dosed with microencapsulated form of chloropicrin.</p> <p>The shorter exposure duration used in [REDACTED] et al., 2009 (draft OECD GL 2000) is therefore questionable.</p> <p>SI: We agree with RMS that the study is fit for purpose in case of chloropicrin. In our view the available data regarding physical chemical properties and toxicity of chloropicrin support that exposure via inhalation is the primary concern and not exposure via diet.</p> <p>Meeting discussion EFSA explained that this type of study has not been accepted before as it does not cover all of the phases of reproductive cycle of birds.</p>	<p>Open point RMS to add a footnote to the LoEP to clearly indicate that the available reproductive bird endpoint cannot be used in the risk assessment as it does not cover all phases of the reproductive cycle.</p> <p>Open point RMS to update the DAR and the LoEP by removing the risk assessment performed using the available 6-week NOEL. Data gap and assessment not finalised will be identified.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>Some experts suggested that maybe in this case the study could be accepted given the fact that the substance is an acute toxin and considering the GAP where dietary exposure could be considered as less relevant compared with inhalation. However, the new RMS (IT) was of the opinion that the study was insufficient and a new study should be requested. The original RMS (UK) considered that the study was acceptable.</p> <p>If the endpoint from the study was used in a tier 1 risk assessment (using RUDs for spray applications) a high risk was indicated. However, the refined TER values calculated with measured residue values were greater than the trigger value. It was noted that the acute LD₅₀/10 (=6.2 mg a.s./kg bw) would be lower than the NOEL from the 6-week reproductive study (=10.6 mg a.s./kg bw per day). It was noted that if this endpoint was used in the refined risk assessment a high risk would be indicated. Nevertheless, it should be decided whether the 6-week study is sufficient to assess reproductive toxicity in this case.</p> <p>Overall, the majority of the experts agreed that the study was not sufficient as it did not cover all of the reproductive phases and therefore a new study would be required. However, some experts did not agree as for this substance the exposure via inhalation was more relevant.</p> <p>Open points</p> <p>RMS to add a footnote to the LoEP to clearly indicate that the available reproductive bird endpoint cannot be used in the risk assessment as it does not cover all phases of the reproductive cycle.</p> <p>RMS to update the DAR and the LoEP by removing the risk assessment performed using the available 6-week NOEL. Data gap and assessment not finalised will be identified.</p>	
Experts' consultation 5.3 Experts to discuss about the appropriateness of the dietary endpoint selected by the RMS for the reproductive long-	<p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>FR: Since different issues regarding the mammals' chronic risk assessment need to be considered, we will give our opinion during the meeting.</p>	The experts agreed with the RMS regarding the tier 1 endpoint (0.1 mg a.s./kg per day) and using a refined endpoint (1 mg a.s./kg bw per day) in the higher tier. Therefore, no open point is needed and the point is closed.

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
<p>long term dietary risk of mammals. See points 5(14); 5(20). See reporting table 5(13)</p>	<p>SI: We consider the dietary endpoint selected by the RMS for the reproductive long-term dietary risk of mammals fit for purpose in case of chloropicrin. In our view the available data regarding physical chemical properties and toxicity of chloropicrin support that exposure via inhalation is the primary concern and not exposure via diet. Developmental and reproductive toxicity are agreed to be unlikely at chloropicrin dose levels not causing general toxicity as a consequence of local effects.</p> <p>Meeting discussion The RMS summarised the reasoning for the selection of the endpoints for the long-term dietary risk of mammals. The RMS considered that the lower endpoint should be used for tier 1 (0.1 mg a.s./kg per day) but given the GAP and considering the type of exposure, and that the BW effects were only apparent after approximately 90 weeks of exposure, a refined endpoint (1 mg a.s./kg bw per day) can be used for the higher tier assessment. It was noted that effects on hyperkeratosis had been dismissed for other substances given that, in these assessments, the concentrations were high and the effect was sometimes shown to be reversible. Some experts expressed the view that they would agree with the RMS that effects on hyperkeratosis, hyperplasia and emesis were excluded as they were not considered to be relevant to the population. The experts agreed with the RMS to use the available chronic dietary studies for the selection of the endpoint for the wild mammal risk assessment given that reproductive data were available for the inhalation route of exposure. The experts agreed with the RMS regarding the tier 1 endpoint and using a refined endpoint in the higher tier. Therefore, no open point is needed and the point is closed.</p>	
<p>Experts' consultation 5.4 Experts to discuss the approach and the outcome of the risk assessment to bees</p>	<p>Preliminary comments submitted by MSs before the meeting: FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p>	<p>Open point RMS to invalidate (and remove from the LoEP) both the oral and the contact acute endpoints with bees. RMS to remove the risk assessment and to clarify that these routes of</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
<p>carried out in the DAR. In carrying out this task, the experts should consider</p> <ol style="list-style-type: none"> 1) vapour exposure and possible effects of chloropicrin on bee colonies 2) relevance of dietary and contact exposure and suitability of the available ecotoxicological data (Patnaude 2010, Patnaude 2011). <p>See also points 5(46); 5(48); 5(50); 5(51); 5(61); 5(62); 5(63).</p> <p>See reporting table 5(47)</p>	<p>FR: FR repeats its comment performed during the commenting period: The inhalation toxicity study is a reliable option for bees in the case of chloropicrin, especially regarding the persistence in air of the active substance after the VIF removal (as observed in operator study). The available endpoint covered the acute risk for inhalation for bees. It is FR opinion that without other data with longer exposure or with other development stage of bees, it would not be possible to have a robust conclusion of the effects of chloropicrin on bee colonies.</p> <p>SI:</p> <ol style="list-style-type: none"> 1) We are not aware of guidance to assess the risk to bee colonies via inhalation. We suggest to consider risk mitigation measures. 2) We consider that shortcomings of the ecotoxicological data (Patnaude 2010, Patnaude 2011) are sufficiently highlighted in the RAR. We agree with assessment of RMS/CoRMS that the exposure of bees via oral consumption and contact exposure is minimal given the nature of the active substance and application method. <p>Meeting discussion</p> <p>The RMS summarised the available toxicity data for honeybees.</p> <ul style="list-style-type: none"> - The acute oral toxicity study was not considered reliable - The acute contact study was considered reliable - The acute inhalation study was reliable - No chronic adult toxicity study or study with honey bee larvae were available. <p>The experts agreed that the acute oral toxicity endpoint was not reliable for the reasons suggested by the RMS UK (e.g. likely low exposure as volatilisation was not accounting for). It was noted that the solvent control in both the acute oral and acute contact study resulted in >10% mortality meaning that the validity criteria (in the OECD TG) were not met. Therefore, it was questioned whether the contact study was also not reliable. The experts at the meeting agreed that neither of the studies should be considered as reliable. This should be amended in the DAR and in the LoEP.</p>	<p>exposure are not considered relevant.</p> <p>Open point RMS to update the DAR to reflect the outcome of the discussion regarding the mitigation addressing the chronic risk to honeybees and reflect the need for further assessment.</p> <p>Open point RMS to update the study summary of Porch (2009) adding additional details of the study design.</p> <p>Open point RMS to put the details of the statistical calculation of the NOEC from the study of Porch in the DAR.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>It was questioned whether there could be exposure following deposition after a volatilisation event. It was noted that this substance is highly volatile and not comparable to other substances which have been shown to deposit in the field margin. It is feasible that a rain event would lead to deposition but in this case there would be dilution.</p> <p>In addition, a study measuring residue concentration on potted plants above and in the vicinity of the tarped soil treated with chloropicrin is available (Bartolomé, 2009). In this study the residue concentration was found to be very low and no residue could be detected 7 days after the treatment. Overall, the experts agreed with the RMS that, for the representative GAP, exposure to honeybees via contact and oral routes is unlikely and therefore a low risk can be concluded.</p> <p>The experts questioned whether the study design of the inhalation study would have resulted in exposure, i.e. where the test substance was ventilated into the chamber with the bees. The methodology description in the DAR was not clear. It was noted that there was analytical confirmation of the a.s. in the air in the bag supplying the chamber with the bees. From the original study report, it seems that the bee chambers were placed in sealed bags containing the test item.</p> <p>An open point was identified for the RMS (IT) to add more details of the study design to the DAR.</p> <p>It was questioned whether the NOEC was sufficiently robust as no statistical analysis was performed. The RMS (IT) performed the statistical assessment during the meeting and confirmed that the NOEC was 12.2 ppm (nominal 10 ppm). The RMS is requested to include the details of the calculation in the DAR.</p> <p>It was noted that the exposure in the study was only 1 hour where other similar substances used a 4 hour exposure period in an acute inhalation study. The RMS IT suggested that the substance would cause an irritating effect (e.g. as with mammals) thus the bees would not be likely to remain in the exposure area for a sustained period of time. It was noted that it would be preferable to have a study where effects are observed to clearly define a NOEC (in the present study, the NOEC was the highest</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>tested level – no observed effect at any tested concentration).</p> <p>The risk assessment for inhalation for honeybees used the air concentration values from the operator exposure assessment and compared with the NOEC for inhalation. The resulting margin of safety was considered to result in a low acute inhalation risk to bees.</p> <p>It was noted that no chronic inhalation toxicity study for honey bees was available and therefore the RMS (UK) proposed that risk mitigation to remove hives during application and the VIF plastic sheeting removal. All experts agreed that the chronic risk to honey bees (in this case defined as exposure of greater than 1 hour as this was tested in the acute assessment) was not resolved.</p> <p>The RMS (IT) suggested that there will be negligible exposure if mitigation measures to remove or cover hives during the application and removal of the VIF sheeting. Some experts noted that there were measurable levels of the a.s. up to 28 days after the treatment. It was therefore questioned whether the mitigation would indeed be sufficient to mitigate the risk. It was suggested that the mitigation could be extended to include restriction for not bringing back the bee hives for a two-weeks period after removal of the VIF sheeting. It was noted that there was no risk assessment to support the suggested waiting period of 2 weeks. Furthermore, it was noted that the adjacent field could contain flowers to attract the bees. The experts noted that it had not been demonstrated that there would be negligible exposure.</p> <p>Overall, the experts agreed that further data would be needed to either exclude chronic inhalation exposure to honeybees or demonstrate a low risk.</p> <p>The RMS (IT) raised the concern that this type of exposure is not covered in the data requirements and available guidance documents. However, the experts agreed that this would not negate the need for an assessment.</p> <p>Open points:</p> <ul style="list-style-type: none">- RMS to invalidate (and remove from the LoEP) both the oral and the contact acute endpoints with bees. RMS to remove the risk assessment and to clarify that these routes of exposure are not considered relevant.- RMS to update the DAR to reflect the outcome of the discussion regarding the	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>mitigation addressing the chronic risk to honeybees and reflect the need for further assessment.</p> <ul style="list-style-type: none"> - RMS to update the study summary of Porch (2009) adding additional details of the study design. - RMS to put the details of the statistical calculation of the NOEC from the study of Porch in the DAR. 	
<p>Experts' consultation 5.5</p> <p>Experts to discuss the chronic risk assessment for soil macro-organisms. In particular experts should discuss:</p> <ul style="list-style-type: none"> - the suitability for the tier 1 endpoint for earthworms (Patnaude, 2013). - the potential for recovery/recolonization of earthworms and other soil macro-organisms based on the available data. <p>See also points 5(70); 5(72); 5(74); 5(77); 5(80); 5(81); 5(82).</p> <p>See reporting table 5(69)</p>	<p>Preliminary comments submitted by MSs before the meeting:</p> <p>DE: we consider that no safe used has been demonstrated in the current risk assessment. We are of the opinion that higher Tier RA needs to demonstrate the recovery of earthworm populations in-field within one year. Demonstrating a potential for recolonization is not enough, especially (i) in the view of the biology of earthworms (i.e. time needed to recolonize an agricultural field might be > 1 year) and (ii) if it has not clearly demonstrated that there is no risk off-field.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>The applicant provided an unusual refined risk assessment for soil macro-organisms. The guidance document on terrestrial ecotoxicology (SANCO 2002) does not contain methodology to assess risk for uses requested for chloropicrin (soil fumigation). However, it is FR opinion that the protection goal, i.e. recovery of earthworm population in-field within one year following chloropicrin application, is not addressed. A field study should have been submitted.</p> <p>SI:</p> <p>We do not consider the tier 1 endpoint for earthworms (Patnaude, 2013) reliable for use in risk assessment. It seems however likely that high variability of exposure is difficult to avoid in a Tier 1 test design. Field studies better reflect the actual GAP and this</p>	<p>Open point RMS to update the DAR and remove the standard chronic endpoint for earthworms (Patnaude, 2013) and the related risk assessment from the LoEP.</p> <p>Open point RMS to check and ensure that it is clear in the LoEP that the two aged residue studies with earthworms (Patnaude, 2015 and Rodgers, 2009b) are not suitable for risk assessment.</p> <p>Open point RMS to highlight in the LoEP, e.g. by means of a footnote, the uncertainties with the tier 1 endpoint (Wainwright, 2004a) for <i>Folsomia</i>.</p> <p>Open point RMS to remove the endpoint and risk assessment performed using the endpoint from the aged residue study</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>justifies in our view to waive a Tier 1 risk endpoint.</p> <p><u>Meeting discussion</u></p> <p><u>Earthworms:</u> It was noted that there were several issues with the available tier 1 reproduction study with earthworms i.e. low measured soil concentrations, large reduction of the reproductive performances at all tested concentrations ($\geq 20\%$). The experts at the meeting agreed with the concerns raised by the RMS (IT) and therefore the study was not considered reliable. The experts noted that if this endpoint was used in a tier 1 risk assessment a high risk would be indicated.</p> <p>Open point for the RMS to update the DAR and remove the endpoint from the LoEP.</p> <p>The experts at the meeting noted that aged residue studies for earthworms are not a standard refinement. The experts agreed with the RMSs (UK and IT) that both of these studies are not sufficient for demonstrating recovery of earthworms.</p> <p>Open point: RMS to check and ensure that it is clear in the LoEP that these studies are not suitable for risk assessment.</p> <p><u>Overall the experts agreed with the RMS that the risk to earthworms cannot be resolved with the available data.</u></p> <p><u>Soil macro-organisms other than earthworms</u> The new RMS (IT) summarised the assessment performed by the original RMS (UK) where a high in-field risk was expected after application but there was the potential for recolonization. The available aged residue studies were used to try to demonstrate the potential for recolonization from external areas which the RMS (UK) agreed. The RMS (UK) acknowledged the uncertainty regarding the exposure in the aged residue studies but overall concluded the studies were sufficiently reliable for the risk assessment.</p>	<p>with <i>Hypoaspis</i> from the DAR and LoEP.</p> <p>Open point RMS to update the DAR to reflect the outcome of the discussion at the experts meeting indicating high risk for soil macroorganisms.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>The RMS (UK) indeed noted that the aged residue studies did not have analytical confirmation of the concentrations in the soil. Furthermore, the aged residue studies with both species comprised a treatment with no ageing. In the case of <i>Hypoaspis</i> the "no aging treatment" (i.e. organisms exposed immediately after the tarp removal – 21 days after the treatment) resulted in a low level of effect. It was questioned whether there was sufficient evidence that the animals were exposed in the study.</p> <p>For the study with <i>Folsomia</i> the "no aging treatment" (tarp removed 4 days after the treatment) resulted in 100% mortality at day 1 indicating that some exposure was achieved. It was questioned whether this was sufficient reason to conclude a reliable endpoint.</p> <p>Some experts noted that the uncertainty about the exposure would concern the tier 1 study with <i>Folsomia</i>, which also did not confirm the analytical concentrations in the soil. It was noted that chemical analysis of the test item is not 'normally' required for tier 1 soil studies; however, owing to the high volatility of this substance it would be preferable if the concentrations in the soil were confirmed. It was further noted that the lids in the tier 1 studies were replaced with ventilated lids after 4 days which was suggested to replicate the field conditions. However, the experts noted that the VIF plastic sheeting should remain for 21 days and so the conditions of the field were not replicated. The experts noted several uncertainties with the study, but it was also acknowledged that testing this type of substance is technically challenging. The experts noted that tier 1 studies should be a simple hazard characterisation and not account for field conditions.</p> <p>Overall, the experts considered that the tier 1 endpoint for <i>Folsomia</i> should be maintained in the LoEP but with a clear footnote explaining the uncertainties with the endpoint (Open point for the RMS).</p> <p>For the aged residue study with <i>Hypoaspis</i> the experts were concerned with the reliability and whether exposure had been achieved in the study.</p> <p>Overall the experts agreed that the study should not be considered as reliable.</p> <p>Open point for the RMS to remove the endpoint and risk assessment performed using the endpoint from the aged residue study with <i>Hypoaspis</i> from the DAR and LoEP.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>For the refined risk assessment for <i>Folsomia</i>, the RMS (IT) was of the opinion that the data were insufficient to conclude recolonization within 1 year. All experts at meeting agreed.</p> <p>Therefore a high risk to soil macroorganisms is indicated.</p> <p>Open point for the RMS to update the DAR to reflect the outcome of the discussion at the experts meeting.</p>	
<p>Experts' consultation 5.6 added by EFSA to allow decision in line with the new ED criteria applicable from 10/11/2018.</p> <p>Experts to discuss the ED potential of chloropicrin</p>	<p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DE: We do not agree with the conclusion that the ED criteria are not met for non-target organism. The provided dataset is insufficient to assess the ED properties of the active substance for non-target organism. According to the ED guidance scenario 2 a(iii) is met: EATS mediated parameters are not sufficiently investigated, generate missing level 2 and 3 information. For non-target organisms a test in line with OECD TG 231 (AMA) and a test in line with OECD TG 229 (FSTRA) needs to be provided to complete the dataset for the assessment.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>FR: FR considers that the available evidence is not sufficient to conclude on the EATS-mediated endocrine activity in non-target organisms with the available dataset. Therefore, FR would recommend following the tiered assessment strategy as shown in the ED guidance document (EFSA_ECHA 2018).</p> <p>In the case of chloropicrin, where no EATS mediated adverse effects were observed based on an limited data set, level 3 tests would be required to complete the current data package:</p> <ul style="list-style-type: none"> • A study in line with the OECD TG 231 (AMA); • A study in line with the OECD TG 229 (FSTRA). 	<p>Further investigation of the ED properties of the substance should be performed. In particular, level 3 tests should be conducted as follows:</p> <ul style="list-style-type: none"> • A test according to OECD TG 229 • A test according to OECD TG 231. <p>In case of positive result/s based on the level 3 tests, additional testing (OECD TG 241 and/or OECD TG 240) might be needed in order to further investigate the adversity.</p> <p>Open point: RMS to align the DAR with the outcome of the discussion.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>SI: ED properties cannot be excluded based on the available data. ED disrupting effects seem however unlikely at chloropicrin dose levels not causing general toxicity as a consequence of local effects.</p> <p><u>Meeting discussion</u> Since the outcome of the ED discussion for humans was not available prior to the ecotoxicology meeting, it was agreed that a post-meeting note would be added with this regard for completeness (see below).</p> <p>According to the RMS, there is no sufficient data to identify the potential ED properties for NTOs. Only one ELS study according to OECD 210 with fish and a reproductive toxicity study with birds were available.</p> <p>Due to the fact that chloropicrin is highly toxic to fish (acute LC50 is equal to the chronic NOEC), a consideration has been given to the possibility of waving the requirement for further testing. Additionally, the experts noted that in order to test potential ED properties, the tested concentration should be low enough to capture the effects (for further information see OECD TG 229). However, taking into account other aspects of the substance (i.e. solubility of the substance), testing seems to be plausible for this substance and therefore the majority of the experts agreed that testing may be required.</p> <p>In line with the ECHA/EFSA guidance, level 3 studies should be required, i.e. AMA (according to OECD TG 231) and a FSTRA (according to OECD 229). In case of positive results, further studies might be needed to further investigate the adversity (OECD TG 241 and/or OECD TG 240).</p> <p>. It is noted that XETA test was suggested by some of the experts instead of the AMA. The RMS confirmed that a literature review was conducted according to the ECHA/EFSA guidance.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>Post-meeting note: The outcome of the Mammalian Toxicology meeting was as follows:</p> <ul style="list-style-type: none">- For the T-modality: the data package is complete, and no T-mediated adversity was observed.- For EAS-modalities: the data package is not complete. However, given the mode of action of the active substance, i.e. local irritant with minimal systemic effects, no further testing is necessary (data waiver).	

REPORT OF PESTICIDE PEER REVIEW MEETING 13

CHLOROPICRIN

Rapporteur Member State: IT

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
September 2019	DE, DL, EL	Preliminary comments submitted by MSs before the meeting have been entered into the discussion table below.

2. Documents submitted for meeting:

Date	Supplier	File Name
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.docx
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.pdf
March 2019	IT	Chloropicrin_DAR_02_Volume_2_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_02_Volume_2_2019_03_19.pdf
March 2019	IT	chloropicrin_DAR_08a_volume3_B6opex_2019_03_19.doc
March 2019	IT	chloropicrin_DAR_08a_volume3_B6opex_2019_03_19.pdf
March 2019	IT	Chloropicrin_DAR_08_Volume_3CA_B-6_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_08_Volume_3CA_B-6_2019_03_19.pdf
March 2019	IT	Chloropicrin_DAR_12_Volume_4_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_12_Volume_4_2019_03_19.pdf
March 2019	IT	Chloropicrin_evaluation table_section 2_2019_03_19.doc
July 2019	IT	Chloropicrin_List of endpoints_all sections_July_2019.doc

Date	Supplier	File Name
March 2019	IT, EFSA	Chloropicrin_reporting table_2018_06_14.doc
March 2019	APPL	ED assessment provided by APPL

3. Documents tabled at the meeting: None

Appendix 1: Discussion table: CHLOROPICRIN

Appendix 1: Discussion Table, Chloropicrin (Fu, In, Ne, Hb)

2. Mammalian Toxicology

Subject	Discussion Pesticide Peer Review Meeting			Conclusions Pesticide Peer Review Meeting																		
<p>Experts' consultation 2.1</p> <p>Genotoxic potential of chloropicrin to be discussed by the experts.</p> <p>See also data requirement in 2(23).</p> <p>See also open point in 2(24).</p> <p>See also comments 2(22), 2(26), 2(27), 2(28), 2(29), 2(30).</p> <p>See reporting table 2(21)</p>	<p>Background information:</p> <table border="1"> <thead> <tr> <th>Study</th> <th>Results</th> <th>Reference</th> </tr> </thead> <tbody> <tr> <td><i>In vitro</i> bacterial gene mutation</td> <td>Positive</td> <td>San & Wagner (1990)</td> </tr> <tr> <td><i>In vitro</i> cytogenetic assay</td> <td>Positive</td> <td>Putman & Morris (1990)</td> </tr> <tr> <td><i>In vitro</i> gene mutation in mammalian cells</td> <td>Negative</td> <td>San & Sigler (1990)</td> </tr> <tr> <td><i>In vivo</i> mouse bone marrow micronucleus test</td> <td>Negative</td> <td>[REDACTED] (2003a)</td> </tr> <tr> <td><i>In vivo</i> unscheduled DNA synthesis</td> <td>Negative</td> <td>[REDACTED] (2003b)</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Ames test: positive with limitations - FR: Ames positive for several strains. TA100 shows borderline results, i.e. reproducible dose-related increases with a maximum value just below the threshold of 2-fold increase. First assay: increase is 1.7-fold. No results without S9 Confirmatory assay: increase is 1.8- and 1.7-fold with and without S9 mix, dose-related - NL/FR: Ames does not include <i>E. coli</i> or TA102 able to detect cross-linking mutagens - AT: Ames test positive → UDS is not appropriate follow up - UK RMS: the available mammalian gene mutation is negative; no further animal 	Study	Results	Reference	<i>In vitro</i> bacterial gene mutation	Positive	San & Wagner (1990)	<i>In vitro</i> cytogenetic assay	Positive	Putman & Morris (1990)	<i>In vitro</i> gene mutation in mammalian cells	Negative	San & Sigler (1990)	<i>In vivo</i> mouse bone marrow micronucleus test	Negative	[REDACTED] (2003a)	<i>In vivo</i> unscheduled DNA synthesis	Negative	[REDACTED] (2003b)	<p>The genotoxic potential of chloropicrin cannot be concluded in the absence of appropriate follow up test <i>in vivo</i> for the observations of gene mutations <i>in vitro</i>.</p>		
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Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>testing is required.</p> <p>- APP: additional position in the revised RAR (p. 99-104)</p> <ul style="list-style-type: none">• <u><i>In vitro</i> gene mutation test in mammalian cells</u> (1990): Additional details/assessment provided in the revised RAR (OP) → reliability? No 24h exposure part• <u><i>In vitro</i> clastogenicity in mammalian cells</u> (Puttman and Morris, 1990) Positive at cytotoxic concentrations• <u><i>In vivo</i> micronucleus assay</u> (██████████, 2003): Negative results, exposure of the bone marrow demonstrated based on ADME data <p>- APP: also significant decrease in the proportion of immature erythrocytes at the HD</p> <p>- AT: only 2000 erythrocytes examined per animal instead of 4000 → acceptable where only negative <i>in vitro</i> results but questionable for follow up of positive <i>in vitro</i> results.</p> <p>- DEP: Based on the updated information and revised text in the DRAR for this endpoint, there is evidence to indicate that chloropicrin is mutagenic in bacteria and clastogenic in mammalian cells. The <i>in vitro</i> mouse lymphoma mutagenesis assay shows also negative results but with limitation, i.e. no 24-h exposure to confirm the negative results. This limitation should be reflected in Vol. 1, B.2.6.4, where it is currently stated that "<i>clear negative results were seen in an <i>in-vitro</i> mammalian cell gene mutation assay</i>".</p> <p><i>In vivo</i> results showed no clastogenicity in mice (micronucleus test). Exposure of the bone marrow to chloropicrin was assumed by extrapolation of rat ADME data showing that chloropicrin entered systemic circulation and reached the bone marrow.</p> <p>The rat liver UDS assay also showed negative outcomes. Even though it was conducted in compliance with an (at that time) acceptable test guideline, the limitations of this test (lack of specificity and assessment of liver tissue) have been brought up in discussion (e.g. see EFSA 2017 publication on "Clarification of some aspects related to genotoxicity assessment"). These limitations should be considered now.</p> <p>Even though the existing overall data seem to indicate the lack of genotoxic potential <i>in</i></p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p><i>vivo</i>, there is some uncertainty for this endpoint. One suggestion for reducing the level of uncertainty is to perform <i>in silico</i> assessment (QSAR, read across) to provide further support for the evaluation of genotoxicity. This should be discussed in the meeting.</p> <p>- ELP: The RMS/co-RMS evaluation is supported.</p> <p>Chloropicrin in the presence of metabolic activation may cause GC base substitution in <i>S. typhimurium</i> strains (TA98 & RSJ100). Ames test is considered to be a good predictor of rodent carcinogenicity with approx. 87.4% positive predictivity (EFSA, 2011).</p> <p>Chloropicrin was clearly negative in carcinogenicity studies performed in two different rodent species, thereby lowering the concern raised by the positive Ames test.</p> <p>Moreover, when tested for forward gene mutations in mammalian cells chloropicrin appeared to be negative.</p> <p>Regarding the induction of chromosomal aberrations, it is noted that positive results were only observed <i>in vitro</i> in the absence of metabolic activation and at doses producing significant toxicity while this is not confirmed <i>in vivo</i>. Acute inhalation toxicity studies have shown that chloropicrin is causing necrosis and degeneration of epithelium with ulceration accompanied by oedema. Since chloropicrin induces local irritation, ulceration and necrosis at site of contact, the possibility for local genotoxicity <i>via</i> the oxidation of DNA may be suspected. Oxidative DNA damage following administration in the drinking water to mice was also observed.</p> <p>Oxidative DNA damage is an important general indicator of intracellular oxidative stress capable of reaching the nucleus that would reflect a specific mechanism of carcinogenesis. Oxidative damage caused by chloropicrin does not lead to carcinogenic effects.</p> <p>No further testing is proposed.</p> <p>Peer Review Meeting 13:</p> <p>Positive results were observed in the Ames test and in the <i>in vitro</i> chromosome aberration assay. The RMS indicated that the substance did not show carcinogenic and reproductive toxicity potential. Some of the metabolites showed a similar pattern (positive results in the Ames test for the metabolite DCNM).</p> <p>One expert noted that the Ames test showed some limitations (some strains were not</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>tested), nevertheless positive results were observed. The results in the Ames test were more clear with metabolic activation. Other expert noted that some published Ames tests showed also positive results. The applicant performed the <i>in vivo</i> UDS test to follow up the positive results <i>in vitro</i> for gene mutation. The <i>in vivo</i> micronucleus test negative, bone marrow exposure was considered as demonstrated considering the toxicokinetic data on chloropicrin. Published literature indicated similar results to regulatory studies (positive results in the Ames test and in the <i>in vitro</i> Comet assay).</p> <p>The RMS recognised the low sensitivity of the <i>in vivo</i> UDS test. Considering the toxicological mode of action of chloropicrin (local irritant effects are expected <i>in vivo</i>, and inhalation is the main route of exposure), and the absence of carcinogenic potential by inhalation, the RMS concluded that chloropicrin is unlikely to be genotoxic <i>in vivo</i>.</p> <p>One expert noted that a longer duration is missing in the available gene mutation assay. Some experts considered that no sufficient information is available to conclude on the genotoxic potential of chloropicrin, since an appropriate <i>in vivo</i> follow up is not available and the <i>in vitro</i> gene mutation assay in mammalian cell has some limitations.</p> <p>One expert noted that extrapolation of toxicokinetic data between rat and mice should be further justified. The RMS did not expect differences between species regarding toxicokinetic properties. The RMS also considered that there are clinical signs indicating systemic exposure. The ratio % PCE/(PCE+NCE) is decreased at the top dose level indicating bone marrow exposure.</p> <p>The RMS noted that the data requirements applicable to chloropicrin are the old data requirements (<i>in vivo</i> UDS test or mouse spot test would be required). It is noted that the SC Opinion was available at the time of submission.</p> <p>One expert proposed a QSAR analysis, however experimental data are available. Some experts would consider that if a new <i>in vivo</i> genotoxicity test is required it should be submitted for confirmation (a combined Comet and micronucleus test by inhalation might be suggested with the lung, liver and nasal tissues in line with DMDS). However, confirmatory data are up to risk managers. A conclusion should be drawn on the basis of the available data.</p> <p>Slight majority of the experts considered that a final conclusion cannot be drawn on the genotoxicity of chloropicrin since some uncertainties remains: i.e. lack of appropriate</p>	

Subject	Discussion Pesticide Peer Review Meeting				Conclusions Pesticide Peer Review Meeting																																
	follow up <i>in vivo</i> for gene mutation <i>in vitro</i> .																																				
Experts' consultation 2.2 Long term inhalation mouse study to be discussed by the experts. See also comment 2(33). See reporting table 2(32)	Background information: <table border="1"> <thead> <tr> <th rowspan="2">Study</th> <th>NOAEL</th> <th>LOAEL</th> <th rowspan="2">Effects at LOAEL</th> <th rowspan="2">Reference</th> </tr> <tr> <th>(mg/kg bw/d or ppm)</th> <th></th> </tr> </thead> <tbody> <tr> <td>Oral 104 weeks; SD CD rat 0, 0.1, 1, 10 mg/kg bw/day</td> <td>Chronic toxicity M and F: 0.1 mg/kg bw/day</td> <td>Chronic toxicity M and F: 1 mg/kg bw/day</td> <td>Chronic: Histopathology of the non-glandular forestomach (hyperplasia and hyperkeratosis)</td> <td>[REDACTED], R.W. (1995)</td> </tr> <tr> <td>Gavage</td> <td>Carcinogenicity: 10 mg/kg bw/day</td> <td>-</td> <td>No carcinogenicity at highest dose level</td> <td></td> </tr> <tr> <td>Inhalation 107 weeks; CD rat Whole body 6h/day 5d/wk, 0.1, 0.5, 1 ppm</td> <td>M and F: Chronic toxicity NOAEC 0.1 ppm</td> <td>M and F: Chronic toxicity LOAEC 0.5 ppm</td> <td>Chronic: ↑ Mortality and ↓ bodyweight gain. At highest dose level, adverse nasal histopathology (rhinitis)</td> <td>[REDACTED], H.D. et al., (1995)</td> </tr> <tr> <td>Inhalation 78 weeks (18 month); CD-1 mouse</td> <td>Carcinogenicity: 1 ppm</td> <td>-</td> <td>No carcinogenicity</td> <td></td> </tr> <tr> <td></td> <td>M and F: Chronic toxicity NOAEC 0.1 ppm</td> <td>M and F: Chronic toxicity LOAEC 0.5 ppm</td> <td>Chronic: adverse nasal histopathology (rhinitis, olfactory hyaline inclusions and epithelium atrophy), decreased body weight (gain), increased lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates) ↓ bodyweight and</td> <td>[REDACTED], H.D. et al., (1995)</td> </tr> </tbody> </table>				Study	NOAEL	LOAEL	Effects at LOAEL	Reference	(mg/kg bw/d or ppm)		Oral 104 weeks; SD CD rat 0, 0.1, 1, 10 mg/kg bw/day	Chronic toxicity M and F: 0.1 mg/kg bw/day	Chronic toxicity M and F: 1 mg/kg bw/day	Chronic: Histopathology of the non-glandular forestomach (hyperplasia and hyperkeratosis)	[REDACTED], R.W. (1995)	Gavage	Carcinogenicity: 10 mg/kg bw/day	-	No carcinogenicity at highest dose level		Inhalation 107 weeks; CD rat Whole body 6h/day 5d/wk, 0.1, 0.5, 1 ppm	M and F: Chronic toxicity NOAEC 0.1 ppm	M and F: Chronic toxicity LOAEC 0.5 ppm	Chronic: ↑ Mortality and ↓ bodyweight gain. At highest dose level, adverse nasal histopathology (rhinitis)	[REDACTED], H.D. et al., (1995)	Inhalation 78 weeks (18 month); CD-1 mouse	Carcinogenicity: 1 ppm	-	No carcinogenicity			M and F: Chronic toxicity NOAEC 0.1 ppm	M and F: Chronic toxicity LOAEC 0.5 ppm	Chronic: adverse nasal histopathology (rhinitis, olfactory hyaline inclusions and epithelium atrophy), decreased body weight (gain), increased lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates) ↓ bodyweight and	[REDACTED], H.D. et al., (1995)	For the 104-week rat study by gavage, the <ul style="list-style-type: none"> - NOAEL for chronic toxicity is 0.1 mg/kg bw per day based on adverse findings in the non-glandular forestomach (hyperplasia and hyperkeratosis) - NOAEL for carcinogenicity is 10 mg/kg bw per day (high dose tested) For the 107-week rat study by inhalation, the <ul style="list-style-type: none"> - NOAEL for chronic toxicity is 0.1 ppm based on increased mortality and decreased body weight gain - NOAEL for carcinogenicity is 1 ppm (high dose tested) For the 78-week mouse study by inhalation, the <ul style="list-style-type: none"> - NOAEL for chronic toxicity is 0.1 ppm based on nasal findings (rhinitis, olfactory hyaline inclusions and epithelium atrophy), decreased body weight (gain), increased lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates)
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	M and F: Chronic toxicity NOAEC 0.1 ppm	M and F: Chronic toxicity LOAEC 0.5 ppm	Chronic: adverse nasal histopathology (rhinitis, olfactory hyaline inclusions and epithelium atrophy), decreased body weight (gain), increased lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates) ↓ bodyweight and	[REDACTED], H.D. et al., (1995)																																	

Subject	Discussion Pesticide Peer Review Meeting					Conclusions Pesticide Peer Review Meeting						
	<table border="1" data-bbox="478 306 1518 652"> <tr> <td data-bbox="478 306 646 620">Whole body 0, 0.1, 0.5, 1 ppm</td><td data-bbox="646 306 878 620"></td><td data-bbox="878 306 1064 620"></td><td data-bbox="1064 306 1372 620">bodyweight gain, ↑ lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates)</td><td data-bbox="1372 306 1518 620"></td></tr> <tr> <td data-bbox="478 620 646 652"></td><td data-bbox="646 620 878 652">Carcinogenicity: 1 ppm</td><td data-bbox="878 620 1064 652">-</td><td data-bbox="1064 620 1372 652">No carcinogenicity at highest dose level</td><td data-bbox="1372 620 1518 652"></td></tr> </table> <ul style="list-style-type: none"> • <u>78-week inhalation mouse</u>: additional tabulated data - FR/EFSA: increased incidence of lung adenomas in M and F → HCD ? relevance for humans ? Also increased incidence, stat sign and dose-related, of lung peribronchial lymphocyte infiltration for both M and F, associated with bronchiectasis from the low dose level → LOAEC could be 0.1 ppm. - APP: no HCD from the performing laboratory. - RMS: peribronchial lymphocyte infiltration in isolation is not sufficiently robust to base a LOAEC on. It has been used to support a LOAEC at 0.5 ppm based on clearer markers of respiratory tissue damage. No dose-response in carcinomas or adenomas. - EFSA: need for normalisation for 5 days/7 days of exposure for conversion from ppm to mg/kg bw per day <p>DEP: With regard to incidences and historical control data (HCD) of tumour formation, we agree with the arguments brought forward by RMS and applicant. However, the peribronchial lymphocytic infiltration seems to be treatment-related in both sexes. Although this finding might be a common finding in long-term mouse studies or could be interpreted as a response to inhalation of an (irritating) xenobiotic, its incidence was clearly increasing with a concentration-response relationship. This effect is indicative of a chronic inflammatory process, which could be regarded as adverse, but does not</p>	Whole body 0, 0.1, 0.5, 1 ppm			bodyweight gain, ↑ lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates)			Carcinogenicity: 1 ppm	-	No carcinogenicity at highest dose level		<p>- NOAEL for carcinogenicity is 1 ppm (high dose tested).</p> <p>New open point: RMS to correct the statistical significance of the peribronchial lymphocytic infiltration at the low dose level in a revised DAR.</p>
Whole body 0, 0.1, 0.5, 1 ppm			bodyweight gain, ↑ lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates)									
	Carcinogenicity: 1 ppm	-	No carcinogenicity at highest dose level									

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	<p>seem to be an immunologic response. Whether 0.1 ppm should be considered rather as the LOAEC than the NOAEC depends on the adversity of this reactive finding, but without HCD for this effect, it is not possible to conclude that this is due to a "<i>non-specific inflammatory lesions which occurs fairly commonly in mice</i>".</p> <p>ELP: The RMS assessment is agreed. It is considered unlikely that the low incidence of peribronchial lymphocyte infiltrates at the low dose level (0.1 ppm) is of toxicological significance since there is no treatment-related increase in airway disease.</p> <p>Peer Review Meeting 13:</p> <p>The experts agreed with the conclusion of the RMS considering the rat long-term toxicity studies.</p> <p>The experts discussed the relevance of peribronchial lymphocytic infiltration and lung tumours in the 78-week mouse study by inhalation.</p> <p>Regarding <u>lung tumours</u> the RMS considered that this finding was not treatment-related since no clear dose-response was observed. One expert noted that a dose-related increased incidence for adenoma is observed in females. No dose-related increase was observed for carcinoma. The majority of the experts considered that chloropicrin did not show carcinogenic potential (also supported by the absence of carcinogenic findings in the long-term rat toxicity studies).</p> <p>Regarding the finding of <u>peribronchial lymphocytic infiltration</u> one expert considered that the low dose level should be the LOAEC. One expert noted that an increase in lung weight (females only) and bronchiectasis were also observed from the low dose level. The RMS considered that these effects at the low dose level were treatment-related but not adverse. Historical control data are not available. A slight majority of experts supported the RMS opinion.</p> <p>The agreed NOAEC for long-term toxicity is 0.1 ppm as proposed by the RMS. The agreed NOAEC for carcinogenicity is the top dose level.</p> <p>New open point</p> <p>RMS to correct the statistical significance of the peribronchial lymphocytic infiltration at the low dose level in a revised DAR.</p>	

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<p>Experts' consultation 2.3 Mortality in the multigeneration rat study to be discussed by the experts. See also comment 2(35). See reporting table 2(34)</p>	<p>Background information: <u>Multigeneration rat study:</u> mortality Proposed maternal NOAEC: 1.0 ppm based on adverse pulmonary inflammation in females (F0) at the high dose Proposed offspring/reproductive NOAEC: 1.5 ppm based on the lack of adverse effects</p> <p>- EFSA: During the first peer review, based on the tables B.6.6.1-3 and B.6.6.1-5, the increased incidences at the HD of animals who died or were euthanised in extremis was considered potentially treatment-related.</p> <p>→ RMS: No deaths in F1 generation to support a consistent effect, the deaths occurred at a very low frequency, including in the ctrl group. In addition, there were no indications of respiratory distress which would be expected (similar to other inhalation studies in which chloropicrin vapour induced mortality) to support the mortality being a test substance related effect.</p> <p>- FR: Considering the observed mortality in several other studies, the deaths observed at HD in the 2G study should be considered as treatment-related. No impact on the NOAEC.</p> <p>DE^P: It cannot be excluded that the few deaths in parental animals were not treatment-related. This would reflect the severe toxicity of this substance. However, the parental NOAEC of 1.0 ppm is agreed.</p> <p>EL^P: Considering that the mortality incidence noted at the F0 animals was low while no mortality occurred at F1 animals, the RMS conclusion that this is not a treatment related effect is supported.</p> <p>It is noted that in case of F0 female animals, mortality was noted also at the control group.</p> <p>Peer Review Meeting 13: The 2-generation study by inhalation was well conducted. The experts discussed whether mortality observed at the high dose (F0 males and females) should be considered treatment related. The RMS did not consider it treatment related, since it has</p>	<p>For the multigeneration rat study, the</p> <ul style="list-style-type: none"> - parental NOAEC is 1.0 ppm based on adverse pulmonary inflammation in females; - offspring and reproductive NOAEC is 1.5 ppm (high dose tested).

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	<p>been observed in the control group in a similar range and it was not observed in the second generation. In addition, it was not accompanied by clinical signs. The RMS considered that it should not be included as an effect triggering the NOAEC.</p> <p>The RMS proposed a:</p> <ul style="list-style-type: none"> • maternal NOAEC: 1.0 ppm based on adverse pulmonary inflammation in females (F0) at the highest dose. • offspring/reproductive NOAEC: 1.5 ppm based on the lack of adverse effects on reproductive or offspring indices. <p>All experts agreed with the proposed NOAEC while only the majority agreed that the relevant effects triggering the NOAEC should exclude mortality.</p>	
<p>Experts' consultation 2.4</p> <p>Maternal and developmental toxicity in the rabbit developmental toxicity study with chloropicrin to be discussed by the experts.</p> <p>See reporting table 2(37)</p>	<p>Background information:</p> <ul style="list-style-type: none"> • <u>Rat developmental study</u> (inhalation): Agreed maternal NOAEC 0.4 ppm based on decreased BW and FC Agreed developmental NOAEC 0.4 ppm based on delayed ossification and total skeletal variations - EFSA: conversion from ppm to systemic levels (in mg/kg bw per day) should be described. • <u>Rabbit developmental study</u> (inhalation): additional tabulated results for lungs Proposed maternal NOAEC 0.4 ppm based on deaths, clinical signs, necropsy findings (pulmonary pathology), reduced body weight (gain) and food consumption Proposed developmental NOAEC 1.2 ppm based on reduced foetal bodyweight at 2.0 ppm - FR: developmental NOAEC should be 0.4 ppm based on abortions → RMS: abortions not relevant because observed in the presence of significant (50%) maternal mortality at the HD and in a single dam at the mid dose - DEP: In the █ (1993) developmental toxicity rabbit study, considering the presence of marked maternal toxicity (e.g. with half of the does dead), the abortions at the highest concentration level of 2 ppm are likely to be related to the poor health status of 	<p>For the rat developmental toxicity study, the</p> <ul style="list-style-type: none"> - maternal NOAEC is 0.4 ppm based on decreased body weight and food consumption; - developmental NOAEC is 0.4 ppm based on delayed ossification and increased incidence of total skeletal variations. <p>For the rabbit developmental toxicity study, the</p> <ul style="list-style-type: none"> - maternal NOAEC is 0.4 ppm based on mortalities, clinical signs, necropsy findings (lungs), reduced body weight (gain) and food consumption; - developmental NOAEC is 0.4 ppm based on increased foetus mortality and abortions.

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	<p>the does and most likely do not mask teratogenic findings. However, in general, it is questionable if this highest concentration is suitable to evaluate for developmental effects since the number of viable foetuses and litters were much lower than in the other concentration groups. Nevertheless, given the existing data, a developmental NOAEC of 1.2 ppm for this study is supported.</p> <p>- ELP: It is agreed to set the developmental NOAEC at 0.4 ppm. However, the increased incidence of abortions at doses of severe maternal toxicity (Table B.6.6.2.2-3 & B.6.6.2.2-4a, page 174) should pose no concern regarding classification of chloropicrin as developmental toxicant.</p> <p>Peer Review Meeting 13: For the rabbit developmental toxicity study, the experts discussed the high mortality in dams (2/20 at 1.2 ppm and 10/20 at 2.0 ppm, the high dose) and the abortions. The RMS considered that the study was acceptable despite the high mortality observed in the dams. Taking into account the narrow dose-spacing between the mid concentration (1.2 ppm) and the high concentration (2.0 ppm), a new developmental study (with a high concentration group between 1.2 and 2.0 ppm) would not add relevant information for the risk assessment. The RMS concluded that the available information is sufficient to establish NOAECs for both maternal and developmental toxicity.</p> <p>The RMS proposed:</p> <ul style="list-style-type: none">maternal NOAEC: 0.4 ppm based on mortality, clinical signs including respiratory distress, pulmonary pathology, bw loss, decreased bw gain and low food consumption.developmental NOAEC: 1.2 ppm based on decreased foetal bodyweight. <p>Regarding the relevance of abortions, the RMS considered that they were found in presence of significant maternal mortality in 2 dams at the high concentration (2.0 ppm) and in a single dam at the mid-dose (1.2 ppm). In a weight of evidence perspective, the historical control data show that abortions can occur in control groups with a maximum</p>	

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	<p>frequency of 2, which is similar to chloropicrin (1 at 1.2 ppm and 2 at 2.0 ppm). Therefore the RMS concluded that the abortions are not relevant to set the developmental NOAEC.</p> <p>For the abortions, the experts noted that only the maximum incidence was reported for HCD, therefore an overall picture could not be drawn. For foetus mortality no HCD are reported in the DAR.</p> <p>Abortion was observed at the same concentrations as maternal toxicity and it might not be considered a specific developmental toxicity effect. One expert noted that a low number of litters is observed at the top dose level, this could mask an effect that was observed at the mid dose level (2 foetus mortality in 2 litters). Some experts proposed a developmental NOAEC of 0.4 ppm based on foetus mortality and abortion.</p> <p>The experts noted that high toxicity was noted at the top dose level, and therefore it is difficult to assess properly the dose response toxicity.</p> <p>The majority of experts agreed on a developmental NOAEC of 0.4 ppm based on foetus mortality and abortions. The RMS did not agree.</p>	
<p>Experts' consultation 2.5</p> <p>Neurotoxic potential of chloropicrin to be discussed by the experts.</p> <p>See reporting table 2(38)</p>	<p>Background information:</p> <p>Additional position of the applicant in the revised RAR (p. 183-185)</p> <ul style="list-style-type: none"> - NL: a waiver is included indicating that no effects indicative of neurotoxicity were observed in the database. However, in some of the short term studies effects were mentioned that might be related to neurotoxicity (e.g. decreased activity and tremor in the 8-week dog study; impaired limb function in the 90-day rat study) → APP: the isolated clinical signs are seen at high dose levels, associated with marked general toxicity and are not indicative of neurotoxicity. → RMS: the overall database of effects across a range of species support the conclusion that these infrequently noted signs are due to general toxicity, not a neuro-active effect? - DEP: We do not completely support the current argument regarding the absence of neurotoxicity. <p>Most of the repeated dose toxicity studies conducted observations to note any clinical signs, which is one component for assessing neurotoxicity. However, none of the</p>	<p>Based on the available data chloropicrin is unlikely to be neurotoxic.</p>

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	<p>mentioned studies performed functional tests, e.g. sensory reactivity, limb grip strength and assessment of motor activity. Some of the studies did report evidence of reduced motor activity (████, 1996b with dogs at 10 and 30 mg/kg bw/day; █████, 1987 with rats at 0.37 ppm onwards). The studies with negative findings are considered not comparable due to different species, route of exposure, dose/concentration levels, or exposure period.</p> <p>It is consistently mentioned in DRAR that histopathology revealed no effects in the nervous system, but this statement is too general. For example, reduced motor activity could be effects occurring in the motor cortex or cerebellum of the brain, so histopathology should have been assessed for these brain regions. Without further description to the histopathology assessment, it is not possible to unequivocally conclude that the neurological effects are secondary to general toxicity.</p> <p>This point should be discussed further in the meeting.</p> <p>ELP: The RMS assessment is supported. Based on the available data chloropicrin is unlikely to be neurotoxic.</p> <p>Peer Review Meeting 13:</p> <p>As a starting point, it was noted that the chemical structure of chloropicrin is not related to organo-phosphate or carbamate compounds (well-known neurotoxicants).</p> <p>Effects potentially related to specific neurotoxicity of chloropicrin were observed in the 8-week dog study (decreased activity and tremor) and in the 90-day rat study (impaired limb function). The RMS considered that these indications of neurotoxicity were rather in line with general toxicity and/or local toxicity resulting from the irritant effects of chloropicrin. In addition, histopathology did not reveal any effects on the nervous system.</p> <p>One expert questioned how histopathological examination was done for neurotoxicity and highlighted that some parameters were not specifically investigated (e.g. brain morphometry).</p> <p>The RMS however concluded that further specific investigation of neurotoxicity is not considered necessary.</p> <p>One expert noted that none of the mentioned studies performed functional tests, e.g. sensory reactivity, limb grip strength and assessment of motor activity. The expert noted</p>	

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	<p>the main route of exposure is inhalation and there is limited information on whether neurotoxicity has been sufficiently investigated in the available inhalation studies.</p> <p>The RMS noted that local effects are the main/leading concern for the substance and will limit systemic and neurotoxicity effects.</p> <p>Overall, the available toxicity studies do not raise concerns for specific neurotoxicity, some uncertainties would remain regarding the lack of functional test in the available toxicity studies. However, the experts noted that concentrations showing clinical signs that may be related to neurotoxicity are above the NOAEC in the long-term toxicity studies.</p> <p>The experts agreed that further specific investigation of neurotoxicity is not considered necessary and that chloropicrin is unlikely to be neurotoxic.</p>	
<p>Experts' consultation 2.6</p> <p>Human sensory irritation data and testing with chloropicrin to be discussed by the experts.</p> <p>See also data requirement in 2(40).</p> <p>See reporting table 2(39)</p>	<p>Background information:</p> <ul style="list-style-type: none"> • <u>Human Sensory Irritation study</u> (████, 2004) <p>- FR: not clear whether the concentration of 75 ppb could be NOAEC. In phase 2 results, effects were noted at 75 ppb. → RMS: at 75 ppb in phase 2, the 'volunteers' responses over time did not cross the confidence threshold which determined whether or not the subject perceived very mild ocular irritation. So although the curve at 75 ppb has a positive gradient, it flattens out before it crosses the level at which there is confidence in the subjective perception of the existence of any ocular symptoms. Therefore 75 ppb is considered the NOAEC.</p> <ul style="list-style-type: none"> • <u>BMC approach to Human Sensory Irritation data</u> (████, 2007) <p>- FR: please detail how the BMCL10 was derived → RMS: additional information in an updated DAR</p> <p>- DEP: EFSA published a guidance document on the use of the benchmark dose (BMD) approach in risk assessment (last updated in 2017), which presents how the BMD (or benchmark concentration) approach should be presented, e.g. programme used, assumptions made, data used, etc.</p> <p>Without further presentation of the BMD approach, such as data fitted in the various</p>	<p>According to Regulation (EC) No 1107/2009, <i>the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans.</i></p> <p>Consequently, the human sensory irritation study (████, 2004) was not further considered for the assessment of chloropicrin.</p>

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	<p>models, AIC, p-values, in the DRAR, it cannot be clearly determined whether the BMCL₁₀ was correctly calculated or can be considered as reliable.</p> <ul style="list-style-type: none">- ELP: The proposed NOAEC for eye irritation, i.e. 0.075 ppm, is supported. <p>Peer Review Meeting 13:</p> <p>The conclusions drawn by the RMS on the human sensory irritation study (████, 2004) were:</p> <ul style="list-style-type: none">- thresholds have been identified for odour pungency and eye irritation. Eye irritation found to be a more uniform human response that increases sharply with exposure- ocular irritation sub-threshold exposures may become detectable in a longer exposure but the perception does not increase markedly- 1-hour exposures at 100 and 150 ppb did not cause exposure-related signs in pulmonary function testing, nasal and ocular cytology- concentration of 0.075 ppm is not likely to cause noticeable sensory irritation in general population and is not a serious health threat: mild, reversible ocular irritation, a transient effect without long-term carry-over. <p>In conclusion, the RMS considered 75 ppb the study NOAEC for sensory irritation in humans after chloropicrin exposure based on ocular irritation findings.</p> <p>The experts noted that according to the EU Regulation (EC) No 1107/2009, human studies on their own should not be used for the risk assessment of PPP in the EU:</p> <p><i>(13) For ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human 'no observed effect level' of an active substance. Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.'</i></p> <p>The RMS considered the study well conducted and ethically valid. The experts noted that this type of studies is not conducted to international/OECD guideline (not available). Lack of reproducibility of the results might be a concern for some experts. It is not mentioned whether the study is GCP compliant.</p>	

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	Overall, most of the experts were not able to conclude on the scientific acceptability of the study and considering the restrictions of the Regulation 1107/2009 with regard to the use of human studies, the results were not further discussed.	
Experts' consultation 2.7 Experts to discuss the endocrine disruption potential of chloropicrin. See reporting table 2(41)	Background information: APP: Chloropicrin has not been screened for ED endpoints with ToxCast. The literature search did not reveal any publications demonstrating ED properties. Regulatory studies did not show adverse effects on endocrine organs. - DE^P: The ED assessment from RMS and the applicant are not totally in line with the ED guidance template format and the evaluation is difficult to follow. The T modality seems sufficiently investigated, but it is not clear if there were effects in the thyroid weight as this information was not included in the Appendix E, Excel table. The ToxCast Models for ER and AR are available (and are negative for agonist and antagonist activity) but were not included in the assessment. By the UK RMS description, the database is limited, but overall we agree that there were no findings in these <i>in vivo</i> studies indicating an adverse effect on the endocrine system. We also consider that in case of only local irritancy with minimal systemic toxicity profile, further <i>in vitro</i> and <i>in vivo</i> testing are not justified and it will not be able to provide meaningful information with the possibility of waiving the ED assessment. - EL^P: Chloropicrin has been <i>Inactive</i> in all available ToxCast assays (EDSP21; https://comptox.epa.gov/dashboard/dsstoxdb/results?search=DTXSID0020315#invitro-b-bioassays-toxcast-data) while there are no ER-model scores (https://comptox.epa.gov/dashboard/dsstoxdb/results?search=DTXSID0020315#bioactivity-toxcast-models) We agree with the RMS that generation of further <i>in vitro</i> and <i>in vivo</i> testing is not needed. In accordance with the ED Guidance, further testing for this purpose is not technically possible.	T-modality: the data package is complete and no T-mediated adversity was observed. EAS-modalities: the data package is not complete. However, given the mode of action of the active substance, i.e. local irritant with minimal systemic effects, no further testing is necessary (data waiver).

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	<p>Peer Review Meeting 13:</p> <p><u>T-modality</u>: According to the RMS the data package for the T-modality is complete and no T-mediated adversity was observed. The experts agreed.</p> <p><u>EAS-modalities</u>: According to the RMS the data package for EAS-modalities is not complete. However, given the mode of action of the active substance, i.e. local irritant with minimal systemic effects, the RMS concluded that further testing is not considered necessary and justifiable. The RMS proposed data waiver. The experts agreed with the data waiver since local irritant properties are the leading effect/critical effect of the substance. The majority of experts agreed.</p>	
<p>Experts' consultation 2.8</p> <p>Toxicological profile of the metabolite DCNM to be discussed by the experts.</p> <p>See also data requirements in 2(42) and 2(45).</p> <p>See reporting table 2(43)</p>	<p>Background information:</p> <p><u>Metabolite DCNM</u></p> <p>Also impurities: [REDACTED] + DCNM at max 1 g/kg</p> <p>Previous peer review: insufficient info to conclude on tox relevance</p> <p>- FR/EFSA: "DCNM was found at levels of approximately 20% of the parent". Please justify.</p> <p>→ RMS: 20% was concluded by the previous peer review</p> <p>→ DR: further assessment of DCNM in rat metabolism</p> <p>- FR: DCNM should be considered relevant considering the uncertainties on the genotoxicity profile of chloropicrin and the lack of data for acute oral and inhalation.</p> <p>→ APP: Chloropicrin is not genotoxic and this covers the hazard of DCNM (major metabolite). DCNM is not a relevant GW metabolite. Based on the transient nature of DCNM, and similarity to its parent compound, its toxicological nature and the fact that it occurs as a 20% dechlorination breakdown product of chloropicrin, it is not of more concern than the parent.</p> <p>→ RMS: absence of genotoxic potential can be concluded for chloropicrin. Oral toxicity of DCNM is addressed by the parent, but the same cannot be done for inhalation toxicity, hence why the RMS has concluded that DCNM is a relevant metabolite.</p>	<p><u>Metabolite DCNM</u>:</p> <p>Based on indications of a genotoxic potential in the published literature, no conclusion can be drawn for the metabolite DCNM.</p> <p>Data gap</p> <p>A full assessment of the relevance and reliability of the published studies with results of toxicological testing for the metabolite DCNM should be provided.</p> <p>Data gap</p> <p>Further assessment of the toxicological profile (first step: genotoxicity, second step: other toxicological endpoints in view of deriving reference values for consumers) of the metabolite DCNM should be provided.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>- EFSA: the conclusion that DCNM is less toxic than chloropicrin should be supported by more robust data → APP: DCNM is a major metabolite of chloropicrin and is covered by tox studies with chloropicrin.</p> <p>- AT: No studies on DCNM were provided but publicly available data. These data should be further assessed for their relevance and reliability, and if these criteria are fulfilled, they should be summarised in a robust study summary.</p> <p>- DE^P: We support the concerns about DCNM (e.g. considering the uncertainty of genotoxicity potential of chloropicrin) as brought forward by EFSA, France and Austria. For now, DCNM is considered a relevant metabolite.</p> <p>- EL^P: Based on the available data it is agreed that the metabolite DCNM can be considered of similar toxicity as the parent compound.</p> <p>Peer Review Meeting 13: The RMS explained that it could be a groundwater metabolite (above 0.1 ug/L; under discussion by fate experts). In the ADME study (by oral route) the main route of excretion of the parent active substance is expired air. The substance was extensively metabolized and converted into polar metabolites. According to the RMS, DCNM accounted for at least 10% (considering the pathway and the amount of polar metabolites). However, polar metabolites were not clearly identified (likely to be DCNM and MCNM). According to the RMS the metabolite is covered by the parent. According to the available data, DCNM is 6 times less acutely toxic to mice compared to parent (dehalogenation is associated with decreased toxicity, by intraperitoneal administration). Other <i>in vitro</i> assays, including <i>in vitro</i> genotoxicity assays showed that the metabolite is qualitatively similar but less potent compared to the parent. One expert considered that further data on toxicokinetic should be available for the main route of exposure, i.e. inhalation, to confirm whether it is a major metabolite (since reproductive toxicity studies were performed by the inhalation route).</p>	

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	<p>If the guidance on groundwater metabolites is followed, as a first step the genotoxicity of DCNM has to be addressed, i.e. an <i>in vitro</i> test battery should be provided. The RMS indicated that regulatory studies with DCNM are not available. According to available published genotoxicity studies, DCNM showed positive results in the Ames test and in the <i>in vitro</i> Comet assay. Provided that these studies are relevant and reliable (see data gap below), the metabolite DCNM could be considered as a relevant groundwater metabolite.</p> <p>Regarding the second step of the guidance on GW metabolites, the general toxicity and consideration for classification and labelling of the parent compound (chloropicrin) should also be taken into account once the genotoxicity potential is clarified.</p> <p>Overall, most experts agreed that it could not be concluded either if DCNM can be considered covered by the parent or on its toxicological profile (including genotoxic potential and setting of reference values). The experts also noted that the genotoxic potential of the parent should be clarified.</p> <p>Data gap A full assessment of the relevance and reliability of the published studies with results of toxicological testing for the metabolite DCNM should be provided.</p> <p>Data gap Further assessment of the toxicological profile (first step: genotoxicity, second step: other toxicological endpoints in view of deriving reference values for consumers) of the metabolite DCNM should be provided.</p>	
Experts' consultation 2.9 Reference values for chloropicrin (ADI, ARfD, AOEL, AAOEL) to be discussed by the experts.	<p>Background information: <u>Acceptable Daily Intake (ADI):</u> Proposed ADI is 0.001 mg/kg bw per day based on the 2-year rat study (gavage), UF100 - FR: agreed, also covers the results of the 2-yr rat study by inhalation. - EL: supported</p> <p><u>Acute Reference Dose (ARfD):</u></p>	Since the genotoxic potential of chloropicrin could not be concluded based on the available data, the proposed reference values are considered informative and will not be mentioned in the EFSA conclusion.

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
<p>See also comments 2(46-50), 2(52-57).</p> <p>See reporting table 2(51)</p>	<p>Proposed ARfD is 0.001 mg/kg bw based on the 1-yr dog study (capsule), UF100</p> <ul style="list-style-type: none"> - FR: Agreed. The setting of an ARfD is supported by the results of the rat and rabbit developmental studies by inhalation where body weight loss was observed in the dams at the beginning of the treatment. - EL: supported <p><u>Acceptable Operator Exposure Level (AOEL):</u></p> <ul style="list-style-type: none"> - FR: agrees with the use of an AOEC instead of an AOEL, given the tox profile of chloropicrin → pending clarifications on derivation of BMCL10 and agreement on study to be used as point of departure → APP: AOEC was derived from the most sensitive human endpoint (eye irritation) and is protective of other potential health effects. Calculation of BMCL10 is a conservative estimation of the NOAEC for eye irritation, and application of an assessment factor of 3 is conservative and protective. - EL: the proposed AOEC is higher than the one agreed by the previous EU. Considering the systemic toxicity of chloropicrin, the basis of the AOEC derivation should be discussed. - NL: new AOEL is based on a human volunteer study, contrary to the previous use of animal studies, this should be discussed. → APP: the volunteer study (████, 2007) was not specifically conducted to set an AOEL/AOEC for use in a regulatory risk assessment of PPP. Chloropicrin is used in low concentrations as an alerting/warning agent with other fumigants. The aim of the study was to determine levels at which humans could detect the presence of chloropicrin (odour threshold), at levels below irritation became apparent. - EFSA: uncertainty factor of 3 might be insufficient → APP: the PoD for NOAEC derivation is the BMCL10 for the most sensitive effect in humans (ocular irritation). As eye irritation is a local effect, variability in sensitivity is likely to be limited and it is debatable whether an assessment factor is required. 	<p>Open point RMS is kindly requested to provide the conversion of the AOEC in ppm into a AOEC in mg/m³, based on the ECHA guidance document and considering the appropriate temperature range.</p> <p>Open point RMS is kindly requested to provide revised and more detailed calculations for the non-dietary exposure estimates for phosgene, covering acute and short-term exposure.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>- FR: supports the use of SCOEL information for the AOEL for phosgene. What is the rationale used to choose the 15-min STEL value of 2 mg/m³ (0.5 ppm) instead of the 8h-TWA value (0.4 mg/m³ or 0.1 ppm)</p> <p>- DE^P: The derivation of the AOEL for chloropicrin should be further discussed in the meeting, considering the missing information on the BMC approach leading to the BMCL₁₀ of 0.073 ppm (as commented in Experts' Consultation 2.6 above). Also, we question the use of assessment factor (AF) of 3 for the intraspecies variability. In the [REDACTED] (2004) study, 127 individuals (mostly college students) were recruited for the study. This sample size is small and limited to a specific age group and region (University of California San Diego). Thus, an AF of 3 might not be sufficient to address the intraspecies variability.</p> <p>- DK^P: Reference values should not be based on human studies with deliberate exposure ([REDACTED], 2007). Human studies should not be included and accepted in the DAR and let alone be the basis of the reference values.</p> <p>According to Regulation (EC) No 1107/2009: '(13) For ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human 'no observed effect level' of an active substance. Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.'</p> <p>- EL^P: The ADI and the ARfD proposed by the RMS are supported.</p> <p>Regarding the AOEC derivation based on the human volunteers [REDACTED] (2007) study, it is agreed that the eye irritation is the most sensitive endpoint for assessing effects of chloropicrin exposure. It is agreed that no additional safety factor is warranted for the interspecies extrapolation. The issue of the appropriate safety factor to use in order to cover possible intra-individual differences should be discussed further by the experts.</p> <p><u>Acute Acceptable Operator Exposure Level (AAOEL):</u></p> <p>- EFSA: the derivation of an AAOEL should have been considered</p> <p>→ APP: the proposed AOEC is intended to cover all periods of exposure (also AAOEC)</p>	

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	<p>Reporting table: DR in 2(1): revised tables of tissue residues (including conversions as percentage of administered radioactivity) for the ADME study in rats by oral route, in order to reflect clearly the calculation of the oral absorption value.</p> <p>Peer Review Meeting 13: For chloropicrin: It is noted that the genotoxic potential of the substance should be clarified first before setting/applying reference values. The proposed ADI is 0.001 mg/kg bw per day (2-year rat, UF of 100). The experts agreed provided that the genotoxic potential is clarified. The proposed ARfD is 0.001 mg/kg (1-year dog, UF of 100, based on mortality in rats and vomiting in dogs). The experts agreed provided that the genotoxic potential is clarified. The proposed AOEC was initially based on the human volunteer study. It is noted that it should not be used according to EU Regulation. In the previous review, the AOEL was based on the 90-day mice study when a NOAEC could not be identified (LOAEC of 0.3 ppm for local effects). An UF of 300 was used and then converted to mg/kg bw per day. The RMS proposed to use the same point of departure and UF but only setting an AOEC instead of an AOEL since in the non-dietary exposure for operators, workers bystander and resident only the inhalation route was considered. One expert suggested to use developmental toxicity studies, instead of the 90-day mice study. Overall, the experts agreed with the proposal of the RMS provided that the genotoxic potential is clarified. The RMS will calculate the AOEC in mg/m³. The proposed AAOEC is the same as for the AOEC, since the critical effect is local irritancy. The experts agreed. For phosgene, the occupational exposure limits recommended by SCOEL have been considered for non-dietary exposure estimates. The RMS considered that STE 15 minutes was used (0.5 ppm equivalent to 2.0 mg/m³, with an additional UF of 10). FR asked why the value for 8 hours was not used (0.1 ppm equivalent to 0.4 mg/m³, 5 times lower). Non dietary exposure estimates are below both values (8 hours for</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>operators, workers and 15 minutes for residents/bystanders).</p> <p>Open point RMS is kindly requested to provide the conversion of the AOEC in ppm into a AOEC in mg/m³, based on the ECHA guidance document and considering the appropriate temperature range.</p> <p>Open point RMS is kindly requested to provide revised and more detailed calculations for the non-dietary exposure estimates for phosgene, covering acute and short-term exposure.</p>	
<p>Experts' consultation 2.10</p> <p>Non dietary exposure estimates for the representative uses of chloropicrin to be discussed by the experts.</p> <p>See also data requirements in 2(63), 2(76) and 2(91).</p> <p>See also comments 2(65-69), 2(72-74), 2(77), 2(79-80), 2(84-87), 2(89-90), 2(92-94).</p> <p>See reporting table 2(64)</p>	<p>Background information:</p> <p>OPERATOR / WORKER:</p> <p>For the purpose of the risk assessment, taking into account the specific exposure scenarios for chloropicrin, it is considered that operators are those involved with the application process (including film laying and removal), and are <u>suitably trained</u> in the use of this niche product, compared with re-entry workers who are involved only in aspects of crop production / husbandry such as transplanting scenario.</p> <p>→ APP: both representative formulations will only be applied by trained specialist applicators (professionals). Farmers/growers are not involved in the application process nor in the handling of chloropicrin.</p> <p>→ RMS: specific tasks and associated risk mitigation measures in Table 3.3.1</p> <ul style="list-style-type: none"> - FR: Unit for water supply in the drip irrigation system for chloropicrin EC = L/m² - (FR) Data requirement for more detailed summary tables for exposure scenarios for each representative use (shank and drip), reflecting also the number of monitored individuals by tasks, and the number of monitoring points by study and analysed substance (chloropicrin and phosgene). - DE: for shank application, the <u>surface area treated</u> in the available studies ranged from 7500 to 9200 m². Therefore, acceptable application should be restricted to less than 1 	<p>Open point:</p> <p>RMS to provide a revised version of the exposure estimates for the representative uses of chloropicrin, including all endpoints and parameters agreed during the peer-review assessment.</p>

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	<p>ha.</p> <p>→ APP: the basis for the area restriction is arbitrary</p> <p>→ RMS: There is a relationship between area treated and air concentration and this is one of the factors taken into account in the US EPA system for setting buffer zones for soil fumigants (see https://www.epa.gov/soil-fumigants/buffer-zone-requirements-soil-fumigant-applications). This issue was not explored as part of the applicant's submission and the RMS would agree that uncertainty remains for treated areas >1ha which would need to be considered probably at the authorisation stage when information on potential treatment areas in individual MS could be provided in conjunction with suitable atmospheric modelling.</p> <p>- FR/DE: for operators and workers, the given <u>maximum air concentrations</u> are said "time-weighted averages over the duration of exposure". For bystanders/resident, it is said "concentrations reported are time-weighted averages over approx. 8h). To be clarified.</p> <p>→ APP: the reported maximum air concentrations represent actual concentrations measured over periods of typically 8 hours. As such they are average concentrations and do not show any peak concentrations experienced over shorter time periods during the measurement period.</p> <p>→ RMS: In all cases the values reported are the total measured amounts for the duration of the activity with regard to operators or monitoring period in the case of bystanders.</p> <p>→ The values in Table 8.8-1 are peak air emission values while those in the first row of Tables B.8.6-34 and 35 are worst case air concentrations over a 24 hour time period. In conclusion, they should differ.</p> <p>- FR: since the <u>volatilization rate of gas from soil</u> is highly dependent on soil type, it should be clarified how representative are the experimental grounds compared to the type of soil on which the claimed plants usually grow.</p> <p>→ APP: all activities conducted in horticultural areas</p> <p>→ RMS: soil is a contributory factor to the volatilisation rate. The US EPA buffer zone factsheet 2012 (see link above) assigns credits for site conditions that reduce emissions</p>	

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	<p>which includes soils with high organic or clay content. Most of the chloropicrin studies appear to have been conducted on soils described as sandy, sandy/loam or sandy/silt and therefore provide a good level of representativeness of soil types that may potentially result in higher emissions.</p> <p>- FR: Many studies were performed outside the indicated period in the GAPs (June to September): study 14/2013 (shank injection), studies 12/2012, 13/2012 and CEMS-5732 (drip irrigation). The influences of these differences on the results need to be addressed. → APP: a limited number of studies were performed in April and October a statement to address the influences of these differences can be provided as additional information. → RMS: It is assumed that the main basis for this comment is the <u>possible impact of lower temperatures on volatilisation</u> and if the applicant is able to provide a statement they could compare and contrast mean temperatures and measured air concentrations for the studies undertaken outside the GAP relative to those within.</p> <p>- EFSA: Chloropicrin 99 – Shank injection. The 2 modifications introduced with the years should not be considered standard for all applicators and maximum reported values without these modifications should still be considered.</p> <p>- RMS: The performance of the <u>in-cab air filtration system</u> must be to a recognised standard and it is not possible to assign any such level of protection to the equipment described → APP: the California Department of Pesticide Regulation determined that the fan system was very effective in reducing driver exposure to methyl bromide → further information on its adoption as suitable engineering control (alternative to closed cab/RPE) can be provided.</p> <p>- DE: We do not consider it practicable to work with <u>power-assisted RPE</u> for several hours, especially when conducting labour-intensive tasks, such as cutting and sheeting removal.</p>	

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	<p>→ APP: appropriate power-assisted equipment is available from many suppliers with specific recommendations for prolonged use – additional information on this point can be provided on request</p> <p>→ RMS: UK Health and Safety Executive advice concerning (see http://www.hse.gov.uk/pubns/books/hsg53.htm) is that continuous wear time for tight-fitting (unpowered) RPE is less than an hour, after which the wearer should take a break (the RPE can become uncomfortable to wear, leading to loosening or removal of the mask in the work area). Where RPE is required to be worn continuously for long periods, powered respirators with a loose-fitting facepiece such as a hood or helmet, are considered suitable options.</p> <p>→ Col. 4: Time restriction for the use of appropriate RPE can be further considered at MS level but it is noted that this might lead to increased exposure to chloropicrin/phosgene.</p> <p>- FR: in Table 30, for operator chloropicrin samples corresponding to the studies 12/2012, 13/2012 and 15/20013, we should read the value 13 instead of 26 (in accordance with the content of table 24)?</p> <p>→ APP: No, the operators in these studies wore two sampling tubes on the left and right hand side of the chest.</p> <p>- EFSA: Chloropicrin EC – drip irrigation. The <u>duration of the worker exposure</u> might have been extended to 6 or 8 hours per day.</p> <p>→ APP: Exposures were measured for different activities over representative time periods</p> <p>→ RMS: This is not relevant when considering local effect AOEC for which maximum measured values are needed. NB The highest reported concentrations occurred during the shorted operation i.e. disconnection phase of between 4 and 11 minutes. It would not be appropriate to either scale the maximum values up or average it out over a 6-8 working hour day.</p> <p>- EFSA: Chloropicrin EC – drip irrigation. Considering the Table 32, it might be realistic to sum up the exposures measured for the different activities, knowing that in some</p>	

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	<p>countries, the same worker might perform all activities.</p> <p>→ APP: Summing of exposures is not relevant for airborne concentrations as the AOEC is based on local effects.</p> <p>- EFSA: It should be clarified why the previously submitted field studies (eg by Trevisan) have been discarded from the exposure assessment.</p> <p>→ APP: The study by Trevisan, M (2009) Chloropicrin: concentration in air and operators exposure assessment during and after soil application was not included in the NAS dossier as it does not reflect the current GAP (the study was conducted at a higher rate and the post-application procedures do not reflect currently supported practice). The ECG therefore considers the study not to be relevant to the current GAP and to be superseded by the studies conducted in 2012-2013.</p> <p>- RMS: <u>Disconnection study</u> – Reduced application rate could be the reason why the measured values are significantly less in the drip disconnection trial compared to the original drip trials.</p> <p>→ APP: disconnection exposure is due to release of chloropicrin from the application equipment and not related to the application rate. The release during disconnection is independent of whether the rate of application is high or low.</p> <p>- RMS: Disconnection study – The two methods for minimising exposure during disconnection (long handled wrench and partial loosening with operator standing away from the cylinder for 5 minutes) do not eliminate the need for RPE and do represent further measures that can be undertaken by the operator to further reduce the risk of exposure.</p> <p>→ APP: these methods were incorporated in the standard operating procedures for chloropicrin application.</p> <p>DE^P: Use acceptable with restrictions</p> <p>O/W: Fan system or closed tractor cabin Cat. 4 for application RPE for disconnection, film cutting and removal Restriction of re-entry to treated greenhouses before venting</p>	

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	<p>ELP: Based on the available data it can be demonstrated that there are specific mitigation measures that could be taken in order to reduce operator/worker exposure when the whole procedure of either shank or drip application is performed by trained personnel using specific equipment.</p> <p>While the intended application rate is 188 to 376 g a.i./ha, the exposure calculations currently presented in the DAR consider only the higher intended application rate, i.e. 376 g a.i./ha as a worst case.</p> <p>Depending on the AOEC value established during the expert meeting the consideration of the lower intended application rate for the exposure calculations might be required.</p> <p>It is further noted that the assumptions currently made for the exposure estimation consider also the fact that the AOEC used for the risk assessment has been derived for local effects.</p> <p>Bystander:</p> <ul style="list-style-type: none">- Public (French Chambers of Agriculture): a <u>buffer zone of 50 m</u> can be implemented in site specific considerations by the applicators supported by the farmer.- EL: The acceptance/applicability of a 50 m buffer zone restriction should be further discussed.- FR: Since a buffer zone of 50 m has been proposed as RMM for B/R, until all concentrations of chloropicrin are below the AOEC, how long should it be maintained (and also for phosgene) ? → APP: based on the monitoring data, maintaining the buffer zone for 24 hours following treatment would seem to be appropriate- DE: substantial uncertainty remains regarding the capturing of <u>bystander peak concentrations</u> and the potential underestimation of <u>child exposure</u>. Regarding the high acute toxicity of chloropicrin, the level of remaining uncertainty might be too high to conclude a safe use.- FR/EFSA: No data for the child bystander (no measurements taken below 1.50 meters height) while it appears to be necessary to have some measurements at least at a	

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	<p>reasonable infant height since the density of chloropicrin and phosgene is higher than that of air resulting in a higher concentration of both chloropicrin and phosgene at this height.</p> <p>→ APP: a more recently performed study (→ data requirement) shows that measured chloropicrin concentrations at a height of 1 m are only marginally higher than those measured at 1.5 m and none exceed the proposed AOEC. Furthermore, this study also measured peak (1-hour) exposures of chloropicrin and demonstrates that the power law approach followed by the RMS provides a conservative method of estimating peak exposures.</p> <p>→ RMS: the greater uncertainty lies with using the power law approach to predict peak exposures</p> <p>- DE: Modelling of bystander short-term exposure by applying the CALMET/CALPUFF model (air dispersion modelling) with refined assessment factors adjusting for model uncertainty.</p> <p>→ APP: For bystanders and residents, the studies cover a range of environmental and meteorological conditions and provide a very large number of measurements of chloropicrin concentrations at distances of 50 meters or more from the treated area (in total over 5000 individual measurements are available at 50 metres or more). None of the measured (c.6-12 hour) concentrations at these distances comes close to exceeding the AOEC of 0.164 mg/m³ proposed by the RMS and co-RMS. In order to address the potential risk from 'peak' concentrations the 'power law' formula has been adopted and accepted by the RMS and co-RMS. This provides a conservative predictor of peak 1-hour concentrations. Using this approach, no predicted 1-hour exposures derived from the monitoring data exceed the proposed AOEC at 50 metres. The RMS assessment, underpinned by this extensive data set, is supported. In addition, a recently conducted (2017) monitoring trial is available.</p> <p>→ RMS: Taken in isolation, the power law estimation can be used to provide a rough approximation of the relationship between short and long-term concentrations. It is based on a limited number of observations and has no way to account for any specifics about the site including terrain, land use, time of day or local meteorology. It was anticipated that the use of a more sophisticated approach using a suitably validated atmospheric dispersion modelling tool would give much more accurate site specific</p>	

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	<p>predictions. However, <u>CALPUFF has not previously been validated</u> and used for similar regulatory purposes. The proposed assessment factors reflected significant uncertainty in the model outputs and further work would be required to fully validate the model and accept its use for regulatory purposes.</p> <p>→ APP: the use of additional assessment factors to cover the potential for peak chloropicrin exposures over shorter periods of 15 minutes and 1 hour is not supported. In many cases, the use of this approach results in airborne concentrations of chloropicrin in excess of the maximum theoretically possible.</p> <p>- APP: Although it is a possibility that released gas may not pass directly through the measurement locations, it should be recognised that each study included measurements at multiple locations. In view of this and the large number of monitoring studies (including hundreds of individual measurements), it is considered unlikely that the released gas would have not passed directly through the measurement locations in all studies.</p> <p>- APP: In view of the theoretical possibility that concentrations of chloropicrin may be higher at heights below 1.5 m, an <u>additional monitoring study</u> has been performed. This study includes directly comparable measurements at sampling heights of 1.5 and 1 m, in order to address concerns raised by the RMS in relation to the exposure of child residents. The study included measurements using different sampling heights and at distances of 15, 25 and 50 meters from the site of application. The study indicates that airborne concentrations at a sampling height of 1m are (on average) marginally (1.04 times) higher than those at 1.5m, but do not exceed the proposed AOEC (→ DR).</p> <p>- DE^P: Use acceptable with restrictions Bystander/Resident: 50 m safety distance from treated greenhouses or fields (slight exceedance of AOEC at this distance from 1-h peak measurement in only one case, highest 8-h TWA value is nearly 10 times lower than AOEC) Uncertainties: Exposure duration of residents might exceed 1 hour which is the basis for the AOEC</p>	

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	<p>In almost all studies only 8-h average concentrations were determined Modelling of 1-h peak concentrations is not acceptable</p> <p>PHOSGENE:</p> <p>- FR: info lacking on kinetic and rate conversion from chloropicrin to phosgene in air. → APP: It is correct that fewer data are available for phosgene. However, it should be noted that, in addition to operator and worker monitoring, atmospheric sampling for phosgene was also conducted in the majority of the trials at 1 m with measurements at 50 and 200m in five trials. No phosgene was detected above the LOQ in air samplers of any operators/workers monitored in the studies. In the atmospheric monitoring phosgene was only detected at 50m or beyond in one study (application by drip irrigation under protection). The maximum measured value at 50m was 0.0104 mg/m³ and 0.0081 mg/m³ at 200m which is equivalent to 5% and 4% respectively of the AOEC proposed for phosgene for bystanders and residents [AOEC of 0.2 mg/m³ based on the EC Scientific Committee on Occupational Exposure Limits 15-minute short-term exposure limit value of 2 mg/m³ with an additional uncertainty factor of 10 for intra-species variation]. The maximum estimated 15 min peak exposure for phosgene occurring at 50m is below the proposed AOEC.</p> <p>It should be noted that the conversion of chloropicrin to phosgene is a theoretical possibility and the available data do not indicate that this occurs to any great extent. As noted above the majority of phosgene measurements were <loq and measured values were very low. The proposed AOEC for chloropicrin is low compared to that proposed for phosgene; therefore, even if chloropicrin were quantitatively converted to phosgene, based on the more comprehensive chloropicrin measurements, levels of phosgene would not be of concerns.</p> <p>→ RMS: Phosgene was monitored in 8 out of the 11 studies. Based on the very low levels detected in almost all cases it is reasonable to conclude that the risk of exposure to phosgene is very low by comparison to chloropicrin and further information in this area is unlikely to add anything to the overall conclusions.</p> <p>- FR: in the case of shank injection, data from a single study (study 08/2012) are available to assess the bystander/resident exposure to phosgene. A more robust</p>	

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	<p>argument needs to be added in order to support the conclusion related to the bystander/resident exposure to phosgene for this type of application. → APP: see comment above</p> <p>- EFSA: Chloropicrin 99 – Shank injection. The 2 modifications introduced with the years should not be considered standard for all applicators and maximum reported values without these modifications should still be taken into account. Phosgene was not monitored in all studies, and the levels were reported at or below the LOQ. A worst-case approach could be to consider phosgene as always present at the LOQ. Regarding possible standardisation of parameters, it could be appropriate to consider a workday with a duration of 6 or 8 hours.</p> <p>→ RMS: The assumption that phosgene is always present at the LOQ does not affect the outcome of the risk assessment as we are not trying to derive 75th or 95th percentile exposures from a distribution of exposure but rather are only interested in identifying the maximum values observed for the purposes of comparison with the short term local effects AOEC.</p> <p>- FR: There is a lack of nighttime sampling of phosgene after DAT0. → APP: as phosgene is a postulated photodegradation product of chloropicrin, sampling during the night is considered less relevant → DR: APP to provide further information on the phosgene generation by photodegradation of chloropicrin (by visible and UV light).</p> <p>Peer Review Meeting 13: Representative uses included shank injection and drip irrigation.</p> <p><u>Shank injection</u> In 4 field studies (3 in Italy, 1 in Austria), air concentrations (chloropicrin and/or phosgene) were measured at the site of application, 1.5 m height (relevant for bystander and resident) and different sampling distances (50, 100, 150, 200 m). Measurements were done during the different activities of the operators/workers: fumigation, disconnection, VIF cutting, VIF removal and transplanting.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>In all cases the levels of phosgene were reported at or below the LOQ.</p> <p><u>Drip irrigation</u></p> <p>In 7 field studies (5 in Italy, 1 in Austria and 1 in UK), air concentrations (chloropicrin and/or phosgene) were measured at different sampling distances (1, 50, 100, 150, 200 m).</p> <p>Measurements were done during the different activities of the operators/workers: fumigation, disconnection, opening vents, VIF cutting, VIF removal and transplanting.</p> <p>For the bystander and resident exposure during the shank application, an additional study was provided, measuring air concentrations in the breathing zone of children, and supporting the use of the power law approach with regard to the estimates of the peak to mean ratio.</p> <p>The experts discussed the different comments:</p> <p>All applications: Less <u>analytical</u> data were collected for phosgene compared to chloropicrin. The experts considered that overall there are sufficient data.</p> <p>For the shank application, the <u>surface area</u> treated ranged from 7500 to 9200 m². Historical control from UK reflected area lower than 1 ha. The experts agreed that in the exposure estimates the area treated should be clear. This should be applicable to drip irrigation too (maximum 3000 m²).</p> <p><u>Fan system</u>: there was a consistent decrease of operator exposure considering tractor with fan system compared to tractor without fan system (at least 1 order of magnitude). It was noted that the use of the fan system is still in place in the US. It was not clear if the system is used in the EU (according to the RMS the applicant is implementing this system in the EU). One MS proposed a closed cabin system category 4 (however, there is no experimental field data). The RMS commented that the producer of the active substance is responsible for the production of the active substance and for providing the application system with trained operators. Overall, the experts agreed that it should be clear that exposure estimates reflected the use of fan system in the available field studies.</p> <p>Outside of the period in the GAP: for shank and drip irrigation some studies were outside the period of the GAP. According to the RMS there is no significant difference between</p>	

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	<p>the studies (considering the different periods, GAP vs non-GAP). The experts agreed.</p> <p>Time sampling for phosgene (lack of night-time sampling). Photolysis occurs during the day. It is not expected that phosgene will be formed during the night. The experts agreed.</p> <p>1 hour versus 8 hours: according to the RMS it can be predicted by the <u>power law concentration approach</u>. Some experts noted that it is a theoretical approach. However, it is supported by the <u>new monitoring study</u>:</p> <ul style="list-style-type: none">• At 25 m: some values exceed the current reference values.• At 50 m: a single value slightly exceeds the current reference values (DAT1 T03, A4 50m). <p>Overall, the experts agreed with the RMS' approach considering both power law concentration approach and the new monitoring study. The RMS proposed a buffer zone of 50 m. The experts agreed.</p> <p>Children exposure: 1.5 m sampling point (height). The new monitoring study reported 1 and 1.5 m and according to the RMS there is no difference. Therefore, the RMS considered that children exposure is covered.</p> <p>The RMS indicated that there is no differentiation between operator and worker reflecting the current practices. There is no need to adapt for default worker exposure duration. The RMS considered that it is covered by the current estimates. For shank application, the RMS indicated that all activities including transplanting (only for strawberries) will be done by professional workers. EFSA asked whether all activities could be done by the same operator. Some experts considered that the activities will not take place the same day. Therefore, the experts considered not appropriate to sum up all the activities.</p> <p>Respiratory equipment (power assisted RPE): the use of the RPE is recommended for some tasks such as removal of connection, film cutting and removal (short tasks). In the field studies the operator did not use the RPE.</p> <p>Open point</p> <p>RMS to provide a revised version of the exposure estimates for the representative uses of chloropicrin, including all endpoints and parameters agreed during the peer-review assessment.</p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	EFSA note: the exposure estimates were discussed before the agreement on the reference values, and it is highlighted that lower (A)AOEC than those proposed by the RMS have been agreed during the meeting.	

REPORT OF PESTICIDE PEER REVIEW MEETING 15

CHLOROPICRIN

Rapporteur Member State: IT

Specific comments on the active substance in the section

4. Environmental Fate and Behaviour

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
September 2019	DK, FR	Preliminary comments from MSs submitted before the meeting are entered in the discussion table below

2. Documents submitted for meeting:

Date	Supplier	File Name
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.docx
July 2019	IT	Chloropicrin_DAR_01_Volume_1_revised_July_2019.pdf
March 2019	IT	Chloropicrin_DAR_02_Volume_2_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_02_Volume_2_2019_03_19.pdf
March 2019	IT	Chloropicrin_DAR_10_Volume_3CA_B-8_2019_03_19.doc
March 2019	IT	Chloropicrin_DAR_10_Volume_3CA_B-8_2019_03_19.pdf
March 2019	IT	Chloropicrin_evaluation table_section 4_2019_03_19.doc
July 2019	IT	Chloropicrin_List of endpoints_all sections_July_2019.doc
March 2019	IT, EFSA	Chloropicrin_reporting table_2018_06_14.doc

3. Documents tabled at the meeting: None

Appendix 1: Discussion table: CHLOROPICRIN

Appendix 1: Discussion Table, Chloropicrin (Fu, In, Ne, Hb)

4. Environmental Fate and Behaviour

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Experts' consultation 4.1	<p>Background RT 4(6)</p> <p>MSs experts to examine the acceptability of the degradation in soil study Völkel (2004) in relation to the mass balance, the potential losses by volatility. If the study is to be considered acceptable then the MSs need to consider if there is justification to exclude data of any particular soil in the study.</p> <p>See also 4(7) and the open point therein.</p> <p>See also data requirement in 4(34)</p> <p>See also 4(16), 4(17), 4(36), 4(50), 4(55).</p> <p>Note: since there are</p> <p>DE: We believe that for an active substance as volatile as chloropicrin, an aerobic soil study without a total mass balance should not be considered acceptable. It is possible, that part of the active substance escaped from the system during incubation, besides, the amount of chloropicrin that vaporised from the soil into the headspace need to be considered before deriving DT50 endpoints. Otherwise, the derived DT50 endpoints are dissipation rates but not degradation rates.</p> <p>RMS:</p> <p>It is agreed that the lack of a mass balance from this study is problematic, irrespective of whether chloropicrin is volatile or not.</p> <p>The RMS does note that the endpoints from this study have previously been accepted for use at community level and no requirement for a new aerobic soil degradation study was made in the EFSA conclusion. See also comment 4(7).</p> <p>Applicant:</p> <p>In the previous evaluation detailed in EFSA Journal 2011;9(3):2084 this study was not considered deficient and no further information on the route and rate of degradation of chloropicrin in soil was requested. In this system measures were taken to prevent losses via volatilisation. A closed system was used instead of continuous aeration and headspace was kept to a minimum with the test item injected into the bottom of the soil column and the vessel closed with a screw lid immediately afterwards. This differs to the conditions in Hatton et al (1995) where 50 g soil samples were added to biometer flasks with a significant amount of headspace, therefore the potential for the generation of volatile losses in Hatton et al (1995) was significantly greater. In the light of the measures taken to prevent such losses in Völkel (2004) the Applicant believes it appropriate to use the DT50's from this study as DegT50s. Further argumentation is</p>	<p>Data gap</p> <p>None of the soil degradation studies available allowed reliable degradation DegT50 to be derived. The studies only allowed the determination of dissipation DisT50; however, it was not possible to determine to which extent the dissipation occurring in the laboratory system is representative of field situations.</p> <p>Data gap</p> <p>Reliable soil degradation studies under aerobic conditions with mass balance closed and adequate identification of volatiles was not available. Only in this situation (volatiles identified) could the overall amount of chloropicrin be used to calculate reliable half-lives.</p> <p>Data gap</p> <p>None of the available soil degradation studies allowed the mass balance to be closed and major metabolites to be identified.</p>

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<p>serious doubts on the acceptability of the values derived from study McLaughlin, S. 2013a, the exclusion of soil II in Voelkel (2004) may result in reducing the data set for the active substance to only three soils and the identification of a data gap (and the need to use DT50 = 8.8 d for the rest of the exposure assessment instead of the geometric mean).</p> <p>See reporting table 4(6)</p>	<p>included under Comment 4(8).</p> <p>RT 4(7)</p> <p>EFSA:</p> <p>The aerobic degradation study in soil (Voekel, W. 2004) was already considered in the previous assessment of chloropicrin. It is noted that a slight different end point than the previous agreed is proposed for the soil IV Senozan (silty clay loam) probably due to the use of non-linear fitting vs previously derived values by linear regression.</p> <p>Also it is noted that for the exposure assessment the soil with longest DT50 (soil II) has been discarded as an outlier. However, the reason does not seem to be fully justified in the evaluation of the study.</p> <p>In a more modern study (McLaughlin, S. 2013a, see comments below), important losses of volatiles (either parent or metabolites) are observed not being possible to close an acceptable mass balance. Since in this study material balance was not accounted, it cannot be excluded that a significant fraction of the losses observed are actually volatilization instead of degradation. Therefore, it is doubtful the DT50 can be considered to represent pure degradation.</p> <p>RMS:</p> <p>Point (1): The conclusion by EFSA on the slight difference in endpoints is correct.</p> <p>Point (2): The soil with the longest DT50 has been discarded for higher tier assessment because the microbial biomass of the soil dropped below 1% during the study. This is stated in the overall summary of soil degradation (section B.8.1.1.4) but not explicitly in the study summary. A statement will be added in the study summary.</p> <p>Point (3): The RMS notes that despite the fact that chloropicrin is a highly volatile substance and no mass balance was presented, the study by Völkel was accepted for use at community level as part of the previous assessment. The DT50 values were used to generate an endpoint for modelling and there was no requirement set to provide a new study.</p> <p>It is agreed that the data from the new study shows that there are losses from the system and that strictly speaking the DT50 values generated are dissipation values for the system and not purely degradation values. The RMS also comments that the extraction procedure described is probably not conducive to achieving a good mass balance.</p>	<p>Data gap</p> <p>Reliable soil degradation studies under aerobic conditions with mass balance closed and adequate identification of volatiles was not available.</p> <p>Kinetic parameters for the formation and degradation of metabolites could not be calculated with the available data.</p> <p>Open point</p> <p>RMS to remove the kinetic end points (both degradation and dissipation) for parent chloropicrin and metabolite from the LoEP sections on incubations.</p> <p>Dissipation end points may be left just as the input parameters of the "illustrative calculations" for PEC GW and PEC SW.</p> <p>Open point</p> <p>EFSA to reflect in its conclusion that the experts considered that reliable route of degradation information under aerobic conditions would be needed before the possible consequences of metabolism under anaerobic conditions might be concluded on.</p>

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	<p>The RMS has made the case that the losses are less at the start of the study when chloropicrin and DCNM are present and increase with time concurrent with DCNM degradation. The metabolites likely to be formed from DCNM are chloronitromethane and nitromethane. These are both highly volatile and could quite possibly escape the volatile trap, causing the trend of lower mass balance with time. The RMS does accept that this argument is debatable, given that chloropicrin and DCNM are also volatile.</p> <p>The RMS opinion from looking at all of the aerobic soil studies is that conducting a study that complies with the guideline may not be possible, in terms of maintaining a mass balance or keeping the components in contact with the soil for the duration of the study. Some consideration should be given to the fact that the active substance is a highly volatile soil fumigant and a pragmatic approach taken to interpreting the studies.</p> <p>For example, a case can be made for accepting the data from the study by McLaughlin (2013a) based on the following two points:</p> <p>(1) If kinetic assessment is made using the data where mass balance was approximately 80% or more (to day 7 for Speyer 2.2 and day 2 for the other soils), the kinetic fittings gave very similar DT50 values to those derived for the whole dataset. This suggests that the mass balance does not greatly influence the DT50 value generated for chloropicrin.</p> <p>(2) Mass balances are poorer at the earlier timepoints of the study where DCNM is applied as parent (McLaughlin, 2013b) compared to the study where chloropicrin is applied. This suggests that the greater contribution to the poor mass balance in the chloropicrin study comes from losses of either DCNM itself or metabolites of DCNM. This argument is strengthened by the fact that mass balance generally declines most rapidly after formation of DCNM is first seen.</p> <p>Applicant: It is confirmed that the difference in the end-point for soil IV Senozan soil is due to the method of calculation.</p> <p>Please refer to comment 4(6) regarding the potential for losses via volatilisation in Völkel (2004).</p> <p>The reason for excluding the outlier is not given in the study summary, however, it is discussed under B.8.1.1.4 where it is stated that the microbial biomass of the soil was below the minimum of 1% of total organic carbon stipulated in the OECD guideline (microbial activity at such low levels has been cited as a reason for discarding such soils</p>	

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	<p>in the evaluations of other active substances). In addition the DT50 value in this soil is not in keeping with values from other studies (even that of Hatton 1995 where volatile residues were included in the calculation of the DT50). Indeed when evaluated statistically (using Grubb's test) the DT50 of 26.9 days is identified as an outlier ($P < 0.05$).</p> <p>Open point</p> <p>RMS to provide in an amended DAR, within the B.8 summary of the study, the reason for discarding the results on soil (II) in study Voekel, W. 2004. If loss of microbial activity is considered for a particular soil, this loss should be compared with the loss of microbial activity in the other soils investigated in this study.</p> <p>RMS added further information in relation to the biomass of the different soils in Voekel, W. 2004. See table B.8.1.1-9 (p 13) and the conclusions of the study. In the view of the RMS, it would be justified to exclude half-life observed in soil (II) [Speyer 2.3] based on the lower biomass of this soil and the decline below 100 mg C/kg soil during the experiment.</p> <p>RT 4(16)</p> <p>NL: doesn't agree with the RMS that on basis of the microbial biomass the DT50 of Speyer 2.3 soil is an outlier. The biomass is within the range given in the OECD307 guidance and therefore should not be considered as an outlier. Also the refinements with the shorter DT50 without this soil DT50 should be taken out of the dossier.</p> <p>RMS :</p> <p>The biomass is 1.03% at the start of the study but was 0.84% at day 10 and 0.77% at the end of the study. The guideline recommends that the microbial biomass should be greater than 1% and this is not the case throughout the study.</p> <p>The DT50 from this soil is also significantly longer than that from any other soil. Based on this evidence, the RMS therefore maintains the opinion that as a refinement the DT50 value from this soil could be removed from the data set as a refinement.</p> <p>An explanation of the reason for the potential to omit the data from this soil as a refinement is presented in the summary section B.8.1.1.4 (page 48) but a more complete explanation will be added to the study summary itself.</p>	

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	<p>RT 4(17) NL: the percentage of biomass at the end of the study seems unrealistic high (Vol. 3B.8.1.1 Table B.1-12 and B8.1-17). RMS : The RMS agrees - it appears to be a mistake in the study report. A footnote will be added to the table to point this out. Applicant: In the study the following explanation is provided "Also, these values are higher than typically observed since they were determined with soils dosed with [14C]chloropicrin containing a high amount of carbon and nitrogen which may have stimulated growth of certain segments of the microbial population."</p> <p>RT 4(34) DE: No valid degradation DegT50 for chloropicrin or DCNM in soil are available (see our comments on aerobic soil degradation). Thus reliable PECsoil values can only be derived immediately after one application. RMS : The RMS comments that the study by Völkel has been previously accepted at community level and DT50 values from that study used in an assessment. The RMS has made the case that if the values from the study by Völkel continue to be accepted, then the values from the study by McLaughlin (2013a) should also be accepted – see comment 4(36) for a fuller discussion. Applicant: Please refer to the response to comments 4(8) and 4(13). The applicant is of the opinion that the derived DT50s can be considered DegT50s. However, the use of DissT50s for the calculation of soil PECs is perfectly valid, as evidenced by the use of the longest DT50 from field studies in soil PEC calculations when such data are available. Data requirement Due to the serious doubts on the acceptability of the degradation studies in soil Völkel (2004) and McLaughlin (2013a), applicant is given the opportunity to provide new fully</p>	

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	<p>reliable degradation in soil studies under aerobic conditions.</p> <p>Applicant has not provided any new soil degradation study. A statement (reproduced in p 24 – 25) is presented by the applicant explaining all the preventions taken to avoid losses and comparing the timing of the observed losses with presumed levels of remaining chloropicrin.</p> <p>RMS assessment of the statement seems incomplete. RMS indicates that the complex laboratory system, can still have several losses points (precisely due to the complexity). EFSA also notes the circularity of the argument presented in relation of losses and remaining levels of chloropicrin. The argument is only true if it is presumed that the losses are not chloropicrin... (otherwise the assumed decline will be lower since the mass balance losses would need to be added to chloropicrin).</p> <p>As result of the experts discussion it may be decided on the need of a new study of a re-analysis of the available studies.</p> <p>RT 4(36)</p> <p>EFSA: The DT50 of 8.8 d has been used to refine PEC soil arguing the worst case in Voelkel (2004) of 26.9 d was an outlier (due to low microbial activity). Independently of other issues identified with this study (as lack of mass balance determination) it does not seem that authors of the study found soil II had to be discarded. In addition, since there is serious doubts on the acceptability of the values derived from study McLaughlin, S. 2013a, the exclusion of soil II in Voelkel (2004) may result on reducing the data set for the active substance to only three soils and the identification of a data gap (and the need to use DT50 = 8.8 d for the rest of the exposure assessment instead of the geometric mean).</p> <p>RMS :</p> <p>The author did not identify the soil as one to be discarded but the applicant in their study summary identified the low biomass as a cause for concern, specifically in the context of the much longer DT50 value.</p>	

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	<p>The RMS has not reflected those concerns in the study summary and this will be added. The concerns are discussed in section B.8.1.1.4 (summary of the soil studies).</p> <p>EFSA have questioned the legitimacy of all of the DT50 values in the study by Völkel in comment 4(7). The RMS has argued that if the data in the study by Völkel is accepted, the data in the study by McLaughlin (2013a) should also be accepted in the reply to comment 4(7). Therefore it is the RMS view that there are either no acceptable DT50 values or 7 acceptable values. The case that only the study by Völkel will be accepted and there could only be three DT50 values is perhaps a more unlikely outcome of any discussions.</p> <p>Applicant: It is not unusual for Study Directors to not comment on the suitability of soils used in their studies. It is frequently only on evaluation when compiling the dossier or DAR/RAR when such issues come to light.</p> <p>RT 4(50) EFSA: The results of the PEC SW calculations are very dependent on the DT50 soil, since only the amounts remaining after the covered period contribute to the loads to surface water. Therefore, PEC SW may need to be recalculated once the issues identified during the peer review, with respect to the studies of degradation in soil, are clarified. Specially, in relation to the STEP 4 calculations for which the longest DT50 is proposed to be removed from the set used for geometric mean calculation as an outlier.</p> <p>RT 4(55) EFSA: The results of the PEC GW calculations are very dependent on the DT50 soil, since only the amounts remaining after the covered period contribute to the leaching to ground water. Therefore, PEC GW may need to be recalculated once the issues identified during the peer review, with respect to the studies of degradation in soil, are clarified.</p> <p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DK: Comment before expert discussion. DK agrees with the comments by DE that the</p>	

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	<p>lack of a mass balance is very problematic and that this makes the degradation endpoints derived from the study not reliable. However, DK acknowledges that with such a volatile substance where the OECD 307 guideline is not applicable it can be very challenging to make a proper degradation experiment, and perhaps in this special case, a pure degradation endpoint cannot be estimated and a dissipation endpoint will have to be used.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>The low mass balances reported for this study question the results reliability. No data are available regarding the volatilization of the active substance and its metabolite DCNM since the volatile traps were not analysed. Considering the very high vapour pressures of chloropicrin and its metabolite DCNM, it is very likely that the DT50 values calculated for both compounds are only DT50 values for dissipation and not degradation. In case of fumigants, this kind of DissT50 values have already been derived and accepted (for DMDS for instance), in combination with a vapour pressure of 0 for risk assessments. However, it is noticeable that in previous RA for similar compounds, soil DegT50 values were also available and were combined to the vapour pressures of the active substances for PECgw and PECsw modelings to perform a complete risk assessment with two different approaches for considering the volatilisation of the active substance.</p> <p>Based on the experimental designs of the soil degradation studies available for chloropicrin, the determination of soil DegT50 values is not possible for chloropicrin and metabolite DCNM.</p> <p>In our opinion, in this very specific case, soil DissT50 values calculated for the active substance and its metabolites could be considered acceptable for risk assessments (together with a vapour pressure of 0). In addition, a data gap could be identified for an additional soil degradation study in laboratory in order to determine soil DegT50 values for chloropicrin and its metabolite DCNM to refine the risk assessment if needed.</p>	

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	<p>Expert discussion</p> <p>An expert identified that in the lowest organic carbon content soil (Soil II Volkel, Speyer 2.3) at the beginning of the incubation its value was just higher than 1%. Therefore, the longer DT 50 might be considered and retained in the total data set.</p> <p>There was general agreement that the DT values are dissipation rates due to the mass balance issues in both studies. Whether these values might be used as DegT50 in modelling is questionable.</p> <p>The volatility losses are systematic and mean that the DT50 are quite uncertain. Robust DegT50 are essential for the assessment due to the sensitivity in the leaching modelling that is also impacted by the high application rate.</p> <p>The trapping system in the McLaughlan study was not trapping the volatiles and it is uncertain if the radioactive loss was parent chloropicrin or transformation products.</p> <p>It was discussed if the results for the volatile traps in the study of Hatton indicate that the foam plugs in McLaughlin probably was constituted by parent chloropicrin.</p> <p>While this was uncertain it was proposed to calculate a worst case chloropicrin DegT50 using the results from McLaughlin for the lost radioactivity to add back to the chloropicrin recovered from the soil samples. It was also noted that this approach for the Hatton incubation might be possible but some uncertainty remains if the high radioactivity in the sodium hydroxide trap was carbon dioxide or chloropicrin.</p> <p>It was agreed that the study of Volkel could not be used to estimate DegT50 due to the absence of volatile traps and the fact that unextracted residues were not quantified. These values might be retained but only used as dissipation (DisT50) values (including for the Soil II Volkel, Speyer 2.3).</p> <p>The experts agreed that the available data did not allow the aerobic route of</p>	

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	<p>degradation in soil to be determined. The incubation of Hatton in a single soil appears to be the incubation that gives the best indications of what the route of degradation might be as there are less recovery issues than for the other investigations.</p> <p>The experts agreed that a conservative case chloropicrin DegT50 using the results from McLaughlin for missing mass to add back to the chloropicrin recovered from the soil samples needed to be calculated. The RMS completed this task during the expert meeting. The experts agreed that as the visual fit was poor, usable conservative DegT50 could not be derived from the data.</p> <p>Consequently, it was also agreed that the study of McLaughlin could not be used to estimate DegT50 due to the incomplete mass balance. As for Volkel, the incubations might be retained but only used as dissipation (DisT50) values.</p> <p>It was noted that under the impermeable film it cannot be excluded that the soil environment becomes at least partly anaerobic.</p> <p>Under anaerobic conditions the available anaerobic soil incubation indicated that the major transformation product was nitromethane. It might be hypothesised that this is also an aerobic metabolite. Though not identified in significant amounts in the available aerobic incubations, this metabolite may eventually be a component of the not recovered radioactivity. The experts considered that reliable route of degradation information under aerobic conditions would be needed before the possible consequences of metabolism under anaerobic conditions might be concluded on.</p>	
<p>Experts' consultation 4.2</p> <p>MSs experts to examine the acceptability of the degradation in soil study McLaughlin (2013a) in relation to the mass balance and losses by</p>	<p>Background RT 4(8) DE:</p> <p>We believe that the DT50 values for chloropicrin from this study should not be used. Chloropicrin is extremely volatile and with a total mass balance of only 30- 56 % at the end of the study it is likely that a high amount of chloropicrin escaped from the system or during the extraction. Thus the DT50 values represent dissipation rates and not</p>	<p>See experts' consultation in 4.1</p>

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<p>volatility.</p> <p>See also data requirement in 4(34)</p> <p>See also 4(9), 4(12), 4(50) and 4(55).</p> <p>See reporting table 4(8)</p>	<p>degradation rates. The RMS states that the lost radioactivity is due to loss of a volatile metabolite but there is no evidence provided for this and even if some of the loss is due to a volatile metabolite, additional loss of chloropicrin cannot be ruled out.</p> <p>RMS :</p> <p>The RMS does not state anywhere in the dRR that 'the lost radioactivity is due to a volatile metabolite' as stated in this comment.</p> <p>The RMS does discuss the poor mass balance and sets out the possible reasons for this. The attention of the MS is drawn to the conclusion of this study. There it is stated that one possibility that explains increased losses with time is the production and then loss of a volatile metabolite, although this is not the only possible explanation.</p> <p>The RMS agrees that a strict interpretation of the guidance leads to the conclusion that the DT50 values should be regarded as dissipation values. However, it is possible to make a case for acceptance of the chloropicrin values as degradation DT50 values, made in response to comment 4(7). It is also noted that the DT50 values from the study by Völkel (2004) were accepted at community level in the previous assessment (despite clear deficiencies) and these DT50 values are not significantly different from those in the study by McLaughlin (2013a). Therefore, the RMS is of the opinion that if the results from the study by Völkel continue to be accepted, then the DT50 values from this study should also be added to the data set.</p> <p>Applicant:</p> <p>In the DAR the RMS states that the mass balance was reasonable during the timeframe of chloropicrin degradation in the study. Significant drops in the mass balance were observed at later time-points where the majority of chloropicrin degradation had already occurred indicating that any losses will likely be due to losses of a volatile metabolite. The volatility of chloropicrin and subsequent detection in foam traps in Hatton et al 1995, appears to be the main reason for the concerns about the low mass balance and possible losses of chloropicrin in Völkel (2004) and McLaughlin (2013); however, direct comparison of the results in this manner is not appropriate due to the differing methodologies used. In Hatton et al (1995) 50 g soil samples were incubated in flow through systems using biometer flasks with significant head space. This study design did not maximise contact of the test item with the soil and appears to have led to</p>	

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	<p>significant volatile losses with >30% identified as chloropicrin in the foam traps after 2-3 days incubation. Conversely in Völkel (2004) and McLaughlin (2013) the headspace was kept to a minimum to maximise contact with the soil and to minimise such losses. In McLaughlin (2013a) a flow through system with volatile traps including foam and Harvey's Cocktail traps for organic volatiles was used. Levels of radioactivity in the foam trap were negligible in stark contrast with the observation in Hatton et al (1995) indicating that indeed volatilisation of chloropicrin was minimised in these studies. The mass balances over the initial period of chloropicrin decline in McLaughlin (2013) support this view. For example in the Brierlow soil after 2 days levels of chloropicrin had declined to 12.1 to 15.8 %AR after 2 days when the mass balance is 80.6%AR. This clearly indicates that the primary process for chloropicrin loss is not volatilisation and loss from the system itself. Use of the derived DT50s in these studies as DegT50s is therefore justified.</p> <p>RT 4(9)</p> <p>NL:</p> <p>The NL has the opinion that this study is not acceptable because the mass balance are not sufficient. Since the mass balance are not correct the DT50 derived from this study are also not acceptable a part of the mass is missing, this can be DCNM that is not degraded and this will have an effect on the DT50 value that has been estimated.</p> <p>RMS :</p> <p>It is agreed that the mass balance values do not comply with the guideline. The RMS has made a case, that losses may be due to the formation and loss from the system of a volatile metabolite.</p> <p>The RMS comments that consideration should be given to the high volatility of the test substance and metabolites formed when interpreting the study data. The proposed metabolites formed from degradation of DCNM are chloronitro-methane and nitromethane, both highly volatile substances.</p> <p>RT 4(12)</p> <p>EFSA:</p> <p>In chloropicrin aerobic degradation study (McLaughlin, S. 2013a), recoveries significantly below of 90 % are the symptom of a failure on the experimental methodology. Without</p>	

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	<p>an adequate explanation of the losses the study should be discarded and not used for deriving kinetic end points. The presumed volatile metabolite would need to be identified.</p> <p>Despite to the losses metabolite DCNM can be confirmed as a major soil metabolite by the data in these experiments considering the amounts quantified should be taken as lower values in the actual range.</p> <p>RMS :</p> <p>It is agreed that the study has deficiencies because recoveries are lower than 90% for most timepoints and decrease with time (discussed in the conclusion to the study).</p> <p>The opinion of the RMS is that a pragmatic approach should be taken to the interpretation of studies with a highly volatile test substance and metabolites.</p> <p>A case has been made for the acceptance of the study data for derivation of DT50 values for chloropicrin – see reply to comment 4(7).</p> <p>RT 4(34)</p> <p>DE: No valid degradation DegT50 for chloropicrin or DCNM in soil are available (see our comments on aerobic soil degradation). Thus, reliable PEC_{soil} values can only be derived immediately after one application.</p> <p>RMS:</p> <p>The RMS comments that the study by Völkel has been previously accepted at community level and DT50 values from that study used in an assessment.</p> <p>The RMS has made the case that if the values from the study by Völkel continue to be accepted, then the values from the study by McLaughlin (2013a) should also be accepted – see comment 4(36) for a fuller discussion.</p> <p>Applicant: Please refer to the response to comments 4(8) and 4(13). The applicant is of the opinion that the derived DT50s can be considered DegT50s. However, the use of DissT50s for the calculation of soil PECs is perfectly valid, as evidenced by the use of the longest DT50 from field studies in soil PEC calculations when such data are available.</p>	

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	<p>Data requirement Due to the serious doubts on the acceptability of the degradation studies in soil Völkel (2004) and McLaughlin (2013a), applicant is given the opportunity to provide new fully reliable degradation in soil studies under aerobic conditions.</p> <p>Applicant has not provided any new soil degradation study. A statement (reproduced in p 24 – 25) is presented by the applicant explaining all the preventions taken to avoid losses and comparing the timing of the observed losses with presumed levels of remaining chloropicrin.</p> <p>RMS assessment of the statement seems incomplete. RMS indicates that the complex laboratory system, can still have several losses points (precisely due to the complexity). EFSA also notes the circularity of the argument presented in relation of losses and remaining levels of chloropicrin. The argument is only true if it is presumed that the losses are not chloropicrin... (otherwise the assumed decline will be lower since the mass balance losses would need to be added to chloropicrin).</p> <p>As result of the experts discussion it may be decided on the need of a new study of a re-analysis of the available studies.</p> <p>RT 4(50) and RT 4(55) refer to the need to update on PEC SW and PEC GW</p> <p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DK: Comment before expert discussion. DK agrees with DE, NL and EFSA that the low mass balance is very problematic and that reliable degradation endpoints cannot be derived from the study. See also 4.1.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p>	

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	<p>The same deviations have been observed in both McLaughlin (2013a) and Völkel (2004). Consequently, both studies could be considered acceptable as explained for Experts' consultation 4.1.</p> <p><u>Expert discussion:</u> The discussions reported under expert discussion point 4.1 capture the conclusions regarding the McLaughlin incubations.</p>	
<p>Experts' consultation 4.3 MSs experts to examine the acceptability of the degradation of metabolite DCNM in soil study McLaughlin (2013b) in relation to the mass balance and losses by volatility. See also 4(14) See reporting table 4(13)</p>	<p>Background RT 4(13) DE: Also, for the metabolite study with DCNM, we do not believe that the DT50 values from this study should be used. With a total mass balance of only 50-53 % at the end of the study it is likely that a high amount of DCNM escaped from the system or during extraction of the soil. Thus the derived DT50 values represent dissipation of DCNM and not degradation. Again, the RMS states that the lost radioactivity is due to loss of a volatile metabolite but there is no evidence provided for this and even if some of the loss is due to an additional volatile metabolite, additional loss of DCNM cannot be ruled out. RMS : As with comment 4(8), the RMS would like to make it clear that the dRR does not state at any point in the dRR that 'the lost radioactivity is due to loss of a volatile metabolite'. The attention of the MS is drawn to the conclusion of this study, where it clearly discusses the various possibilities concerning why losses have occurred. See also comment 4(14). Applicant: The results of the study do support the argument that the mass balance losses are due to the losses of an unknown volatile metabolite and due to the very rapid decline of DCNM in the study the mass balances at the end of the study are not best placed to draw conclusions on the route of losses of DCNM. As stated previously, all efforts were made to minimise volatile losses and increase contact of the test item with soil. In the Longwood and South Witham soils after 1 day levels of DCNM decline to 9.3</p>	<p>Data gap The current DT50 calculated represent DisT50 values. Reliable DegT50 values for DCNM were not available. Reliable degradation DegT50's for metabolite DCNM in soil were not available.</p> <p>Open point See open point in 4.1</p>

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	<p>to 17.9% AR, yet mass balances at this time-point were 60-70% AR. In the soils where degradation is slower (Brierlow and Speyer), mass balances were maintained for longer and after 2 days levels of DCNM had declined to 19 to 30% AR after 2 days and mass balances were 77 to 83.8% AR. These results indicate that the rapid losses of DCNM are not due to volatilisation of DCNM itself from the system. Indeed the better maintenance of the mass balances when the degradation of DCNM is slower indicates that the decline in mass balance is due to losses of a volatile metabolite.</p> <p>Data requirement</p> <p>Applicant to provide data or studies to identify the presumed volatile metabolite formed by the aerobic degradation in soil of DCNM.</p> <p>EFSA: No further study or data has been provided by the applicant. Applicant justifies the low mass balances in McLaughlin (2013b) [metabolite DCNM degradation] on the losses due to a more volatile metabolite.</p> <p>The argumentation presented to justify that there are no losses of DCNM is circular (as the arguments presented for the parent). Even if a more volatile metabolite was formed it would not be possible to exclude that at least part of the mass losses was due to volatilization of DCNM and how much the calculated half life would be affected by this. If other(s) major volatile metabolites are actually formed those would need to be identified and assessed.</p> <p>The formation of phosgene (one of the known metabolites of chloropicrin has not been considered).</p> <p>RT 4(14)</p> <p>EFSA:</p> <p>In metabolite DCNM aerobic degradation study (McLaughlin, S. 2013b), recoveries significantly below of 90 % are the symptom of a failure on the experimental methodology. Without an adequate explanation of the losses the study should be discarded and not used for deriving kinetic end points. The presumed volatile metabolite would need to be identified.</p> <p>RMS :</p> <p>It is agreed that the recoveries are significantly below 90% because of a failure in the methodology of the study. The RMS has made a limited case that this could be due to</p>	

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	<p>the formation of a volatile metabolite based on the pattern of mass balance. It is agreed that if this argument were accepted, there would still be the need to identify and quantify the volatile metabolite(s) formed, either in this study or in the study where the test substance was chloropicrin (preferably both).</p> <p>Applicant:</p> <p>Please refer to the response to Comment 4(13). The unknown metabolite is considered unlikely to be a halogenated metabolite of chloropicrin (e.g chloronitromethane) or nitromethane due to their respective volatilities (comparable to chloropicrin) and their possible detections in the soil degradation studies. It is therefore likely that the metabolite is a more volatile potential degradation product such as methylamine.</p> <p>Preliminary comments submitted by MSs before the meeting:</p> <p>DK: Comment before expert discussion. DK agrees with DE and EFSA that the low mass balance is very problematic and that reliable degradation endpoints cannot be derived from the study. See also 4.3.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>The same deviations have been observed in both McLaughlin (2013b) and Völkel (2004). Consequently, both studies could be considered acceptable as explained for Experts' consultation 4.1.</p> <p>Expert discussion:</p> <p>As for the active substance incubations there was a mass balance recovery problem in this experiment. The current DT50 calculated represent DisT50 values. Reliable DegT50 values for DCNM were not available.</p>	
Experts' consultation 4.4 MSs experts to discuss the acceptability of end	Background RT 4(26) NL: the mass balances in the study, especially towards the end, are not acceptable. This has	Data gap The available incubations with sediment water systems did not allow the route of degradation to be

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<p>points derived from water sediment study McLaughlin, 2013c.</p> <p>See also 4(28) and 4(37).</p> <p>See reporting table 4(26)</p>	<p>been observed after 7-14 days however no discussion and explanation was given. NL doubts if this study is acceptable. Is it possible that volatiles are formed from the metabolite DCNM that are not are not trappable ?</p> <p>RMS :</p> <p>For all systems, chloropicrin was either not detected or was present only low %AR at a timepoint where mass balance was still greater than 90% (either 7 or 14 days). Therefore it can be concluded that the loss of chloropicrin from the system is by degradation and a whole system degT50 can be derived.</p> <p>For DCNM the same case could be made for one system (Weweantic River, no headspace). It is less clear for the other three systems as DCNM was still detected at the last timepoint with acceptable mass balance and a case needs to be made based on losses of a volatile metabolite from the formation of DCNM.</p> <p>The RMS agrees that the discussion of mass balance is inadequate and will add text, including making the case that a whole system degT50 can be derived for DCNM. This is based on the fact that mass balance was acceptable when chloropicrin and DCNM were present in the system at relatively high concentrations.</p> <p>Applicant:</p> <p>Every effort was made to prevent loss of volatile radioactivity in the study. As stated by NL mass balances to day 7 to 14 were acceptable but they declined after this. Examination of the detections of chloropicrin and DCNM reveals that the entirety of the decline of chloropicrin and all the formation and majority of the decline of DCNM are covered by the period over which mass balances were acceptable. Any losses of radioactivity are therefore due to non-trappable volatile metabolites. As the losses are not attributable to losses of chloropicrin or DCNM the study is valid. The unknown metabolite is considered unlikely to be a halogenated metabolite of chloropicrin (e.g chloronitromethane) or nitromethane due to their respective volatilities (comparable to chloropicrin) and their possible detections in the soil degradation studies. It is therefore likely that the metabolite is a more volatile potential degradation product such as methylamine.</p> <p>Data requirement</p>	<p>characterised.</p> <p>The experts agreed that for parent chloropicrin whole system DegT50 might be considered reliable (values currently proposed by the RMS) and that transfer to sediment was limited.</p> <p>A data gap was identified for a water/sediment investigation with a closed mass balance, to enable the characterisation of the route of degradation of chloropicrin in the aquatic environment to be determined.</p>

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	<p>Due to the serious doubts on the acceptability of the water sediment study McLaughlin, 2013c, the applicant is given the opportunity to provide a new fully reliable water sediment study.</p> <p>No further data or study has been provided by the applicant. A statement with argumentations in the same line as the ones presented in for the soil studies to justify the los mass balance and the non-identification of the metabolites is provided instead. (See RAR p 94-95)</p> <p>The formation of phosgene (one of the known metabolites of chloropicrin has not been considered).</p> <p>Open point.</p> <p>RMS to provide in an updated DAR further assessment on the validity of the water / sediment study (McLaughlin, 2013c) and / or summary and assessment of any new study presented by the applicant.</p> <p>Further details and assessment of the McLaughlin, 2013c water sediment study have been provided by the RMS in the RAR (p 88-101). Main issues of the study are low mass balance and non-identification of major metabolites.</p> <p>RT 4(28)</p> <p>DE: We believe that the DT50 values for chloropicrin and DCNM from this study should not be used. Chloropicrin is extremely volatile and with a total mass balance of only 62-63 % (with headspace) or 40 % (without headspace) at the end of the study it is likely that a high amount of chloropicrin escaped from the system or during the following extraction. Thus, the DT50 values represent dissipation rates and not degradation rates.</p> <p>RMS :</p> <p>Whole system degT50 values can be derived for chloropicrin as mass balance was acceptable during the timeframe of chloropicrin degradation – see also comment 4(26).</p> <p>The RMS opinion is that a case can be made for derivation of whole system degradation</p>	

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	<p>values for DCNM – see reply to comment 4(26).</p> <p>Applicant: Please refer to the response to Comment 4(26). Acceptable mass balances are obtained over the entire decline of chloropicrin. Any decline in mass balance is therefore not due to loss of volatile chloropicrin. The degradation rates can therefore be considered to be DegT50s.</p> <p>RT 4(37)</p> <p>DE: No valid DegT50 values of chloropicrin or DCNM in soil, water and sediment representing real degradation are available (see our comments above). The DT50 values used for PECSW and PECGW calculation represent dissipation rather than degradation and are not sufficient for surface water and groundwater modelling.</p> <p>RMS :</p> <p>Endpoints for chloropicrin in soil were accepted at community level previously and there are suitable endpoints available for chloropicrin in water and sediment (see comment 4(26)). The RMS has made the case that the endpoints for DCNM are also acceptable, also in response to comment 4(26). It is freely acknowledged that the acceptability of the endpoints for chloropicrin in soil, and DCNM in soil, water, and sediment are contentious and open to discussion.</p> <p>See also comment 4(38) and 4(50).</p> <p>Applicant:</p> <p>Please refer to the response to Comments 4(6), 4(8), 4(13), 4(26) and 4(28).</p> <p>Although not currently recommended practice, it is possible to run the models assuming that the parameters are DissT50s and disabling other dissipation processes (e.g. volatilisation). This was common practice in the past.</p> <p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DK: Comment before expert discussion. DK agrees with RMS that even though the mass balance by the end of the study is unacceptable the mass balance is acceptable within the time of chloropicrin degradation. A whole system degradation endpoint for chloropicrin can be derived from the study.</p>	

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	<p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>The mass balances are good (> 90% AR) or pretty good (> 70%) for both water-sediment systems considered in this study except for the last timepoints (day 30 and 45). Since the active substance and its metabolite DCNM are degraded from water-sediment systems in few days, they are therefore not any longer present at the end of the study. The mass balances are good during the time period when degradation of the active substance and its metabolites is occurring.</p> <p>Consequently, in this very specific case and as proposed by RMS, the endpoints derived from this study for chloropicrin and its metabolite DCNM are considered acceptable.</p> <p>Expert discussion:</p> <p>The available incubations do not allow the route of degradation to be characterised.</p> <p>The experts agreed that for parent chloropicrin whole system DegT50 might be considered reliable (values currently proposed by the RMS) and that transfer to sediment was limited.</p>	
Experts' consultation 4.5 MSs to consider if the data provided in relation to the possible impact of water treatment procedures on the residues of chloropicrin are satisfactory in relation to what is required in Regulation	<p>Background RT 4(29)</p> <p>DE: Since chloropicrin is very toxic and very prone to leaching into groundwater, the impact on water treatment procedures should really be addressed for this compound.</p> <p>RMS :</p> <p>The impact has been addressed, although not directly for groundwater – the MS is referred to the statement in section B.8.3.5. See also comment 4(30).</p> <p>Applicant: Although the Koc indicates that chloropicrin is mobile, based on the other</p>	<p>Data gap</p> <p>The experts considered that the data requirement in relation to the possible impact of water treatment procedures on the residues of chloropicrin remains open.</p> <p>Uncertainty remains over the nature of residues in surface water and groundwater as satisfactory information on the route of degradation in surface water and soil</p>

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(EC) No 1107/2009 under the approval criteria. See also 4(30) and 4(60) See reporting table 4(29)	<p>properties of chloropicrin (impersistence and volatility) and its controlled use it is highly unlikely groundwater contamination arising from the proposed use would occur. The Applicant also does not believe that there is evidence of groundwater contamination from crop protection uses from groundwater monitoring programmes. The possible impact of water treatment procedures is however presented in response to Comment 4(30).</p> <p>Data requirement Applicant to provide further data, or a more elaborated and substantiated case, on the possible impact of water treatment procedures on the residues of chloropicrin.</p> <p>Applicant has provided a statement. It referred to WHO/SDE/WSH/03/04/52. This document states that chloropicrin may be formed during the chlorination processes for water disinfection from humic acids. Also that in certain circumstances or processes the formed chlorpycning can be transformed to chloroform. It also states that with the scarce data available to the WHO working group and the high mortality observed in the carcinogenesis bioassay a guideline value for chloropicring in drinking water could not be proposed.</p> <p>Open point RMS to update the DAR with further information and assesment of the data presented by the applicant on the possible impact of water treatment procedures on the residues of chloropicrin.</p> <p>See updated RAR p 104.</p> <p>RT 4(30) EFSA: Regulation (EC) No 1107/2009 requires in its approval criteria that 'it shall have no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health,through drinking water (taking into account substances resulting from water treatment). Further data, or a more elaborate and detailed case, is</p>	was not available.

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	<p>needed on the impact of water treatment procedures may have on residues of chloropicrin.</p> <p>RMS :</p> <p>It is agreed that the argument presented is not detailed enough. The Applicant has proposed a case (see previous comment and below). The RMS could also propose an alternative case based on the following:</p> <p>'Chloropicrin itself is recognised as a bi-product of disinfection of water systems by chlorination with some evidence that formation is enhanced by ozonation. The RMS therefore considers that the impact of chlorination / ozonation on residues of chloropicrin is not relevant to any risk assessment but that the relative potential concentrations of chloropicrin that reach a water treatment facility compared to reported concentrations of chloropicrin produced by the disinfection process should form the basis of any assessment.</p> <p>The regulatory acceptable concentration for chloropicrin in surface water is 0.016 µg/L. This is an order of magnitude below reported concentrations of chloropicrin formed in disinfection processes. This does not consider the considerable dilution that will occur before any contaminated surface water becomes a source for drinking water.</p> <p>The regulatory trigger for chloropicrin in groundwater is 0.10 µg/L. This is approximately the same order of magnitude as concentrations of chloropicrin reported to be formed in disinfection processes but does not consider the considerable dilution that will likely occur before any contaminated groundwater becomes a source for drinking water.</p> <p>Overall it is highly likely that the presence of chloropicrin from use as a plant protection product in water treatment facilities will be lower than from its direct formation as a disinfection bi-product and therefore it is considered that the risk is acceptable'.</p> <p>Applicant: Due to the properties of chloropicrin and the highly controlled manner in which it is used it is highly unlikely to be present in groundwater or at surface water abstraction points. However, the possible effects of drinking water treatment on chloropicrin have been considered. In the EU the main processes of drinking water treatment are filtration (sand and activated carbon filters), ozonation, chlorination and UV treatment. Based on the properties of chloropicrin slow sand filtration will be an effective removal mechanism for both chloropicrin and its metabolites via degradation,</p>	

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	<p>and there will also be the potential for volatilisation in such systems. Activated carbon is also an effective removal mechanism for chloropicrin. Based on the structure chloropicrin is unlikely to be oxidised in the presence of ozone or the hypochlorite ion, however under reducing conditions it will be readily degraded via DCNM, NCM and chloroform. It is extensively degraded under UV light to terminal degradation products, such as chlorine and carbon dioxide (WHO/SDE/WSH/03.04/52). A more detailed consideration of this issue can be submitted as additional information on request.</p> <p>RT 4(60)</p> <p>EL: Even if it is unlikely that the a.s. will occur in such facilities it is proposed to present the possible fate of chloropicrin in WTP, after a scientifically based theoretical assessment.</p> <p>RMS :</p> <p>Please see comment 4(30).</p> <p>Applicant: It is considered reasonable to exclude consideration of the effects of WTP if it can be argued that the compound will not be present in groundwater or surface water abstraction points. However, the possible effect of drinking water treatment is addressed in the response to comment 4(30).</p> <p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DK: Comment before expert discussion. The justifications presented by the notifier seems likely to demonstrate that the use of chloropicrin as a plant protection product will not be problematic in relation to water treatment procedures.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>FR opinion is that the argumentation provided by the notifier is not sufficient enough to address this point. Chloropicrin is indeed a disinfection by-product in water treatment facilities but no referenced data are given about the concentrations of chloropicrin</p>	

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	<p>formed by disinfection treatments.</p> <p>Moreover, no data have been provided for the products potentially formed by water treatments from metabolite DCNM.</p> <p>Expert consultation:</p> <p>The experts considered that the data requirement remains open. Uncertainty remains over the nature of residues in surface water and groundwater as satisfactory information on the route of degradation in surface water and soil was not available.</p>	
<p>Experts' consultation 4.6</p> <p>MSs to consider the proposals of the applicant for the assumptions used in the calculation of PEC GW. In particular in relation to the fate of the substance in soil during the time it is covered.</p> <p>See data requirement in 4(54) and open point in 4(58).</p> <p>See also 4(56)</p> <p>See reporting table 4(57)</p>	<p>Background</p> <p>RT 4(57)</p> <p>EFSA:</p> <p>considerations by the RMS in relation to the reliability or representativeness of the values obtained by FOCUS GW model for a substance of the characteristics of chloropicrin are agreed. Whether the values calculated can be considered representative worst cases for the respective scenarios may be subject to discussion.</p> <p>RMS :</p> <p>Comment noted.</p> <p>Applicant:</p> <p>see applicant comment at 4(53). It is recognised that, despite the contention that the models do not reliably estimate exposure for highly volatile substances, acceptable risk to groundwater is identified for half of the FOCUS groundwater scenarios modelled allowing 'safe use' to be demonstrated. It is noted that some reviewers have concerns about the parameterisation of the models. The lack of an appropriate accepted validated tool to assess the exposure for highly volatile compounds should dictate a more pragmatic approach and recourse to unrealistic extreme worst case parameterisation should be avoided. For example in the DAR the applicant proposed that the evidence of a raised temperature under the impermeable tarp could be used to refine the degradation assumed under the tarp (one of the purposes of such a tarp is to increase soil temperature). The RMS are reluctant to accept this having concerns that the elevated soil temperature may lead to elevated levels in the gas phase, thus affecting the degradation rate; however, this principle has been accepted in the</p>	<p>Open points</p> <p>RMS to highlight in the LoEP that the available groundwater modelling (and surface water modelling) cannot be relied upon and has been maintained for illustrative purposes only to show the relevance of the concern and that in the absence of degradation half-lives the consequent assumption of no degradation during soil coverage would result in groundwater concentrations of chloropicrin largely above the parametric drinking water value.</p> <p>RMS to produce new surface water calculations assuming no reduced dose rate accounting for the time the tarpaulin is in place (i.e. considering there was no degradation in this period) to illustrate the potential concern from surface water exposure.</p>

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	<p>evaluation of other fumigants (e.g. dazomet). Data in the Dossier relating to the possible effect of temperature on degradation (Volkel (2004) where degradation rates in a single soil were 9.8 and 3.9 days at 10 and 20°C) give no indication of any retardation of degradation due to increased levels in the gas phase at the higher temperature. Daily soil temperature data are available from two sites, one in EU CZ and one in EU SZ. At both sites the average difference between covered and uncovered plots was ca 6°C. Application of such an adjustment to the soil temperature over the 21 day covered period results in a significant reduction in the residue available after removal of the membrane with consequent improvements for the PECgw. Additional information can be submitted on request in support of this contention and a more detailed case made in relation to the overestimation of exposure for highly volatile substances by the accepted models.</p> <p>RT 4(54)</p> <p>EFSA:</p> <p>the presumption that there is not significant leaching or downwards movement of chloropicrin during the time the soil is covered is not realistic. By its nature chloropicrin may distribute to over the upper soil horizons even in the absence of leaching water. In addition the water entering laterally to the field can increase this effect and cannot be precluded without further data. For the drip irrigation applications, according GAP table, water is added in high amounts at the precise moment of application.</p> <p>RMS :</p> <p>The RMS does not disagree with the argument presented that there will movement (vertical and to a lesser extent lateral). Although drip irrigation involves the addition of water, experimental evidence suggests the presence of chloropicrin is generally restricted to shallower depths than when it is introduced by shank injection.</p> <p>There are different options for parameterising the models, more so in PEARL than PELMO. The RMS used the option of incorporation to 20 cm as a refinement for shank injection. A refinement using a different depth of incorporation could be used.</p> <p>There are a number of issues considering the parameterisation and suitability of the models which are open to discussion and the parameterisation of injection could be part</p>	<p>RMS to remove groundwater modelling results for drip irrigation application from the LoEP.</p> <p>RMS to remove the lab soil dissipation from the LoEP main entries. They should just remain as being the input values in the available 'illustrative' modelling.</p> <p>RMS to remove the metabolites assessment and modelling results for the metabolites from the LoEP.</p>

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	<p>of that discussion. See also comment 4(38).</p> <p>Applicant: It is agreed that there is the potential for diffusion throughout the soil column while the tarpaulin (VIF) is in place; however, the levels reaching the deeper depths, as indicated in the field study, will represent a very small proportion of the total applied. While the tarp (VIF) is in place chloropicrin will be extensively degraded there will be no net downward movement of water in the soil column (a principle accepted in the evaluation of other similarly applied fumigants, e.g. dazomet), even when applied in drip irrigation (in 14-18 mm water) as the water volume applied is not that high. In the situations in which the product is used it is highly unlikely that the water table would be shallow enough for lateral groundwater flow to be an influence. The comments on this issue have concentrated on potential downward movement of chloropicrin; however, there will also be upward movement in the soil column which the available models cannot simulate. The approach taken for the modelling is a pragmatic approach in the light of the limitations of the models used for simulating the highly controlled manner of application of a volatile substance. The FOCUS models are not designed to simulate either aspect.</p> <p>Data requirement</p> <p>Applicant to propose more realistic distribution of chloropicrin over the soil horizons during the time the soil is covered to be considered for the PEC GW calculations.</p> <p>In order to identify a realistic worst case for the distribution of chloropicrin over the soil horizons it is suggested that results of the study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox section are considered.</p> <p>Other studies produced by the applicant or found in the open peer reviewed scientific literature may also be considered.</p>	

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	<p>No further proposal has been made by the applicant. Current proposal ignores the distribution of the substance to deeper horizons that may occur independent without rain and during the tarp covered period.</p> <p>RT 4(58)</p> <p>EFSA:</p> <p>Study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004. (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions.) presented in the ecotox section needs to be summarized in fate chapter and be considered with respect to its implications for the soil and ground water assessment.</p> <p>RMS :</p> <p>Thank you for pointing out this study. It will be summarised in the soil section with the other literature papers (page 50).</p> <p>Open point</p> <p>RMS to summarize and assess in an updated DAR the study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox section of the dossier with respect to its implications for the soil and ground water assessment.</p> <p>See data requirement in 4(54), and expert consultation in 4(57).</p> <p>See also 4(56)</p> <p>When evaluating this study, care should be taken in assessing if residues measured for soil injection (Bartolome, 2009) can be extrapolated to the drip irrigation uses, see 5(16).</p>	

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	<p>Results of the above studies have not been considered with respect to PEC GW calculations</p> <p>RT 4(56)</p> <p>EFSA:</p> <p>For the reasons given in a comment above, assuming the application depth as 0 cm is not realistic even for the drip application. Movement of chloropicrin through the upper soil horizons during the time soil is covered cannot be excluded. Actually, it seems necessary in order the treatment is efficacious.</p> <p>For the same reasons the “refinement” by reducing the injection depth to 5 cm seems also not realistic, since even if the injection is produced at this depth chloropicrin will move deeper during the time the soil is covered.</p> <p>RMS :</p> <p>Point (1): The RMS agrees that an application depth of 0 cm is not realistic for drip irrigation, given that the active substance will spread through the soil while the tarp is in place. The refinement used for the shank injection was incorporation to 20 cm. The RMS proposes that this parameterisation should form part of the general discussion on parameterisation and suitability of the models.</p> <p>Point (2): There was no refinement to an injection depth of 5 cm. This was proposed by the applicant and reported as such (page 122) but was rejected by the RMS.</p> <p>See also comment 4(38).</p> <p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DK: Comment before expert discussion. DK agrees that chloropicrin will distribute in the soil during the time the soil is covered, and hence an application depth of 0 cm is not realistic, and the refinement to 5 com is also not realistic.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p>	

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	<p>As proposed for the active substance DMDS at Pesticides Peer Review 02 (in April 2019), a fumigant with the same application method with shank injection and tarp and a similar fate during the time the soil is covered (diffusion through the soil horizons, diffusion in the soil gaseous phase, etc.), the initial chloropicrin application rate should be considered for PECgw calculations in addition to the corrected application rate (after tarp removal) proposed in the DAR.</p> <p>Depending of the outcomes of expert's consultations 4.1 and 4.2, if a DissT50 value is considered, then a vapour pressure of 0 should be used for chloropicrin.</p> <p>Moreover, considering the uncertainties raised in the laboratory soil degradation studies for the active substance, PECgw calculations for the metabolite DCNM should be considered separately from the parent. The metabolite may be applied directly at the soil surface at an application rate considering the initial application rate of the parent corrected by its molecular weight and its maximal level of occurrence in soil.</p> <p>FR agrees with the incorporation in soil at 20cm for the application method in modelings</p> <p>Expert discussion:</p> <p>As soil degradation values for the active substance were not available (only dissipation soil DT values available) then the approach to reduce the dose rates whilst the tarpaulin is in place based on a degradation rate is not valid. Therefore, the available groundwater modelling (and surface water modelling) cannot be relied upon. The experts agreed that in this case further groundwater calculations were not needed as clearly if no degradation during soil coverage was considered (which is all that is possible to do when only dissipation rates are available) then groundwater concentrations of chloropicrin would always be largely above the parametric drinking water value.</p> <p>New surface water calculations assuming no reduced dose rate accounting for the time the tarpaulin is in place (i.e. considering there was no degradation in this period) were identified as having utility for illustrative purposes.</p> <p>The experts concluded that the way the drip irrigation had been parameterised was not appropriate as the active substance would be more distributed over the soil layers (deeper) at the time of application than had been represented by the available</p>	

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	<p>simulations. Therefore, this modelling results (drip irrigation application) should be removed from the list of endpoints.</p> <p>The experts also considered that the available soil laboratory dissipation DissT₅₀ values could not be used in leaching simulation modelling also for the period after tarpaulin removal. This was because the volatilisation from the small volume sieved soil samples in the soil incubations would not be representative of what happened in the field / would be simulated by the soil column leaching models. The lab soil dissipation values should not be left in the list of endpoints. They should just remain as being the input values in the available 'illustrative' modelling.</p> <p>The whole metabolite assessment was considered as unreliable due to the lack of reliable route of degradation information.</p>	
<p>Experts' consultation 4.7</p> <p>MSs to consider the need for a specific risk assessment for uses of chloropicrin in permanent glasshouses, accounting for the emissions occurred at the time of the necessary ventilation.</p> <p>See reporting table 4(69)</p>	<p>Background</p> <p>RT 4(69)</p> <p>DE:</p> <p>We disagree with the conclusion that no risk assessment is necessary for crops grown under permanent protection. This is due to the fact of the extreme volatility of chloropicrin. Permanent greenhouses or tunnels need to be aired sometime after application to allow personnel entering the greenhouse/tunnel. Since chloropicrin is a pulmonary agent, entering the greenhouse without protective clothing cannot take place before airing. Therefore, it is expected that once airing takes place high amounts of chloropicrin enter the surroundings and concentrations exiting the greenhouse/tunnel might even be higher than after lifting the VIF.</p> <p>This needs to be taken into account and addressed in the risk assessment. This statement is valid as well for the risk assessment for birds.</p> <p>Applicant:</p> <p>The RMS has used maximum measured air concentrations of chloropicrin following shank, drip and protected (outside the glasshouse) applications. The exemption for permanent and full protection reflects the usual physical exclusion of birds and mammals</p>	<p>The experts considered that a separate assessment for permanent greenhouse was not needed provided that the practice for tarpaulin covering in the permanent greenhouse was the same as in the field.</p>

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>that applies for glasshouses of this type.</p> <p>RMS:</p> <p>It is acknowledged that airing of permanent greenhouses can result in chloropicrin being present in the air leaving such structures. However, it must be remembered that there will be significant reduction in the mass of chloropicrin present in the greenhouse by the time it is aired. It must also be remembered that air leaving greenhouses via windows will leave at height and will quickly mix with surrounding air, thus diluting chloropicrin concentrations.</p> <p>In the inhalation and deposition risk assessment for birds and mammals conducted by the RMS, the maximum air concentration at 1 m used in the assessment comes from a study involving a protected use drip irrigation application. This maximum value occurred on day 3 following treatment (see section B.6.4.2.2.1), with any subsequent peaks in the air concentration being below this value. Therefore, it is considered that the risk assessment performed will be protective of any emissions from glasshouses at later time points. This justification can be added to an updated DAR.</p> <p><u>Preliminary comments submitted by MSs before the meeting:</u></p> <p>DK: Comment before expert discussion. DK agrees with DE that chloropicrin will most likely escape from greenhouses after airing. However, DK agree with RMS that the risk assessment performed is also protective for the use in glasshouses.</p> <p>FR: Based on the available information and before the discussion in expert meeting, FR has the following preliminary comments.</p> <p>Considering the very high volatility of the active substance and its non-negligible redeposition, the exposition of surface water by chloropicrin redeposition after glasshouses ventilation could also be estimated. As proposed for field intended uses, experimental data from toxicology studies could be used if available.</p> <p><u>Expert discussion:</u></p>	

Subject	Discussion Pesticide Peer Review Meeting	Conclusions Pesticide Peer Review Meeting
	<p>The experts considered that a separate assessment for permanent greenhouse was not needed provided that the practice for tarpaulin covering in the permanent greenhouse was the same as in the field. If this was not the case (absence of tarpaulin coverage) then a separate assessment would be needed.</p>	

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Open point 1.1 RMS to add in the DAR information on the vapour pressure measured at different temperatures See reporting table 1(14)	This information has been added to the DAR section B.2.1.5 as requested.			Addressed.
Open point 1.2 RMS to include a statement about the acceptability of the used methods (on their similarity to the OECD/EC methods) See reporting table 1(18)	This information has been added to the DAR section B2.1 as requested.			Addressed.
Data requirement 1.1 Accelerated storage stability study for 'Chloropicrin 99' in accordance with	No data has been submitted, this data remains outstanding and a data requirement has been set in the DAR			Data gap: Accelerated storage stability study for 'Chloropicrin 99' according to Regulation (EU) No 545/2011 should be submitted.

Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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Regulation (EU) 545/2011 should be submitted See also 1(22) See reporting table 1(23)	Data requirement			
Data requirement 1.2 The surface tension of the preparation 'Chloropicrin EC' should be provided. According to Vol. 4, the co-formulant added indeed is a surfactant and therefore extrapolation from the surface tension of the technical material to the preparation is not acceptable. See also 1(29), 1(32) See reporting table 1(24)	Study submitted and evaluated. The study was found to be acceptable and the results added to the DAR section B.2.2.11			Addressed. A new surface tension study was provided and considered acceptable.
Data requirement 1.3 Accelerated storage	Study submitted and evaluated. The study was found to be deficient as			Addressed. EFSA agrees that the study has some deficiency however could

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Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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stability study for 'Chloropicrin EC' in accordance with Regulation (EU) 545/2011 should be submitted See also 1(32), 1(33) See reporting table 1(25)	insufficient data was submitted with respect to active substance validation, pH and packaging stability. The available data was reported in the DAR section B2.2.14/2, but the data requirement remains outstanding			be considered as acceptable.
Data requirement 1.4 Applicant to submit the final report on the 2 years shelf life study including determination of the technical characteristics relevant for the EC formulation before and after storage. See also 1(31), 1(32), 1(33) See reporting table 1(26)	Study submitted and evaluated. The study was found to be deficient as insufficient data was submitted with respect to emulsifiability, pH and packaging stability. The available data was reported in the DAR section B2.2.15/2, but the data requirement remains outstanding			Data gap: The study was provided, however for the part of the content of the active substance in the formulation before and after the storage, no technical characteristics relevant for the EC formulation were measured.
Open point 1.3	Explanatory footnote added			Addressed.

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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RMS please present the GAP table in the agreed harmonised template including presentation of the water amount in L/ha See also comment in 2(62). See reporting table 1(35)	to GAP table.			The GAP table was presented in the latest agreed format.
Data requirement 1.5 Applicant to provide information on the temperature of storage. See reporting table 1(42)	Information on temperature of storage added to DAR			Addressed.
Open point 1.4 RMS to check and correct, where it is needed, the residue definition in the environmental compartments. Please	The residue definitions for environmental matrices have been checked and updated in the Volume 1 and LoEP to be consistent. RMS notes that DCNM is included in the residue			Data gap: A monitoring method for phosgene in air is required.

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Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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<p>note that even in the LoEP there is a discrepancy between components of the residue definition reported on p.23 and p. 97 See also 1(60)</p> <p>See reporting table 1(43)</p>	<p>definition for monitoring in ground and surface water. A method of analysis is not available for this metabolite and hence it has been set as a data requirement</p>			
<p>Data requirement 1.6 Additional validation data according to SANCO/825/00/rev. 8.1 should be submitted for the method Gilberto, 2009 in order the method to be considered validated as a monitoring method for high water content matrices, in particular: additional samples at each fortification level for the confirmatory method and an ILV. See also 1(51), 1(57)</p>	<p>Study submitted by the applicant and evaluated by the RMS.</p> <p>Study found to be acceptable ILV for the method Gilberto, 2009 hence addressing this data requirement.</p> <p>Within the study validation data is generated for the confirmatory method. Acceptable recovery and precision data for the confirmatory method at the LOQ (n=6) is provided which addresses the requirements for the</p>			<p>Addressed. A new ILV and additional validation data for the confirmatory method were submitted and considered acceptable.</p>

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Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

(21/01/2020)

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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See reporting table 1(44)	<p>confirmatory technique as set out in SANCO/825/00 rev. 8.1:</p> <p><i>"recovery and precision data for samples fortified at the respective LOQ (n≥3)"</i></p> <p>RMS considers that the monitoring method for high water commodities is now acceptably validated and that no further data is required.</p>			
<p>Data requirement 1.7</p> <p>Monitoring methods for analysis of the residue definition in high oil content and dry matrices according to SANCO 825/00/rev. 8.1 are required.</p> <p>See also 1(52), 1(53), 1(54), 1(58)</p> <p>See reporting table 1(47)</p>	No data has been submitted, this data remains outstanding and a data requirement has been set in the DAR			<p>Data gap:</p> <p>Monitoring methods for analysis of the residue definition in dry and high oil content matrices are required.</p>
Open point 1.5	The RMS has clarified the			Addressed.

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Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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RMS to make it clear in an amended DAR which methods are considered acceptable as monitoring methods although some deviations from SANCO/825/00 rev. 8.1 were identified and which methods are not considered acceptably validated unless additional data are provided. The additional data requirements should be clearly stated. See reporting table 1(50)	conclusion for each method in section B.5.2-5.4 to note when the method is acceptably validated and where additional data is required. Data requirements are explicitly listed in section 5.5			
Data requirement 1.8 A confirmatory method is required for the monitoring method in high acid content matrices (strawberry) See data requirement in 1(44)	No data has been submitted, this data remains outstanding and a data requirement has been set in the DAR			Addressed. The confirmatory method (Brown, D.C., 2013) using different chromatographic phase was already submitted and considered valid. Monitoring method in high acid content commodities is considered validated according to SANCO/825/00 rev. 8.1.

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section 1 – Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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See reporting table 1(51)				
Open point 1.6 RMS either delete the study or make it clear that it is reported only for completeness. See reporting table 1(55)	Clarification has been added to the DAR that the study is reported for completeness only.			Addressed.
Open point 1.7 RMS to include consideration on the matrix effects for the monitoring methods in an amended DAR See reporting table 1(56)	Consideration of matrix effects have been added to section B5.2.			Addressed.

section 2 – Mammalian toxicology

2. Mammalian toxicology

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Data requirement 2.1 Applicant to provide revised tables of tissue residues (including conversions as percentage of administered radioactivity) for the ADME study in rats by oral route, in order to reflect clearly the calculation of the oral absorption value. See reporting table 2(1)	UK RMS: Information has been added to the DAR.			Data requirement fulfilled.
Data requirement 2.2 Applicant to provide the full study reports and robust study summaries for the missing acute toxicity studies with chloropicrin (i.e. acute oral and dermal toxicity studies, skin irritation, eye irritation), including	UK RMS: New information on acute oral and dermal toxicity has been added to the DAR. The dermal toxicity study informs on dermal and ocular irritation. No human cases are available. The RMS has updated the Tables B.6.2-1 and -B.6.2-2			Data requirement fulfilled. The level of reporting is considered sufficient to allow an expert judgement on the results of the acute toxicity studies.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>data on human cases if available (for consideration of C&L).</p> <p>See also comments 2(5), 2(6), 2(7), 2(8), 2(10), 2(11), 2(12), 2(16), 2(17), 2(19).</p> <p>See reporting table 2(4)</p>				
<p>Experts' consultation 2.1</p> <p>Genotoxic potential of chloropicrin to be discussed by the experts.</p> <p>See also data requirement in 2(23).</p> <p>See also open point in 2(24).</p> <p>See also comments 2(22), 2(26), 2(27), 2(28), 2(29), 2(30).</p> <p>See reporting table 2(21)</p>		<p><u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u></p> <p>The genotoxic potential of chloropicrin cannot be concluded in the absence of appropriate follow up test <i>in vivo</i> for the observations of gene mutations <i>in vitro</i>.</p>	<p>The conclusions of the meeting have been included in the revised DAR.</p>	<p>The genotoxic potential of chloropicrin cannot be concluded in the absence of appropriate follow up test for the observations of gene mutations <i>in vitro</i>.</p> <p>See the data gap in Data requirement 2.3.</p>
<p>Data requirement 2.3</p> <p>Applicant to provide</p>	<p>UK RMS : Information has been added to the DAR, below 'Table B.6.4- 1: Summary of</p>			<p>Data gap:</p> <p>Further assessment/data on the gene mutation potential of</p>

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section 2 – Mammalian toxicology

<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>further assessment/data on the in vivo gene mutation potential of chloropicrin, as follow-up for a positive Ames test.</p> <p>See also experts' consultation in 2(21).</p> <p>See reporting table 2(23)</p>	genotoxicity studies'. RMS commentary added below the Applicant's assessment.			<p>chloropicrin, as follow up for a positive Ames test, should be provided (e.g. transgenic rodent mutation assay or rodent comet assay, including inhalation exposure and adequate target tissues could be an appropriate follow up).</p> <p>See also experts' consultation 2.1.</p>
<p>Open point 2.1</p> <p>For the in vitro gene mutation test in mammalian cells (mouse lymphoma mutagenesis assay), the RMS should provide in a revised DAR:</p> <ul style="list-style-type: none">- additional information on positive controls- a check of the units for mutant frequency values- a more extensive description of the deviations when comparing to the current	UK RMS: Information has been added to the DAR, Study B.6.4.1.3			Open point fulfilled.

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OECD guideline See also comment 2(25). See also experts' consultation in 2(21). See reporting table 2(24)				
Data requirement 2.4 Applicant to provide summary tables of results for the organ weight changes and non-neoplastic lesions observed in the respiratory tract during the long term mouse study with chloropicrin. See reporting table 2(32)	UK RMS: the information has been added to the DAR			Data requirement fulfilled.
Experts' consultation 2.2 Long term inhalation mouse study to be discussed by the experts. See also comment 2(33).		Pesticide Peer Review Meeting <u>13 (16 – 20 September 2019)</u> : For the 104-week rat study by gavage, the - NOAEL for chronic toxicity is 0.1 mg/kg bw per day based on adverse findings in	The revision of the statistical significance of peribronchial lymphocytic infiltration findings has been included in the revised DAR. The RMS notes that it results statistically significant in the 0.1 ppm male group when only the animals sacrificed at	For the 78-week mouse study by inhalation, the - NOAEL for chronic toxicity is 0.1 ppm based on nasal findings (rhinitis, olfactory hyaline inclusions and epithelium atrophy), decreased body weight (gain), increased lung weight and upper airway

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See reporting table 2(32)		<p>the non-glandular forestomach (hyperplasia and hyperkeratosis)</p> <ul style="list-style-type: none"> - NOAEL for carcinogenicity is 10 mg/kg bw per day (high dose tested) <p>For the 107-week rat study by inhalation, the</p> <ul style="list-style-type: none"> - NOAEL for chronic toxicity is 0.1 ppm based on increased mortality and decreased body weight gain - NOAEL for carcinogenicity is 1 ppm (high dose tested) <p>For the 78-week mouse study by inhalation, the</p> <ul style="list-style-type: none"> - NOAEL for chronic toxicity is 0.1 ppm based on nasal findings (rhinitis, olfactory hyaline inclusions and epithelium atrophy), decreased body weight (gain), increased lung weight and upper airway lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates) 	<p>study termination are considered, whilst the statistical significance is achieved starting from the 0.5 ppm male group when all the study animals are considered.</p>	<p>lesions (bronchiectasis, bronchial submucosal fibrosis, peribronchial lymphocytic infiltrates)</p> <ul style="list-style-type: none"> - NOAEL for carcinogenicity is 1 ppm (high dose tested).

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		<p>- NOAEL for carcinogenicity is 1 ppm (high dose tested).</p> <p>New open point: RMS to correct the statistical significance of the peribronchial lymphocytic infiltration at the low dose level in a revised DAR.</p>		Open point fulfilled.
Open point 2.2 RMS to present additional details on the conversion from ppm to systemic dose for the long term mouse study in a revised DAR. See experts' consultation in 2(32). See reporting table 2(33)	UK RMS: This has now been added to 'material and methods' sections of the rat and mouse chronic studies. Systemic daily doses have been added to DAR Vol 3 p 206 "Overall summary Toxicology and Metabolism Data" and Vol 1 The mathematical formula to convert from external ppm to systemic mg/kg bw/day is presented in the DAR Vol 3 p206 "Overall summary Toxicology and Metabolism Data" and Vol 1			Open point fulfilled.
Experts' consultation 2.3		Pesticide Peer Review Meeting	The conclusions of the	For the rat multigeneration

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Mortality in the multigeneration rat study to be discussed by the experts. See also comment 2(35). See reporting table 2(34)		<u>13 (16 – 20 September 2019):</u> For the multigeneration rat study, the - parental NOAEC is 1.0 ppm based on adverse pulmonary inflammation in females; - offspring and reproductive NOAEC is 1.5 ppm (high dose tested).	meeting have been included in the revised DAR.	study, the majority of the experts agreed that the relevant effects triggering the NOAEC should exclude mortality.
Open point 2.3 RMS to present additional details on the conversion from ppm to systemic doses for the reproductive and developmental toxicity studies with chloropicrin in a revised DAR. See reporting table 2(36)	UK RMS: Please see response to Open point 2.2			Open point fulfilled.
Open point 2.4 RMS to provide tabulated results for the pulmonary pathology (necropsy)	UK RMS: The information has been added to the DAR Table B.6.6.2.2.3-a			Open point fulfilled.

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findings) in the developmental rabbit study. See reporting table 2(37)				
Experts' consultation 2.4 Maternal and developmental toxicity in the rabbit developmental toxicity study with chloropicrin to be discussed by the experts. See reporting table 2(37)		<p><u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u></p> <p>For the rat developmental toxicity study, the</p> <ul style="list-style-type: none"> - maternal NOAEC is 0.4 ppm based on decreased body weight and food consumption; - developmental NOAEC is 0.4 ppm based on delayed ossification and increased incidence of total skeletal variations. <p>For the rabbit developmental toxicity study, the</p> <ul style="list-style-type: none"> - maternal NOAEC is 0.4 ppm based on mortalities, clinical signs, necropsy findings (lungs), reduced body weight (gain) and food consumption; - developmental NOAEC is 0.4 ppm based on increased 	<p>The conclusions of the meeting have been included in the revised DAR.</p>	<p>For the rabbit developmental toxicity study, the</p> <ul style="list-style-type: none"> - maternal NOAEC is 0.4 ppm based on mortalities, clinical signs, necropsy findings (lungs), reduced body weight (gain); - developmental NOAEC is 0.4 ppm based on increased foetus mortality and abortions.

Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

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section 2 – Mammalian toxicology

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		foetus mortality and abortions.		
Data requirement 2.5 Applicant to provide further assessment of the potential of chloropicrin for neurotoxicity. See reporting table 2(38)	UK RMS: The Applicant's assessment has been incorporated into the DAR Vol3 B.6.7 and the RMS agrees with the conclusion that there is no evidence for acute or delayed neurotoxicity.			Data requirement fulfilled. Chloropicrin is unlikely to be neurotoxic. See experts' consultation 2.5 below.
Experts' consultation 2.5 Neurotoxic potential of chloropicrin to be discussed by the experts. See reporting table 2(38)		<u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u> Based on the available data chloropicrin is unlikely to be neurotoxic.	The conclusions of the meeting have been included in the revised DAR.	Based on the available toxicological data, the experts agreed that further specific investigation of neurotoxicity is not considered necessary and that chloropicrin is unlikely to be neurotoxic.
Experts' consultation 2.6 Human sensory irritation data and testing with chloropicrin to be discussed by the experts. See also data requirement in 2(40).		<u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u> According to Regulation (EC) No 1107/2009, <i>the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans.</i>	The conclusions of the meeting have been reported in the revised DAR. However, the RMS reported also the disagreement with respect to the conclusions reached at the meeting. Please to refer to pages 199-203 of Volume 3 CA chapter B.6.8.2 and Volume 1 at	According to Regulation (EC) No 1107/2009, <i>the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans.</i>

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See reporting table 2(39)		<p><i>involving the deliberate administration of the active substance or plant protection product to humans.</i></p> <p>Consequently, the human sensory irritation study (████, 2004) was not further considered for the assessment of chloropicrin.</p>	pages 38-40 of chapter 2.6.13.	Consequently, the human sensory irritation study (████, 2004) was not further considered for the assessment of chloropicrin. The RMS disagreed.
Data requirement 2.6 Applicant to provide additional details on how the BMCL 10 was derived in the use of human sensory irritation data in exposure standard setting for chloropicrin. See also experts' consultation in 2(39). See reporting table 2(40)	UK RMS: The applicant has submitted the original citation in which the BMCL ₁₀ was derived. However, the applicant has not provided their summary of the BMCL ₁₀ modelling details which were formally requested by EFSA. The UK RMS confirms that the BMCL ₁₀ methodology is contained within the original citation (TERA, 2005). However, this point is not addressed. The applicant also provided additional details on the use of assessment factors in the use of human sensory			Data requirement obsolete. Since it is not allowed to use human volunteer studies for the derivation of toxicological reference values, this data requirement is not considered critical anymore and can be waived.

Evaluation table, Chloropicrin (Fu, In, Ne, Hb)

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	irritation data which were not formally requested by EFSA. Therefore, these have not been included in the updated DAR.			
Data requirement 2.7 Applicant to provide an additional scientific assessment of the potential ED properties of chloropicrin, following the OECD Conceptual Framework (as analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors, 2013). See reporting table 2(41)	UK RMS: The RMS review of the applicant's ED assessment has been added to the DAR at Vol 3 B.6.8. The applicant's ED assessment has been incorporated into the DAR as a separate Appendix.			Addressed. It is acknowledged that the data requirement is partially fulfilled, but can be closed since, given the mode of action of chloropicrin, i.e. local irritant with minimal systemic effects, no further testing is necessary (data waiver) to conclude on the ED potential.
Experts' consultation 2.7 Experts to discuss the endocrine disruption potential of chloropicrin. See reporting table 2(41)		<u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u> <u>T-modality:</u> the data package is complete and no T-mediated adversity was observed. <u>EAS-modalities:</u> the data	The conclusions of the meeting have been included in the revised DAR.	Chloropicrin is not an endocrine disruptor in humans.

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		package is not complete. However, given the mode of action of the active substance, i.e. local irritant with minimal systemic effects, no further testing is necessary (data waiver).		
Data requirement 2.8 Applicant to provide further assessment of the levels of DCNM (as % of the administered parent) identified in the rat metabolism study. See also comments 2(2), 2(44). See also experts' consultation in 2(43). See reporting table 2(42)	UK RMS: The Applicant's assessment has been incorporated into the DAR "Overall conclusion of ADME studies". The RMS has provided comments below the applicant's case.			In the absence of clear identification of the polar metabolism resulting from the metabolic pathway of chloropicrin, DCNM and MCNM cannot be concluded to be major rat metabolites of the active substance. (this should be addressed with the toxicological assessment of the metabolite, see data gap identified at the expert consultation 2.8 below).
Experts' consultation 2.8 Toxicological profile of the metabolite DCNM to be discussed by the		Pesticide Peer Review Meeting <u>13 (16 – 20 September 2019):</u> <u>Metabolite DCNM:</u>	The conclusions of the meeting have been included in the revised DAR.	Data gap: Further assessment of the toxicological profile (first step: genotoxicity, second step: other toxicological endpoints in

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experts. See also data requirements in 2(42) and 2(45). See reporting table 2(43)		<p>Based on indications of a genotoxic potential in the published literature, no conclusion can be drawn for the metabolite DCNM.</p> <p>Data gap A full assessment of the relevance and reliability of the published studies with results of toxicological testing for the metabolite DCNM should be provided.</p> <p>Data gap Further assessment of the toxicological profile (first step: genotoxicity, second step: other toxicological endpoints in view of deriving reference values for consumers) of the metabolite DCNM should be provided.</p>		view of deriving reference values for consumers) of the metabolite DCNM should be provided, including full assessment of the relevance and reliability of the published literature.
Data requirement 2.9 Applicant to provide a more detailed assessment of the	UK RMS: The Applicant's assessment has been incorporated into the DAR 3CA_B.6.8.1.1 "Groundwater metabolites". The UK RMS considers that			See data gap in experts' consultation 2.8.

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<p>available toxicological information/data for the metabolite DCNM (including an assessment of the relevance and reliability of the public data).</p> <p>See also experts' consultation in 2(43).</p> <p>See reporting table 2(45)</p>	DCNM is one of the two major mammalian metabolites of chloropicrin and the available published literature indicates comparable toxicity of DCNM and chloropicrin			
<p>Experts' consultation 2.9</p> <p>Reference values for chloropicrin (ADI, ARfD, AOEL, AAOEL) to be discussed by the experts.</p> <p>See also comments 2(46-50), 2(52-57).</p> <p>See reporting table 2(51)</p>	<p><u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u></p> <p>Since the genotoxic potential of chloropicrin could not be concluded based on the available data, the proposed reference values are considered informative and will not be mentioned in the EFSA conclusion.</p> <p>Open point RMS is kindly requested to provide the conversion of the AOEC in ppm into a AOEC in</p>	<p>The conclusions of the meeting have been included in the revised DAR.</p> <p>The conversion of the AOEC (and AAOEC) from ppm to mg/m³ is also included in Volume 1 at chapter 2.6.13. The conversion followed the procedure of the ECHA guidance document chapter R.8 as also mentioned in Volume 3 from page 217 to page 219 at chapter B.6.9.6. Estimates of the AOEC values as a function of the temperature have been reported in the Volume 3 CP at pages 50-51 of chapter</p>	<p>It is noted that the genotoxic potential of the substance should be clarified first before setting/applying reference values.</p> <p>The agreed ADI is 0.001 mg/kg bw per day (2-year rat, UF of 100).</p> <p>The agreed ARfD is 0.001 mg/kg (1-year dog, UF of 100, based on mortality in rats and vomiting in dogs).</p> <p>The agreed AOEC is based on a LOAEC of 0.3 ppm for local effects in the 90-day mice study, applying an uncertainty factor of 300.</p>	

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		<p>mg/m³, based on the ECHA guidance document and considering the appropriate temperature range.</p> <p>Open point RMS is kindly requested to provide revised and more detailed calculations for the non-dietary exposure estimates for phosgene, covering acute and short-term exposure.</p>	<p>B.6.5 (Exposure and Risk Assessment).</p> <p>The revised calculations for the non-dietary exposure to phosgene are included in the revised DAR.</p>	<p>The agreed AAOEC is the same as for the AOEC, since the critical effect is local irritancy.</p> <p>See the data gap in Data requirement 2.3.</p>
Data requirement 2.10 Applicant to provide more detailed summary tables for exposure scenarios for each representative use (shank and drip). They should also reflect the number of monitored individuals by task, and the number of monitoring points by study and by analysed substance (chloropicrin and phosgene).				Data requirement fulfilled.

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See also experts' consultation in 2(64). See reporting table 2(63)				
Experts' consultation 2.10 Non dietary exposure estimates for the representative uses of chloropicrin to be discussed by the experts. See also data requirements in 2(63), 2(76) and 2(91). See also comments 2(65-69), 2(72-74), 2(77), 2(79-80), 2(84-87), 2(89-90), 2(92-94). See reporting table 2(64)		<u>Pesticide Peer Review Meeting 13 (16 – 20 September 2019):</u> Open point: RMS to provide a revised version of the exposure estimates for the representative uses of chloropicrin, including all endpoints and parameters agreed during the peer-review assessment.	The new exposure estimates have been included in the revised DAR.	<u>Shank injection:</u> - operator/worker: exposure to chloropicrin is below the AOEC only for fumigation activities (tractor driver and tarp cutting) with the use of appropriate PPE but is above the AOEC for activities of disconnection. For all activities, the exposure to phosgene is at or below the LOQ. - bystanders/residents: the highest reported value (time-weighted average 8h) shortly after application is 330% of the AOEC for chloropicrin. For phosgene: measured values were below the LOQ at 50 and 200 m. <u>Drip application:</u> - operator/worker exposure to chloropicrin is below the AOEC only for post application

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				<p>activities (opening vents and transplanting) with the use of appropriate RPE.</p> <p>Considering phosgene, the exposure of workers re-entering polytunnels/greenhouses to begin ventilation is below the AOEC for 12h time-weighted average.</p> <p>- bystanders/residents: in case of protected crops, for chloropicrin, the highest reported value at 50m is 263% of AOEC, at 200m is 47% of AOEC.</p> <p>In case of outdoor activities, the highest reported value is 541% at 50m and 126% at 200m.</p> <p>For phosgene: the maximum estimated peak exposure at 20m was below the AAOEC.</p>
Data requirement 2.11 Applicant to provide further information on the phosgene generation by photodegradation of chloropicrin (by visible				<p>Data requirement obsolete.</p> <p>The lack of night-time sampling for phosgene was discussed by the experts. They agreed that phosgene will not be formed during the night since it results from photolysis of chloropicrin.</p>

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and UV light). See also experts' consultation in 2(64). See reporting table 2(76)				
Data requirement 2.12 Applicant to provide further information on the use of fan system and robust evidence (eg supported by analytical data) supporting its adoption as a suitable engineering control. See also experts' consultation in 2(64). See reporting table 2(77)				Data requirement fulfilled. The fan system described in the DAR and used in the field studies is based on the specification set out in the California EPA guidance and is expected to be applicable by a limited number of specialist application companies.
Open point 2.5 RMS to provide a revised version of the list of end points including all agreed endpoints during the peer review assessment.				Open point fulfilled.

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See reporting table 2(88)				
Data requirement 2.13 Applicant to provide the additional monitoring study including measurements of chloropicrin at sampling heights of 1.5 and 1m (in order to address the concerns raised in relationship with the exposure of child residents). See also experts' consultation in 2(64). See also comment 2(86). See also data requirement in 4(52). See reporting table 2(91)				Data requirement fulfilled. For this additional monitoring study, the 1h concentration exceeds the AOEC at 50m several times until first third of the second day after treatment.
Open point 2.6 RMS to present revised summary tables of toxicology studies in a revised DAR (Vol. 1 and	UK RMS: The external ppm to systemic mg/kg bw/d conversion has been incorporated into the DAR Vol 3 B.6 p. 206 "Overall summary Toxicology and			Open point fulfilled.

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3), including the correction factor of (5d/7d), when relevant, for conversion of dose levels in inhalation studies (in mg/kg bw per day), and including also local and systemic NOAEL(C)/LOAEL(C) where appropriate. See also comments 2(98) and 2(99). See reporting table 2(97)	Metabolism Data" and Vol 1 following Section 2.6.10. Also see UK RMS Column B response at Open point 2.2 of current table. In instances where correction for 5d/7d is not warranted, this has been explained clearly in the DAR Vol 3 B.6			
Data requirement 2.14 Applicant to provide further assessment of the toxicological relevance of the impurities (Table C.1.2.3.2). It is noted that impurities below 1 g/kg might also need to be included in the technical specification if their toxicological profile is such that they might contribute significantly to	UK RMS: The Applicant's assessment has been incorporated into the DAR Vol 4 C.1.2.3. The RMS concludes that none of the impurities will add to the hazard properties of chloropicrin and none of them are toxicologically relevant.			Data gap: The toxicological relevance of one impurity in the technical specification has not been sufficiently investigated. Nevertheless, considering the high purity of the active substance, the material tested in the toxicity studies can be considered as representative of the technical specification.

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the toxicological properties of the parent. Therefore as a first step, the hazardous properties of the identified impurities have to be further assessed (in comparison with the parent's). Pending on the conclusion about the toxicological relevance of the impurities (and the need to include them in the technical specification), it will have to be considered if the composition of the batches used for the toxicity studies (including the levels of impurities) is sufficiently representative of the proposed technical specification. See also data requirement in 2(45). See also data				

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requirement in 4(66). See reporting table 2(101)				
Data requirement 2.15 Applicant to provide a revised report for the literature review, including a clear description for the search terms, the selection criteria (to identify relevant articles) and the reliability criteria that have been applied to each selected article for weight of evidence considerations in comparison with regulatory studies. See reporting table 2(102)	UK RMS: Additional details on the original literature review on chloropicrin have been added to the DAR Vol. 3CA_B.6.11. A summary of the new literature searches for DCNM, CNM and NM (with regards to being potential environmental metabolites; see EFSA Additional Information Data Requirement 4.8, and Reporting Table 4(2)) have also been incorporated into the DAR at Vol 3CA_B.6.11			Data requirement fulfilled.

section 3 – Residues

3. Residues

<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Experts' consultation 3.1 Experts to discuss the storage stability of all compounds covered by the residue definition in the studies on strawberries and tomatoes and if possible conclude on the maximum storage stability for both crop groups and whether it is possible to extrapolate to other water- and acid matrices by default. See also 3(1) – 3(4) See reporting table 3(5)	Based on the available data, RMS concludes that the stability of chloropicrin can be shown for up to 4 days in high water crops. For dichloronitromethane, RMS is of the view that stability can be demonstrated for up to 7 days in high acid crops. It is understood that generally individual results should not be corrected, however given that 0 day and fresh recovery samples all show results of ~80% it was considered more realistic to consider degradation from this level as 100% recovery is never expected even where samples are analysed immediately. Uncorrected recoveries show fairly constant levels on day 1(71%), day 2	<u>Pesticide Peer Review Meeting TC 08 (12 September 2019):</u> It was concluded that the results on the stability of the parent and DCNM can be extrapolated to other high water- and acid content matrices as the instability is most likely independent of the food matrix but an inherent characteristics of the molecule. Regarding DCNM metabolite, since the recoveries of this compound accounted for only 83% at day 0, the DCNM residues can be considered as stable for up to 7 days, although the recoveries at this storage time interval accounted for only 59.8%. Data gap: A storage stability study on chloropicrin in a crop		Data gap: For chloropicrin , recovery data in tomato were available for day 0 (99.6%), day 2 (85 %), day 7 (50%), day 15 (11%) and day 30 (10%). Based on these data, storage stability of chloropicrin has been demonstrated for 2 days. Assuming a linear trend in degradation, stability could be assumed up to day 4 (ca 70 %), for which however no measured recovery data are available. In order to be more confident on the exact storage stability also in view of the storage periods of specimen in the residue field trials, a data gap was identified for an additional storage stability study on chloropicrin in a crop representative of the high water content commodities (preferably fruiting vegetables) covering the storage periods of the valid field trials. For DCNM , recovery data in

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	<p>(68%) and day 4 (69%). Therefore RMS considers that at a minimum based on the uncorrected values the data can be considered to support frozen storage of up to four days.</p> <p>The residues trials were all analysed within 4 days (with the exception of 3 trials), for the majority of trials, it would not be possible to undertake analysis of the samples in a shorter timeframe.</p> <p>Given the demonstrated instability of chloropicrin and dichloronitromethane in high water and high acid commodities respectively, it is considered that they would also be unstable in other commodity groups, and hence it is reasonable to surmise that the compounds will only be stable for the same length of time in other commodity</p>	representative of the high water content commodities (preferably fruiting vegetables) and covering the maximum storage time interval of the residue samples in the trials on fruit crops in order to conclude on the validity of these trials is required.		<p>strawberries were available for closer time intervals (day 0 (83%), 1 (71 %), day 2 (68%), day 4 (69%), day 5 (64%) and day 7(60%)) and demonstrated a slower degradation rate. Regarding DCNM metabolite, since the recoveries of this compound accounted for only 83% at day 0, and the procedural recovery was similar at each time point (79-83%), the DCNM residues can be considered as stable for up to 7 days (decline <30%) although the recoveries at this storage time interval accounted for only 59.8%.</p> <p>It was assumed that the instability is inherent property of the molecule and most likely instability would occur regardless of the food matrix. Therefore, the results on the stability of the parent and DCNM can be extrapolated to other high water- and acid matrices.</p> <p>Bearing in mind the finalisation of the risk assessment residue definition in plants, further</p>

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
	groups.			storage stability data on relevant compounds might be needed.
Data requirement 3.1 Applicant to provide further data/information not yet presented in the DAR to support his claim that the metabolism study with strawberries, green beans, and red beets is sufficiently addressing the data requirement. See reporting table 3(8)	The applicant has provided a case to demonstrate why they believe the metabolism study sufficiently addresses the data requirement. RMS has added this case into the DAR.			The applicant has not provided data or information not yet present in the DAR. The arguments included that the metabolism studies with strawberries, green beans, and red beets were accepted in the first peer-review and no data gap was set. Moreover, the applicant stated that in all submitted trials, residues of chloropicrin and its metabolite dichloromethane (DCNM) were below the LOQ (0.005-0.01 mg/kg) and, with the exception of one crop, no residues were detected in the crops. The exception was a single trial on strawberries where the submitted chromatograms indicated levels of 0.2 µg/kg (i.e. ~4% of the LOQ of 0.005 mg/kg). The argumentation of the acceptance in the first peer-review process is not

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
				acceptable <i>per se</i> . For the evaluation and conclusion on plant metabolism, see the data gap set in the experts' consultation 3.2 below.
Experts' consultation 3.2 Experts to discuss the suitability of the metabolism studies on strawberries, green beans, and red beets for risk assessment in the light of a) the suitability to cover the representative uses (see 3(6)) b) shortcoming (lacking intermediate samplings, the inadequate extraction and identification of terminal harvest samples and the proven instability of parent and DCNM over much shorter storage intervals than applied in the metabolism study)	RMS considers that while the metabolism study has inadequacies as listed in the DAR, when considered alongside all of the available residues trials data, it can be considered that no residues of chloropicrin or metabolites would be expected in food commodities. This is in line with the conclusion reached in the previous peer review, in which the metabolism study was considered adequate given the other available data. Based on the metabolism study and extensive residues trials indicating the absence of chloropicrin or any metabolites or	<u>Pesticide Peer Review Meeting TC 08 (12 September 2019):</u> Data gap: Applicant to make a case that based on the chemical structure of chloropicrin and the overall available data on the metabolism in plants, residue trials, the degradation pathway of chloropicrin in soil (as the representative uses consist of a soil application) (see section 4), the potential toxicological relevance of the metabolites identified in soil (see section 2) and any relevant literature search on the parent and metabolites, the metabolism of chloropicrin in plants is sufficiently investigated.		Data gap: One study was provided, which was conducted under GLP, in which metabolism on strawberries, red beet and green beans was investigated. The soil was covered in plastic sheeting prior to injection of the test substance ¹⁴ C chloropicrin into the soil. The study design is compliant with the critical GAP and employs more severe conditions, i.e. 1.5 N rate for application, 2 instead of 21 days after treatment the plastic was removed and 14 days instead of 28 days after treatment crops were planted. However, the study shows several shortcomings, i.e. the samples were analysed at intervals > 300 days after sampling which

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c) the need for a new metabolism study to address the data requirement. If possible experts should discuss and agree on a residue definition. See also 3(6) - 3(7), 3(9), 3(11), 3(30), 3(28bis), 3(33) See reporting table 3(8)	impurities in the representative uses, RMS considers that a residue definition of parent only for plant commodities is appropriate. Further consideration of the residue definition may be needed if uses are considered on other crops in future.	Residue definition for monitoring is set as chloropicrin. For risk assessment , the residue definition is provisionally set as chloropicrin and should be revisited pending upon the requested additional information to confidently address the metabolism pathway of chloropicrin in plants (see data gap). The proposed residue definitions are set for all categories of crops following soil treatment.		is not covered by the available storage stability data on chloropicrin, no metabolites could be characterised or identified in the extracted fractions whilst the unextracted radioactivity was shown to be incorporated into natural plant components (starch, protein, pectin, lignin, hemicellulose and cellulose). The study has shortcomings especially as no metabolites were identified despite of residues up to several mg eq/kg in various tissues and the bicarbonate extracts. It can therefore not be considered as fully guideline-compliant and not suitable to establish the metabolic pathway of chloropicrin in plants. However, a new study will most likely not bring further insight with respect to metabolites. Therefore a data gap has been identified to further investigate the metabolism of chloropicrin in plants considering the chemical structure of chloropicrin, the

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
				<p>overall data available on the metabolism in plants, residue trials, the degradation pathway of chloropicrin in soil (as the representative uses consist of a soil application) (see section 4), the potential toxicological relevance of the metabolites identified in soil (see section 2) and any relevant literature search on the parent and the soil metabolites.</p> <p>In the meanwhile, the plant residue definition for monitoring is set as chloropicrin. For risk assessment, the residue definition is provisionally set as chloropicrin and should be revisited pending upon the requested additional information to confidently address the metabolism pathway of chloropicrin in plants (see data gap). The proposed residue definitions are set for all categories of crops following soil treatment.</p>
Open point 3.1	Further detail has been added to outline the exact			<p>Addressed. The RMS has added details of</p>

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RMS is kindly asked to update the DAR with the details of the locations where the residue trials were conducted and conclude before experts' consultation whether they can be regarded as independent. See reporting table 3(12)	location for each trial. In addition in the trial summaries, the distance between trial sites used in a particular study is included. RMS has discounted two trials (one on tomato and one on pepper) as not being independent based on trial site. This is detailed in the DAR. The remaining trials are considered to be independent.			the trial locations and evaluated their validity. For the evaluation of all residue trials see data gap in experts' consultation 3.3 below.
Open point 3.2 RMS to remove in Vol. 3, B.7.6.1, Tomato the underline for the result from S12-003523-01 to clearly mark it as not compliant due to storage time of 24 days and therefore not suitable for risk assessment.	The underline has been removed from this trial in table B.7.6.1-1			Addressed. The underlined value for the results with tomato in trial S12-003523-01 in Vol. 3, B.7.6.1 has been removed as the trial is not considered to be valid due to too long storage time of the test specimen of 24 days.

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See reporting table 3(14)				
Open point 3.3 RMS is kindly asked to update the DAR with the details of the locations where the residue trials were conducted and conclude before experts' consultation whether they can be regarded as independent. See reporting table 3(15)	Further detail has been added to outline the exact location for each trial. In addition in the trial summaries, the distance between trial sites used in a particular study is included. RMS has discounted two trials (one on tomato and one on pepper) as not being independent based on trial site. This is detailed in the DAR. The remaining trials are considered to be independent.			Addressed. The RMS has added details of the trial locations and evaluated their validity. For the evaluation of all residue trials see data gap in experts' consultation 3.3 below.
Experts' consultation 3.3 Experts to discuss and conclude on the independency of the residue trials with respect to distance between the trial	Following further consideration of the trial location RMS considers all except two of the residues trials to be independent (see open point 3.3). Based on the number	<u>Pesticide Peer Review Meeting TC 08 (12 September 2019):</u> Open point for RMS: The RMS is asked to check the validity of the residue trials in terms of compliance	RMS: The validity of residue trials in terms of compliance to the GAP for covering "scenario 1 and 2", independence of trials and storage conditions has been checked and amendments have been reported in the revised DAR.	Data gap for the NEU zone - 3 residue trials each on tomato, pepper and strawberry supporting the proposed use in open field with drip tarpred application and removing the virtually impermeable

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<p>locations (tomato) and other factors and whether a sufficient number of valid residue trials is available.</p> <p>Experts should also address the Limit of Quantification of the various methods used and the question which limit should be chosen to establish a MRL.</p> <p>The finding of residues in one strawberry trial should be discussed and a conclusion drawn whether a non-residue situation can be established.</p> <p>See also 3(12), 3(13), 3(16) – 3(19), 3(26), 3(28), 1(12), 1(13)</p> <p>See reporting table 3(15)</p>	<p>available trials and that the residues in the trials are <LOQ RMS considers the data set sufficient to support the proposed uses (even where the replicate trials are discounted).</p> <p>The applicant has provided 26 further trials which have been evaluated by the RMS. Whilst these trials demonstrate some deficiencies such that they cannot be fully relied upon, they provide additional evidence of the 'no residue' situation, irrespective of treatment method, trial location, and indoor and outdoor trials.</p> <p>In the DAR the RMS did not propose any changes to the EU MRLs as they were sufficient to support the representative uses. The available data would indicate that no residues are expected above 0.005</p>	<p>with the representative uses and covering "scenario 1": plastic film not removed and punctured at transplanting and "scenario 2": transplanting after the plastic is removed.</p> <p>Open point for RMS: RMS to re-assess the validity of the residue trials on fruiting vegetables and strawberries with regard to the independency of the trials and acceptable storage stability conditions (see also data gap under expert consultation 3.1) as there is indication that in some trials the samples were stored in cool (stored on ice), dark conditions within 24 hours of harvest and there is no information on whether the samples were stored in freezer or frozen conditions at <-18°C.</p>		<p>film (VIF) one day after cutting of the film ("scenario 2" – explanation see below).</p> <p>Data gap: for the SEU zone</p> <ul style="list-style-type: none"> - 3 residue trials each on tomato, pepper and strawberry supporting the proposed use in open field with drip tarped application and removing the virtually impermeable film (VIF) one day after cutting of the film ("scenario 2" – explanation see below). - 4 residue trials each on tomato, pepper and strawberry supporting the proposed use in open field with shank tarped application and removing the virtually impermeable film (VIF) one day after cutting of the film ("scenario 2" – explanation see below).

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	<p>mg/kg across all commodities and therefore this level could be chosen to propose a consistent MRL if required. An MRL of 0.005 mg/kg would lead to no exceedances of the ADI or ARfD.</p> <p>With respect the proposed 'no residue' situation, RMS considers that sufficient data is available to demonstrate this. In all except one trial no residues were observed, and the one strawberry trial where a peak with the same retention time as chloropicrin was identified, this indicated levels of 0.2 µg/kg (25 x lower than the LOQ and below the LOD). This peak was barely distinguishable from the baselined noise and due to its low level, no further analysis could be undertaken to confirm identity. It is possible this peak could be attributable</p>			<ul style="list-style-type: none"> - 4 residue trials each on tomato, pepper and strawberry supporting the proposed use in open field with shank tarped application and planting through the virtually impermeable film (VIF) ("scenario 1" – explanation see below). - 1, 4 and 2 residue trials each on tomato, pepper and strawberry, respectively, supporting the proposed use in greenhouse with drip tarped application and planting through the virtually impermeable film (VIF) ("scenario 1" – explanation see below). <p>For an overview of all proposed GAPs, the presented residue field trials and resulting data gaps see Appendix 1.</p> <p>Residue trials are available for tomato, pepper, strawberry</p>

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	to a different compound, but this cannot be confirmed.			and cucurbits and they cover partly use in SEU (open field) and greenhouse (polytunnel or glasshouse in SEU zone) but none of the proposed uses in the NEU zone (data gaps). Two different application techniques are proposed and the trials are performed only with drip tarpred and not shank tarpred (proposed for SEU only) application. Therefore, it is not possible to conclude whether the same results are expected by the shank tarpred application and data gaps are set for a sufficient number of residue trials (in SEU only). Before the treatments (both drip and shank) with chloropicrin the soil is fully tarpred with the virtually impermeable film (VIF) which is left for a minim of 21 days. For the procedure of planting, two different scenarios were proposed in the GAP: "scenario 1" : The VIF was cut/punctured 21 days after the application and seedlings transplanted through the VIF

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				<p>28 days after the application (7 days after VIP cutting/puncturing). Only in three trials on tomato (S12-03523/01-03) and in two trials on strawberry (S12-03522/01-02) in greenhouse and with drip application were using this handling.</p> <p>"scenario 2": The VIF was cut 21 days after application and completely removed the day after. Seedlings were then transplanted directly to the bare soil 28-31 days after treatment (7-9 days post barrier film removal). This was performed in all remaining residue trials.</p> <p>The RMS was requested to consider all residue trials with respect to the two scenarios regarding the handling of the virtually impermeable film (VIF) before planting of the seedlings which are covered in the GAPs. EFSA agrees with the final evaluation of the RMS that "Since no clear description is provided on how "<i>barrier film puncturing</i>" is conducted, RMS</p>

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				<p>has concluded that the number of trials conducted under <i>covering "scenario 1"</i> is not sufficient to demonstrate chloropicrin residues in crops to be reduced the same way as shown in trials adopting <i>covering "scenario 2"</i> and requests therefore residue trials applying this technique (<i>scenario 1</i>).</p> <p><u>Open field trials in SEU:</u> For four trials in SEU (open field, both using drip and shank application, scenario 2: removal of film 1 day after) with tomato (44/2016-1, 7, 13, 19), pepper (44/2016-2, 8, 14, 20), courgette (44/2016-3,9,15,21), melon (44/2016-4,10, 16, 22), lettuce (44/2016-6, 12,18,24) and two trials with strawberries (44/2016-5,11) the data on storage are not clearly reported, therefore the results cannot be considered for risk assessment. "Samples were packed in polyethylene bags which were sealed, labelled and immediately transferred to</p>

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			a cool dark place. The samples were all received at the test facility intact, where the specimens were placed into a refrigerator prior to analysis. The refrigeration temperature is not specified. The samples were not stored frozen prior to analysis"	<p>No valid residue trials in open field neither for SEU nor for NEU are submitted. Data gap identified, see at beginning of the section.</p> <p><u>Cucurbits:</u></p> <p>For the SEU zone 1 trial with cucumber, 9 trials with courgette and 8 trials with melon were available with one application compliant with the critical GAP to bare soil at rates ranging from 376 to 408 kg a.s./ha which is covering the 25 % range (282 – 470 kg/ha with respect to 100 % = 376 kg/ha).</p> <p>In total, 10 valid trials with cucurbits in protected structures (polytunnel and glasshouse) with drip application and employing</p>

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				<p>scenario 2 with respect to the VIF treatment are available.</p> <p><u>Tomato:</u> For the SEU zone 16 trials were available with one application compliant with the critical GAP to bare soil at rates ranging from 376 to 447 kg a.s./ha which is covering the 25 % range (282 – 470 kg/ha with respect to 100 % = 376 kg/ha). Two trials (Study LN95/424.N.SAG08)were not GAP compliant as the Barrier film use was split after 7 instead of 21 days and removed 8 days and not 1 day after the splitting. In one trial (<i>S12-03523-01</i>) the storage time for the DCNM was 24 days instead of the maximum supported 4 days. Therefore, the result for DCNM cannot be considered reliable. One of trials (<i>S26/2015-14 and 15</i>) was performed as replicate so only one value can be considered.</p> <p>In total, nine valid trials</p>

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				<p>(for DCNM eight) with tomato in protected structures (polytunnel and glasshouse) with drip application are available (6 and 3 for scenario 2 and 1, respectively).</p> <p>Pepper: For the SEU zone 11 trials were available with one application compliant with the critical GAP to bare soil at rates ranging from 376 to 408 kg a.s./ha which is covering the 25 % range (282 – 470 kg/ha with respect to 100 % = 376 kg/ha). One of trials (<i>S26/2015-16 and 17</i>) was performed as replicate so only one value can be considered.</p> <p>In total, 6 valid trials with pepper in protected structures (polytunnel and glasshouse) with drip application employing scenario 2 with respect to the VIF treatment are available.</p> <p>Strawberry: For the SEU zone 10 trials were</p>

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				<p>available with one application compliant with the critical GAP to bare soil at rates ranging from 376 to 408 kg a.s./ha which is covering the 25 % range (282 – 470 kg/ha with respect to 100 % = 376 kg/ha).</p> <p>In total, 8 valid trials with strawberry in protected structures (polytunnel and glasshouse) with drip application are available (2 and 6 for scenario 1 and 2, respectively).</p> <p>According to Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (SANCO 7525/V1/95 Rev. 10.3 13 June 2017) 4 valid residue trials are needed for major crops in case of residues below LOQ which seems to be the situation in the field trials provided so far. The guideline stipulates also that 8 trials on tomato and 8 trials on cucumbers with treatment before forming of the edible part can be used to extrapolate</p>

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				to the whole group of fruiting vegetables except sweet corn. Therefore, a reduced number of 4 trials on tomato together with 4 trials on cucumber would be necessary for each of the different GAP scenarios and their combinations with respect to zone (NEU; SEU; G), application method (shank and drip tarpred) and treating the Cutting the virtually impermeable film(VIF)/planting (cutting and planting through or cutting and removing 1 day later) of seedlings to cover tomato, pepper and cucurbits (for details see Appendix 1). In total, 6, 6, 8 and 10 valid residue field trials are available on tomato, pepper, strawberry and cucurbits, respectively, for greenhouse use, applying drip tarpred application and scenario 2. All values are below LOQ and the number trials is sufficient to support this specific representative use. Furthermore, 3 and 2 valid residue field trials are available on tomato and strawberries,

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				respectively, for greenhouse use, applying drip tarped application and scenario 1. All values are below LOQ. The number of trials is not sufficient to support this specific representative use. Therefore, data gaps for valid residue trials are set as above (for details see Appendix 1).
Open point 3.4 RMS to correct the typo in Table 7.6.1-1 of the DAR with the correct storage period of 3 days in the residue trials for tomato. See reporting table 3(20)	PHI for trials on tomato from study LN95, corrected to 109 days in Table 7.6.1-1 to be in agreement with the storage period of 3 days.			Addressed. The error in Table 7.6.1-1 of the DAR has been clarified and corrected. In the report LN95 of the field trials with tomato it is stated that samples arrived in the lab at 9/3 and 30/3 and were analysed for chloropicrin and dichloronitromethane at 17/3; 26/3 and 1/4 resulting in storage periods > 3 days. This seemed to contrast with the information given in the DAR in table B.7.6.1-1. It was clarified that only the data from the later sampling was included in the DAR. The samples from the later harvest

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				were harvested on 29 March 2009, extracted on 31/03 and analysed on 01/04, therefore the storage interval was correctly cited as 3 days. The PHI for the later trials was corrected as it was 109 instead of 88 days. For data gap see experts' consultation 3.3.
Data requirement 3.2 Applicant is invited to submit "the further 22 supervised residue trials conducted in 2016 (two trials (one drip and one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons, strawberries and lettuce)." See also 3(21)-3(25)	The applicant has submitted 24 additional residues trials which have been evaluated by the RMS. The trials use both drip and shank application and are conducted outdoors in four sites across northern Italy and Slovenia. The trials demonstrate a no residues situation for chloropicrin in all cases. However there are some deviations which affect the acceptability of the trials:			The applicant submitted "a supplementary document summarising two reports. The first contains the further supervised residue trials conducted in 2016 to quantify residues of chloropicrin in strawberries, zucchini, melons, tomatoes, peppers and lettuce. The second includes additional analyses of samples produced by the same residue trials in the first report to determine the magnitude of residues of the potential metabolite dichlorodinitrimethane (DCDNM) in zucchini, melons, tomatoes, peppers and

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See reporting table 3(29) Estimation of the potential exposure through diet and other sources	<ul style="list-style-type: none"> - analysis of DCNM has not been undertaken to GLP - chromatograms for DCNM in each commodity are not presented -samples are stored refrigerated for 0-4 days prior to analysis rather than frozen. <p>RMS considers that due to these deficiencies, in particular regarding storage, that the trials cannot be considered fully supportive of the GAP. However, they are considered to provide additional evidence of a no residues situation which is not affected by application type, indoor or outdoor location or trial site.</p>			<p>lettuce."</p> <p>For the evaluation of the residue trials and for the identified data gap, see experts' consultation 3.3 above.</p>
Data requirement 3.3 Applicant to provide formally justification for choosing the databases for the literature search and information on the	The applicant has provided a justification for the selection of the databases which appears appropriate and has been included in the DAR.			<p>Addressed.</p> <p>The applicant used the database provider STN international and RTECS (Registry of Toxic Effects of Chemical Substances) for the literature search. The</p>

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main focus of the searched database. See reporting table 3(29) Other comments	The applicant also presented an updated literature review (2014-2018). The results of this review have been included for completeness. No relevant results were identified for residues. RMS considers this requirement to be adequately addressed			argument for using these databases was that these provided access to more than 220 relevant databases (STN international). Three relevant DB (Chemical Abstracts Plus, Toxicology Center Database and the Registry of Toxic Effects of Chemical Substances) were used for the search.
Data requirement 3.4 Applicant to provide the details of the analytical methods including the details of the validation used to determine the impurities B, C, D and F in tomato and strawberries whenever available. See reporting table 3(30) Other comments	The following response was provided by the applicant: <i>Validation data for the determination of impurity F in tomato and strawberry matrices are available in studies 24/2014 and 26/2015, both by Minuto, presented in Tables 1.5.1.2-1 (pg. 36) and 1.5.1.2-3 (pg. 42) of the DAR. The validation data met the data requirements of SANCO/3029/99 rev.4 and was considered acceptable by the RMS. There are no further</i>			Addressed. Method validation data for the analytical method to determine impurities B and F in tomato and strawberries are available and demonstrated that the method is meeting the data requirements of SANCO/3029/99 rev.4. These two impurities (DCNM as breakdown product of B) were measured in tomatoes. For impurities C and D, no method validation data are available as no measurements of these impurities were performed in any crop.

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	<p><i>analytical method details to be provided for this impurity.</i></p> <p><i>Impurities B and C were not analysed for in the trials on tomato and strawberry, therefore no analytical methods or validation data are available or required.</i></p> <p>A more extensive response has been provided by the applicant regarding Impurity D. In summary it is noted by the applicant that Impurity D was not directly analysed for in the trials due to its inherent instability. However, full validation data is provided for the metabolite DCNM in the residues trials, and Impurity D cannot be distinguished analytically from metabolite DCNM. Therefore the method can be said to be appropriately validated for both DCNM</p>			

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	<p>and Impurity D.</p> <p>The applicant's argumentation and RMS comments re Impurity D have been added to Vol 4 section C.1.5.1.3</p>			
<p>Data requirement 3.5</p> <p>Applicant to formally submit information on stability of the eight impurities in food matrices.</p> <p>See reporting table 3(31) Other comments</p>	<p>The following response is provided by the applicant:</p> <p><i>Further information on the stability of the eight impurities in food matrices are not available and are not considered necessary. Samples from supervised residue trials were analysed as quickly as practically possible (1-4 days). Despite this, no residues of the impurities considered relevant and analysable were found in any sample. Limited storage stability data has already been proven for chloropicrin and DCNM (up to 4 days). Additional storage stability data would not provide any further useful information,</i></p>		<p>Addressed.</p> <p>Despite the fact that no information on the stability of the eight impurities in food matrices is provided, the argumentation of the applicant is acceptable that the impurities would be of similar very limited storage stability and considering the fact that analysis took place in very short time intervals.</p>	

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	<p><i>other than to confirm the very limited storage stability.</i></p> <p>As stated in the reporting table 3(31) RMS considers that additional storage stability data would not provide additional useful information, other than to confirm the very limited storage stability of the compounds.</p>			
New open point 3.5: RMS please consider the implication of potential changes in reference values following the mammalian toxicology expert meeting on the consumer risk assessment.			RMS: no changes in reference values has been followed after mammalian toxicology expert meeting.	Due to missing information on <i>in vivo</i> genotoxicity of chloropicrin (see section 2), the consumer risk assessment cannot be conducted.

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Appendix 1: proposed representative uses, number of valid residue field trials and number of missing residue field trials

representative PPP: Chloropicrin 99 (min 990 g/kg)

Zone	plant	green house/field	application method	handling of the VIF	no of valid trials available	no of trials needed
SEU	tomato	G/F* (area intended for walk in tunnels)	shank tarped	Scenario 1: planting through	0	4
SEU	pepper	G/F* (area intended for walk in tunnels)	shank tarped	Scenario 1: planting through		
SEU	strawberry	G/F* (area intended for walk in tunnels)	shank tarped	Scenario 1: planting through		
SEU	cucurbits	G/F* (area intended for walk in tunnels)	shank tarped	Scenario 1: planting through		0 as can be extrapolated from tomato and pepper
SEU	tomato	F (nursery)	shank tarped	Scenario 2: removal 1 d later	0	4
SEU	pepper	F (nursery)	shank tarped	Scenario 2: removal 1 d later	0	4
SEU	strawberry	F (nursery)	shank tarped	Scenario 2: removal 1 d later	0	4
SEU	cucurbits	F (nursery)	shank tarped	Scenario 2: removal 1 d later	0	0 as can be extrapolated from tomato and pepper

representative PPP: Chloropicrin EC (940 g/kg)

Zone	plant	green house/field	application method	handling of the VIF	no of valid trials available	no of trials needed
SEU	tomato	G/F* (area intended for walk in tunnels)	drip tarped	Scenario 1: planting through	3	1
SEU	pepper	G/F* (area intended for walk in tunnels)	drip tarped	Scenario 1: planting through		
SEU	strawberry	G/F* (area intended for walk in tunnels)	drip tarped	Scenario 1: planting through		
SEU	cucurbits	G/F* (area intended for walk in tunnels)	drip tarped	Scenario 1: planting through		0 as can be extrapolated from tomato and pepper
SEU	tomato	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	6	0 (as 4 is enough)
SEU	pepper	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	6	0 (as 4 is enough)
SEU	strawberry	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	8	0 (as 4 is enough)

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section 3 – Residues

SEU	cucurbits	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	10	0 (as 4 is enough)
SEU	tomato	F	drip tarped	Scenario 2: removal 1 d later	0	3 (in total 6 as same GAP as in NEU)
SEU	pepper	F	drip tarped	Scenario 2: removal 1 d later	0	3 (in total 6 as same GAP as in NEU)
SEU	strawberry	F	drip tarped	Scenario 2: removal 1 d later	0	3 (in total 6 as same GAP as in NEU)
SEU	cucurbits	F	drip tarped	Scenario 2: removal 1 d later	0	0 as can be extrapolated from tomato and pepper
NEU	tomato	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	0	0 (covered by SEU greenhouse - same condition)
NEU	pepper	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	0	0 (covered by SEU greenhouse - same condition)
NEU	strawberry	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	0	0 (covered by SEU greenhouse - same condition)
NEU	cucurbits	G (existing protected structure greenhouse/walk-in tunnel)	drip tarped	Scenario 2: removal 1 d later	0	0 (covered by SEU greenhouse - same condition)
NEU	tomato	F	drip tarped	Scenario 2: removal 1 d later	0	3 (in total 6 as same GAP as in SEU)
NEU	pepper	F	drip tarped	Scenario 2: removal 1 d later	0	3 (in total 6 as same GAP as in SEU)
NEU	strawberry	F	drip tarped	Scenario 2: removal 1 d later	0	3 (in total 6 as same GAP as in SEU)
NEU	cucurbits	F	drip tarped	Scenario 2: removal 1 d later	0	0 as can be extrapolated from tomato and pepper

section 4 – Environmental fate and behaviour

4. Environmental fate and behaviour

<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>Experts' consultation 4.1</p> <p>MSs experts to examine the acceptability of the degradation in soil study Völkel (2004) in relation to the mass balance, the potential losses by volatility. If the study is to be considered acceptable then the MSs need to consider if there is justification to exclude data of any particular soil in the study.</p> <p>See also 4(7) and the open point therein.</p> <p>See also data requirement in 4(34)</p> <p>See also 4(16), 4(17), 4(36), 4(50), 4(55).</p>		<p><u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u></p> <p>Data gap None of the soil degradation studies available allowed reliable degradation DegT50 to be derived. The studies only allowed the determination of dissipation DisT50; however, it was not possible to determine to which extent the dissipation occurring in the laboratory system is representative of field situations.</p> <p>Data gap Reliable soil degradation studies under aerobic conditions with mass balance closed and adequate identification of volatiles was not available. Only in this situation (volatiles identified) could the overall amount of</p>	<p>RMS removed the kinetic end points for parent chloropicrin and metabolite from the LoEP sections on incubations. Dissipation endpoints were already no reported in the LoEP.</p> <p>In the LoEP it has been specified that the values used for chloropicrin PEC calculations were dissipation endpoints used for "illustrative calculations" in PEC GW and PEC SW section.</p>	<p>Data gap: A data gap identified for reliable soil degradation studies under aerobic conditions with mass balance closed, reliable kinetic analysis of the degradation of chloropicrin and formation and degradation of metabolites (including DCNM) and adequate identification of volatiles. In particular, to identify the presumed metabolite formed by aerobic degradation of DCNM.</p>

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Note: since there are serious doubts on the acceptability of the values derived from study McLaughlin, S. 2013a, the exclusion of soil II in Voelkel (2004) may result in reducing the data set for the active substance to only three soils and the identification of a data gap (and the need to use DT50 = 8.8 d for the rest of the exposure assessment instead of the geometric mean). See reporting table 4(6)		<p>chloropicrin be used to calculate reliable half-lives.</p> <p>Data gap None of the available soil degradation studies allowed the mass balance to be closed and major metabolites to be identified.</p> <p>Data gap Reliable soil degradation studies under aerobic conditions with mass balance closed and adequate identification of volatiles was not available. Kinetic parameters for the formation and degradation of metabolites could not be calculated with the available data.</p> <p>Open point RMS to remove the kinetic end points (both degradation and dissipation) for parent chloropicrin and metabolite</p>		

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
		<p>from the LoEP sections on incubations.</p> <p>Dissipation end points may be left just as the input parameters of the "illustrative calculations" for PEC GW and PEC SW.</p> <p>Open point EFSA to reflect in its conclusion that the experts considered that reliable route of degradation information under aerobic conditions would be needed before the possible consequences of metabolism under anaerobic conditions might be concluded on.</p>		
Open point 4.1 RMS to provide in an amended DAR, within the B.8 summary of the study, the reason for discarding the results on soil (II) in study Voekel, W. 2004. If loss of microbial activity is	A case has been added within the study summary for exclusion of this soil from the dataset (see page 17-18).			Open point fulfilled.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>considered for a particular soil, this loss should be compared with the loss of microbial activity in the other soils investigated in this study.</p> <p>See experts' consultation in 4(6)</p> <p>See also data requirement in 4(34)</p> <p>See also 4(16), 4(17), 4(36), 4(50), 4(55).</p> <p>See reporting table 4(7)</p>				
<p>Open point 4.2</p> <p>RMS to clarify in an amended DAR the possible reasons for the low mass balance observed in study McLaughlin (2013a).</p> <p>See reporting table 4(8)</p>	<p>The possible reasons for the low mass balance are presented in the conclusion to the study (page 24-25).</p> <p>The RMS has added a case that where mass balance is still reasonable (mostly greater than 80%) then DT₅₀ values are very similar to those derived from the</p>			Open point fulfilled.

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section 4 – Environmental fate and behaviour

<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
	<p>complete data set and the values should therefore be accepted (see pages 23-24).</p> <p>An expanded discussion of the issues with the mass balance has also been added after the two soil studies (McLaughlin 2013a and 2013b) with a case made for acceptance of the data (page 35 and 36).</p> <p>The acceptance of the study is also subject to expert consultation (4.2).</p>			
<p>Experts' consultation 4.2</p> <p>MSs experts to examine the acceptability of the degradation in soil study McLaughlin (2013a) in relation to the mass balance and losses by volatility.</p> <p>See also data requirement in 4(34)</p>		<p><u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u></p> <p>See experts' consultation in 4.1</p>		<p>See experts' consultation at 4.1</p>

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
See also 4(9), 4(12), 4(50) and 4(55). See reporting table 4(8)				
Data requirement 4.1 Applicant to provide data or studies to identify the presumed volatile metabolite formed by the aerobic degradation in soil of DCNM. See reporting table 4(13)	The applicant has not provided any further study. They have speculated that a volatile component such as methylamine may be formed (no evidence provided). The applicant statement and a RMS comment has been added to the dossier (page 35).			See data gap under experts' consultation 4.1
Experts' consultation 4.3 MSs experts to examine the acceptability of the degradation of metabolite DCNM in soil study McLaughlin (2013b) in relation to the mass balance and losses by volatility. See also 4(14)		<u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u> Data gap The current DT50 calculated represent DisT50 values. Reliable DegT50 values for DCNM were not available. Reliable degradation DegT50's for metabolite DCNM in soil were not		See data gap under experts' consultation 4.1

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
See reporting table 4(13)		<p>available.</p> <p>Open point See open point under expert consultation 4.1</p>		
<p>Open point 4.3</p> <p>RMS to highlight in an amended DAR that no storage stability data is available for the field studies.</p> <p>See reporting table 4(19)</p>	<p>A comment has been added (page 47).</p>			Open point fulfilled.
<p>Open point 4.4</p> <p>RMS to add in an updated DAR the assessment of the potential correlation pH and Koc on the adsorption of chloropicrin and DCNM.</p> <p>See also 4(22)</p>	<p>Plots and text have been added to each study summary in the DAR.</p> <p>It was concluded for both chloropicrin and DCNM that there was insufficient evidence to conclude that there was a correlation between pH and Koc (pages 62-63, 65-67).</p>			Open point fulfilled.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
See reporting table 4(21)				
Open point 4.5 RMs to update the DAR to summarize pre test experiments and, in particular, stability test data under the test system of the substance DCNM in the soil batch adsorption desorption study Kang, S., 2013. It needs to be clarified that stability refers to the substance in both phases (aqueous and soil) and not only on total radioactivity recovery. See reporting table 4(23)	The extent of the stability data has been clarified and more information generally added to the study summary (page 64-65).			Open point fulfilled.
Open point 4.6 RMS to either remove or provide reference to the	The mobility classes have been redefined under the McCall classification system and reference to SSLRC classification removed			Open point fulfilled.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
SSLRC classification system in Vol. 1 and 3.B.8 B.8.1.2.4. See reporting table 4(24)	(page 75).			
Data requirement 4.2 Due to the serious doubts on the acceptability of the water sediment study McLaughlin, 2013c, the applicant is given the opportunity to provide a new fully reliable water sediment study. See reporting table 4(26)	The applicant declined to provide a new, fully reliable study stating that 'the three month deadline given for the provision of further information is not sufficient to allow a new study to be generated'. The applicant has made a case why their current study should continue to be considered and this has been added to the DAR (page 94-95). An expanded case for acceptance of the study has been added by the RMS to the study report (pages 90 and 94).			See data gap under experts' consultation 4.4
Open point 4.7 RMS to provide in an updated DAR further assessment on the	Further text making the case for the acceptability of the study has been added to the study report (pages 90 and 94).			Open point fulfilled.

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validity of the water / sediment study (McLaughlin, 2013c) and / or summary and assessment of any new study presented by the applicant. See reporting table 4(26)				
Experts' consultation 4.4 MSs experts to discuss the acceptability of end points derived from water sediment study McLaughlin, 2013c. See also 4(28) and 4(37). See reporting table 4(26)		<u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u> Data gap The available incubations with sediment water systems did not allow the route of degradation to be characterised. The experts agreed that for parent chloropicrin whole system DegT50 might be considered reliable (values currently proposed by the RMS) and that transfer to sediment was limited. A data gap was identified for		Data gap: A data gap was identified for a water/sediment investigation with a closed mass balance, to enable the characterisation of the route of degradation of chloropicrin in the aquatic environment.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
		a water/sediment investigation with a closed mass balance, to enable the characterisation of the route of degradation of chloropicrin in the aquatic environment to be determined.		
Data requirement 4.3 Applicant to provide further data, or a more elaborated and substantiated case, on the possible impact of water treatment procedures on the residues of chloropicrin. See reporting table 4(29)	A more substantial case has been added to the DAR based on information from the applicant and further consideration by the RMS (pages 103 and 104).	The experts considered that the data requirement remains open. Uncertainty remains over the nature of residues in surface water and groundwater as satisfactory information on the route of degradation in surface water and soil was not available.		See data gap under experts' consultation 4.5
Open point 4.8 RMS to update the DAR with further information and assessment of the data presented by the applicant on the possible impact of water treatment procedures	A more substantial case has been added to the DAR based on information from the applicant and further consideration by the RMS (pages 103 and 104).			See data gap under experts' consultation 4.5

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
on the residues of chloropicrin. See reporting table 4(29)				
Experts' consultation 4.5 MSs to consider if the data provided in relation to the possible impact of water treatment procedures on the residues of chloropicrin are satisfactory in relation to what is required in Regulation (EC) No 1107/2009 under the approval criteria. See also 4(30) and 4(60) See reporting table 4(29)	The applicant has provided further information and the RMS has made a separate case based on the fact that chloropicrin is a known bi-product of water disinfection (pages 103-104).	<u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u> Data gap The experts considered that the data requirement in relation to the possible impact of water treatment procedures on the residues of chloropicrin remains open. Uncertainty remains over the nature of residues in surface water and groundwater as satisfactory information on the route of degradation in surface water and soil was not available.		Data gap: A data gap has been identified on the possible impact of water treatment procedures on the residues of chloropicrin as required in Regulation (EC) No 1107/2009 under the approval criteria.
Data requirement 4.4	The applicant declined to provide a new, fully reliable			See data gap under experts' consultation 4.1

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>Due to the serious doubts on the acceptability of the degradation studies in soil Völkel (2004) and McLaughlin (2013a), applicant is given the opportunity to provide new fully reliable degradation in soil studies under aerobic conditions.</p> <p>See also experts consultations in 4(6) and 4(8)</p> <p>See also open points in 4(7) and 4(8)</p> <p>See also 4(9), 4(120), 4(36), 4(37) and 4(55).</p> <p>See reporting table 4(34)</p>	<p>study stating that 'a further additional soil metabolism study is not available and the three month deadline given for the provision of further information is not sufficient to allow a new study to be generated'. The applicant response has been added to the end of the study by McLaughlin (2013a) – pages 24 and 25. The applicant case for accepting the study by Völkel (2004) was that it had been accepted during a previous EU review process and that measures were taken to prevent losses. These arguments have not been added to the DAR.</p> <p>It is noted that the acceptability of these two studies will be subject to expert consultation. An expanded case for the acceptance of the study by McLaughlin (2013a) has been added to the study</p>			

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
	summary.			
Open point 4.9 RMS to updated the DAR with further consideration of the assumed vapour pressures on the result of the PEC GW and PEC SW calculations and to justify the values used in each case. See reporting table 4(41)	The DAR has been clarified to show the consistency of the vapour pressure values reported. The values actually used in the surface water modelling are explained in the text (section B8.4.1, FOCUS STEP 3 section).			Open point fulfilled.
Data requirement 4.5 In the lack of adequate model to simulate volatilization / deposition of a substance with the properties of chloropicrin experimental data at 10 and 20 m is needed (in addition to the available	The applicant provided a further study of atmospheric concentrations after shank injection under a barrier film at 15 m and 25 m distance from the site of treatment. This study was used to provide deposition fluxes and then PECsw values at 15 m and 25 m (reported on page 130).			Data requirement addressed.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>data at 1m and 50 m) for the consideration of adequate risk management measures for the protection of surface water.</p> <p>See also 4(42), 4(45) and 4(46).</p> <p>See reporting table 4(52)</p>				
<p>Data requirement 4.6</p> <p>Applicant to propose more realistic distribution of chloropicrin over the soil horizons during the time the soil is covered to be considered for the PEC GW calculations.</p> <p>In order to identify a realistic worst case for the distribution of chloropicrin over the soil horizons it is suggested that results of the study</p>	<p>The study quoted by EFSA has been summarised in the dossier (pages 55 to 58). The applicant concluded that this study cannot be used to propose a more realistic distribution as suggested by EFSA. The RMS agrees with this conclusion.</p> <p>The RMS also adds that the fundamental issue is the lack of suitability of the groundwater models for handling highly volatile components. The distribution of chloropicrin</p>			See experts' consultation 4.6

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Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox section are considered. Other studies produced by the applicant or found in the open peer reviewed scientific literature may also be considered. See open point in 4(58) and expert consultation in 4(57). See also 4(38), 4(48),	over the soil horizons does not address this.			

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4(53) and 4(56) See reporting table 4(54)				
Experts' consultation 4.6 MSs to consider the proposals of the applicant for the assumptions used in the calculation of PEC GW. In particular in relation to the fate of the substance in soil during the time it is covered. See data requirement in 4(54) and open point in 4(58). See also 4(56) See reporting table 4(57)		<p><u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u></p> <p>Open points RMS to highlight in the LoEP that the available groundwater modelling (and surface water modelling) cannot be relied upon and has been maintained for illustrative purposes only to show the relevance of the concern.</p> <p>RMS produced new surface water calculations assuming no reduced dose rate accounting for the time the tarpaulin is in place (i.e. considering there was no degradation in this period) to illustrate the potential concern from surface water exposure.</p> <p>RMS removed groundwater modelling results for drip irrigation application from the LoEP.</p> <p>RMS removed lab soil</p>	<p>RMS highlighted in the LoEP that the available groundwater modelling (and surface water modelling) cannot be relied upon and has been maintained for illustrative purposes only to show the relevance of the concern.</p> <p>RMS produced new surface water calculations assuming no reduced dose rate accounting for the time the tarpaulin is in place (i.e. considering there was no degradation in this period) to illustrate the potential concern from surface water exposure.</p> <p>RMS removed groundwater modelling results for drip irrigation application from the LoEP.</p> <p>RMS removed lab soil</p>	<p>Open points fulfilled.</p> <p>See updated DAR and LoEP (see also explanation in column D)</p>

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
		<p>no reduced dose rate accounting for the time the tarpaulin is in place (i.e. considering there was no degradation in this period) to illustrate the potential concern from surface water exposure.</p> <p>RMS to remove groundwater modelling results for drip irrigation application from the LoEP.</p> <p>RMS to remove the lab soil dissipation from the LoEP main entries. They should just remain as being the input values in the available 'illustrative' modelling.</p> <p>RMS to remove the metabolites assessment and modelling results for the metabolites from the LoEP.</p>	<p>dissipation from the LoEP main entries. They remained in illustrative modelling section.</p> <p>RMS removed the metabolites assessment and modelling results for the metabolites from the LoEP.</p>	
Open point 4.10 RMS to summarize and assess in an updated	This paper has been summarised and added to the DAR.			Open point fulfilled.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
DAR the study Gao S., Trout, T., Schneider, S., Parlier, CA., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox section of the dossier with respect to its implications for the soil and ground water assessment. See data requirement in 4(54), and expert consultation in 4(57). See also 4(56) When evaluating this study, care should be	It is concluded that it has no direct implications for the soil and groundwater assessments reported in volume 3CA, section 8. The relevance of this paper to the case of whether residues measured for soil injection (Bartolome, 2009) can be extrapolated to the drip irrigation uses is discussed in volume 3CA, section 9.			

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
taken in assessing if residues measured for soil injection (Bartolome, 2009) can be extrapolated to the drip irrigation uses, see 5(16). See reporting table 4(58)				
Data requirement 4.7 Applicant to address potential GW contamination by relevant toxicological impurities. See reporting table 4(61)	The applicant has made the case that none of the impurities are toxicologically relevant in volume 4, section C.1.2.3.			Groundwater exposure assessment of the impurity of the active substance for which the toxicological relevance assessment could not be done (data gap in Section 2), may be needed, depending on the final result of that assessment since this impurity has the potential to be applied to soil in significant amounts.
Open point 4.11 RMS to present in an updated DAR the assessment of PEC GW for all the impurities considered to be toxicologically relevant.	The applicant has made the case that none of the impurities are toxicologically relevant (see data requirement 2.14 and volume 4, section C.1.2.3).			See above.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
See also 4(40) See reporting table 4(61)				
Data requirement 4.8 Applicant to provide an updated review of peer reviewed open scientific literature in relation to the metabolites of chloropicrin identified in the environment. Especially surface water metabolites, chloronitromethane, nitromethane, iminodimethanethiol thiocianic acid should be considered with respect to its fate and behaviour, toxicological and ecotoxicological properties. See also 4(2)	The additional literature review has been added to the dossier (pages 185 to 201).			Data requirement addressed. See updated DAR.

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section 4 – Environmental fate and behaviour

<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
See reporting table 4(66)				
Experts' consultation 4.7 MSs to consider the need for a specific risk assessment for uses of chloropicrin in permanent glasshouses, accounting for the emissions occurred at the time of the necessary ventilation. See reporting table 4(69)	The need for a specific assessment for uses of chloropicrin in permanent glasshouses is subject to an expert consultation.	<u>Pesticide Peer Review Meeting 15 (17 – 20 September 2019):</u> The experts considered that a separate assessment for permanent greenhouse was not needed provided that the practice for tarpaulin covering in the permanent greenhouse was the same as in the field. If this was not the case (absence of tarpaulin coverage) then a separate assessment would be needed.		The experts considered that a separate assessment for permanent greenhouse was not needed provided that the practice for tarpaulin covering in the permanent greenhouse was the same as in the field. If this was not the case (absence of tarpaulin coverage) then a separate assessment would be needed.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Data requirement 5.1 Applicant please provide information on the term "Virtually Impermeable Plastic" See reporting table 5(1)	Co-RMS: The Applicant submitted further information, included in the revised DAR.			Data requirement fulfilled. The applicant submitted further information on the term "Virtually Impermeable Plastic", which has been included in the revised DAR.
Open point 5.1 RMS to include the derived application rate in terms of L/ha into DAR. While doing this, we would appreciate that the indication of the density is specified, as this information is not easily retrieved in Vol 3B9 of the RAR. See reporting table 5(4)	Co-RMS: required information has been included in the revised DAR.			Open point fulfilled. The Co-RMS has included in the DAR the derived application rate in terms of L/ha, specifying the density and the purity.
Experts' consultation 5.1 Experts to discuss the approach and the conclusion of the RMS	Co-RMS: the Applicant submitted further information (included in the revised DAR) to demonstrate a low chronic	<u>Pesticide Peer Review Meeting 12 (09 – 13 September 2019):</u> A low acute risk to birds and	Co-RMS (IT): information on field activities related to air concentration values used for risk assessment have been included in the revised DAR.	Open points fulfilled. The Co-RMS has included in the revised DAR information on field activities related to air concentration values used for

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
<p>for what concern the acute and chronic inhalation risk to birds and mammals.</p> <p>In order to properly discuss this, it would be appreciated if the RMS could include in the assessment any relevant information submitted by the applicant in response to the data requirement 5(8).</p> <p>See also points 5(8); 5(9); 5(12); 5(22); 5(23); 5(25).</p> <p>See reporting table 5(5)</p>	<p>risk for birds and mammals through inhalation of chloropicrin.</p>	<p>mammals from exposure via inhalation was concluded. The long-term inhalation risk assessment for birds cannot be finalised. The majority of the experts considered that a low chronic risk to mammals was indicated.</p> <p>Open point RMS (IT) to check and clarify in the DAR whether the air concentrations used for the risk assessment refer to the application or to other moments (e.g. when the film is cut or removed removed).</p> <p>Open point RMS to reflect the outcome of the discussion for the risk assessment for birds via inhalation exposure in an updated DAR.</p> <p>Open point RMS to reflect the outcome of the discussion in the DAR and to indicate that the majority of the experts</p>	<p>The outcome of the discussion (on risk assessment via inhalation exposure for birds and mammals) has been included as well.</p>	<p>risk assessment. From the analysis of the data, it was clear that the air concentrations represented the worst-case average over 24 hours, irrespectively of the moment. All studies included monitoring from the application, to the VIF cutting, VIF removal, and transplanting.</p> <p>In addition, the outcome of the discussion (on risk assessment via inhalation exposure for birds and mammals) has been included as well.</p>

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
		considered that a low chronic risk to mammals was indicated.		
Open point 5.2 RMS to specify in the footnote of table 9.1.1-28 the meaning of all values. In particular, "24.45" should be presented, as now explained by the RMS, as the gaseous/vapour molar volume [L] at 1 atm and 25°C. See reporting table 5(6)	Co-RMS: required information has been included in the revised DAR.			Open point fulfilled. The Co-RMS has specified in the footnote of table 9.1.1-28 the meaning of all values, as requested.
Experts' consultation 5.2 Experts to discuss about the appropriateness of the dietary endpoint selected by the RMS for the reproductive long-long term dietary risk of birds. See reporting table 5(7)	Co-RMS: noted.	<u>Pesticide Peer Review Meeting 12 (09 – 13 September 2019):</u> Open point RMS to add a footnote to the LoEP to clearly indicate that the available reproductive bird endpoint cannot be used in the risk assessment as it does not cover all phases of	Co-RMS (IT): LoEP and DAR have been revised according to open points reported in column C.	Open points fulfilled. The Co-RMS has added a footnote to the LoEP to clearly indicate that the available reproductive bird endpoint cannot be used in the risk assessment as it does not cover all phases of the reproductive cycle. In addition, the Co-RMS has updated the DAR and the LoEP

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		<p>the reproductive cycle.</p> <p>Open point RMS to update the DAR and the LoEP by removing the risk assessment performed using the available 6-week NOEL. Data gap and assessment not finalised will be identified.</p>		<p>by removing the risk assessment performed using the available 6-week NOEL. A data gap for a standard avian dietary reproductive test has been identified. As a consequence, the long-term dietary risk assessment cannot be finalised.</p>
<p>Data requirement 5.2 Applicant to provide further information to address the reproductive risk to birds and wild mammals via inhalation exposure. See points 5(22); 5(25). In addition, see expert discussion 5(5). See reporting table 5(8)</p>	<p>Co-RMS: required information has been submitted and included in the revised DAR.</p>			<p>Data gap: The applicant provided some information that was included in the DAR. Nevertheless, following the agreement at the expert meeting, the avian short-term inhalation endpoint was not considered suitable to cover for long-term exposure. Hence, a data gap is identified and the long-term avian inhalation risk assessment cannot be finalised.</p>
<p>Open point 5.3 RMS to update the LC50</p>	<p>Co-RMS: value updated in the revised DAR.</p>			<p>Open point fulfilled. The Co-RMS has updated correctly the LC50 value under</p>

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value under Table 9.1.1-10 (should be reported as a 'greater than' value). See reporting table 5(10)				Table 9.1.1-10.
Open point 5.4 RMS to update Table 9.1.2-1, by specifying that the NOAEC from study [REDACTED] (1993a) is < 0.3ppm See reporting table 5(11)	Co-RMS: values updated in the revised DAR.			Open point fulfilled. The endpoints in Table 9.1.2-1 have been corrected in the revised DAR.
Experts' consultation 5.3 Experts to discuss about the appropriateness of the dietary endpoint selected by the RMS for the reproductive long-long term dietary risk of mammals. See points 5(14); 5(20).	Co-RMS: noted.	<u>Pesticide Peer Review Meeting 12 (09 – 13 September 2019):</u> The experts agreed with the RMS regarding the tier 1 endpoint (0.1 mg a.s./kg per day) and using a refined endpoint (1 mg a.s./kg bw per day) in the higher tier. Therefore, no open point is needed and the point is		Point closed at the experts' meeting. A low dietary reproductive risk was concluded for wild mammals based on the refined endpoint.

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See reporting table 5(13)		closed.		
Open point 5.5 RMS to include in the DAR the justification presented in column 3 of the reporting table for what concern the calculation of the predicted exposure for drinking water risk assessment. See reporting table 5(17)	Co-RMS: text amended in the revised DAR.			Addressed. The text has been amended in a revised DAR. Justification for the calculation of the predicted exposure for drinking water risk assessment has been included.
Open point 5.6 Pending on the peer review from fate, the risk assessment to non-target organisms might need to be updated by considering using in permanent greenhouses. See reporting table 5(21)	Co-RMS: DAR will be amended according to the outcome of e-fate expert meeting if necessary.			Addressed. The experts considered that a separate assessment for permanent greenhouse was not needed provided that the practice for tarpaulin covering in the permanent greenhouse was the same as in the field. See Report of Pesticide Peer Review Meeting 15 (consultation point 4.7)

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Data requirement 5.3 Applicant to submit ECx calculations or an argumentation for not calculating ECx values. See reporting table 5(26)	Co-RMS: required information has been submitted by the Applicant			Data requirement addressed. ECx calculations or an argumentation for not calculating ECx values were submitted by the applicant and included in the DAR under the summary of study 8.2.4/01.
Open point 5.7 RMS to include all relevant submitted information in the DAR. See reporting table 5(26)	Co-RMS: required information has been included in the revised DAR.			Addressed. See previous point.
Open point 5.8 RMS to update the DAR by invalidating the study from Flatman (2004). See reporting table 5(30)	Co-RMS: DAR has been amended accordingly.			Open point fulfilled. The study with algae by Flatman (2014) has been invalidated. As such, a data gap for a valid study has been identified (see point below).
Data requirement 5.4 Applicant to provide a	Co-RMS: no new study has been submitted by the Applicant. A data gap is			Data gap: No valid studies with algae are available for chloropicrin.

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<p>valid study with algae for chloropicrin.</p> <p>We agree that a study on a second species is not needed.</p> <p>Nevertheless, following the information provided by the RMS under point 5(30), none of the two available studies (Wilby, 2009a; Flatman 2004) is considered sufficiently reliable for the risk assessment. Hence, a new valid study is needed.</p> <p>See reporting table 5(33)</p>	therefore proposed.			
<p>Open point 5.9</p> <p>RMS to include NOEC values for all studies.</p> <p>See reporting table 5(34)</p>	Co-RMS: NOEC values have been included in the revised DAR.			<p>Open point fulfilled.</p> <p>NOEC values for all studies had been included in table B.9.2.9-1.</p>
<p>Open point 5.10</p> <p>Pending on the</p>	Co-RMS: DAR will be amended according to the outcome of e-fate expert			The risk assessment is still unresolved due to the uncertainties in the

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discussion in the fate area, the risk assessment for aquatic organisms might need to be updated for what concern consideration of buffer strips. See reporting table 5(40)	meeting if necessary.			environmental fate part. No reliable exposure estimates were available for surface water, hence the risk assessment is not finalised.
Data requirement 5.5 Applicant to include additional QSAR calculations. See reporting table 5(41)	Co-RMS: further QSAR calculations have been submitted by the Applicant.			Data have been submitted by the applicant. The QSAR estimations are not considered reliable, but the RMS used this information as indications that the metabolites are not more toxic than the active substance chloropicrin. This argument may be considered further when reliable exposure estimates become available.
Open point 5.11 RMS to review the outcome of these additional QSARs. See reporting table 5(41)	Co-RMS: the submitted QSAR calculations have been included and reviewed in the revised DAR.			See point above.

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Data requirement 5.6 The applicant is being given the opportunity to submit further data to address the risk for scenarios/crop combinations for which a high risk is still predicted despite the application of mitigation measures. See reporting table 5(42)	Co-RMS: no further information has been submitted by the Applicant. The following justification was provided: "There are a number of scenarios where safe has been demonstrated using appropriate mitigation and the assessment can be considered further at Member State level in the context of product applications. The indications of risk arise through consideration of effect and predicted exposure. The current exposure predictions are considered by the Applicant to be conservatively over-estimated by having to resort - in the absence of a suitable alternative - to modelling methods not designed to be used in conjunction with plant protection products with the properties, or applied in the manner of chloropicrin. Please also see the			No sufficient data have been submitted by the applicant to resolve the aquatic risk assessment. See data gap in data requirement 5.4

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	<p>Applicant's earlier responses to Points 30, 32 and 33.</p> <p>The Applicant has provided further background on the chloropicrin GAP and usage information in a separate document, noting that a lower application rate of 188 kg a.s./ha is also specified and supported in the GAP. This lower rate should additionally be considered in any revised risk assessments."</p>			
<p>Data requirement 5.7</p> <p>Applicant to provide toxicity data on foliar dwelling arthropods.</p> <p>See also points 5(54); 5(55).</p> <p>See reporting table 5(45)</p>	<p>Co-RMS: no new studies have been submitted by the Applicant. A position paper has been provided and included in the revised DAR.</p>			<p>Data gap:</p> <p>No sufficient information was submitted to address the toxicity of chloropicrin to foliar dwelling arthropods.</p>
Experts' consultation 5.4 Experts to discuss the	Co-RMS: noted.	<u>Pesticide Peer Review</u> <u>Meeting 12 (09 – 13 September 2019):</u>	Co-RMS (IT): LoEP and DAR have been revised according to open points reported in column	Open point fulfilled. All the amendments requested by the experts have been

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<p>approach and the outcome of the risk assessment to bees carried out in the DAR. In carrying out this task, the experts should consider</p> <ul style="list-style-type: none"> 1) vapour exposure and possible effects of chloropicrin on bee colonies 2) relevance of dietary and contact exposure and suitability of the available ecotoxicological data (Patnaude 2010, Patnaude 2011). <p>See also points 5(46); 5(48); 5(50); 5(51); 5(61); 5(62); 5(63).</p> <p>See reporting table 5(47)</p>		<p>Overall, the experts agreed with the RMS that, for the representative GAP, exposure to honeybees via contact and oral routes is unlikely and therefore a low risk can be concluded.</p> <p>The resulting margin of safety was considered to result in a low acute inhalation risk to bees.</p> <p>Overall, the experts agreed that further data would be needed to either exclude chronic inhalation exposure to honeybees or demonstrate a low risk.</p> <p>Open point RMS to invalidate (and remove from the LoEP) both the oral and the contact acute endpoints with bees. RMS to remove the risk assessment and to clarify that these routes of exposure are not considered relevant.</p>	C.	correctly implemented in the DAR.

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		<p>Open point RMS to update the DAR to reflect the outcome of the discussion regarding the mitigation addressing the chronic risk to honeybees and reflect the need for further assessment.</p> <p>Open point RMS to update the study summary of Porch (2009) adding additional details of the study design.</p> <p>Open point RMS to put the details of the statistical calculation of the NOEC from the study of Porch in the DAR.</p>		
Open point 5.12 RMS to adjust the summary of the Patnaude (2010) study, by correcting the inconsistencies between the replicates and the	Co-RMS: Table with information has been amended in the revised DAR.			Open point fulfilled. Table 9.3.1-4 reporting results for the Patnaude (2010) study has been amended appropriately.

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average mortality after 24 and 48h exposure to 50 µg a.s./bee See reporting table 5(49)				
Open point 5.13 RMS to clarify in the study summaries when the animals were added to the test system in relationship with the removal of the tarp. See reporting table 5(60)	Co-RMS: summaries have been amended in the revised DAR reporting the required information.			Open point fulfilled. For all the three available aged residue studies, information to the study summaries has been added in order to report when the animals were added to the test system in relationship with the removal of the tarp.
Open point 5.14 RMS to amend the LoEP by clarifying the outcome of the risk assessment considering the aged residue tests. See reporting table 5(64)	Co-RMS: LoEP has been amended including the outcome of the risk assessment considering the aged residue studies.			Open point fulfilled. The LoEP has been amended including the outcome of the risk assessment considering the aged residue studies.
Data requirement 5.8	Co-RMS: no new data has been submitted by the			Data gap: No sufficient data have been

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Applicant to provide further information to address the risk to earthworms. See reporting table 5(66)	Applicant, a position has been presented instead and reported in the revised DAR.			submitted. No reliable data are available to carry out the risk assessment for earthworms.
Data requirement 5.9 Applicant to submit ECx calculations or an argumentation for not calculating ECx values. See reporting table 5(68)	Co-RMS: required ECx calculation has been submitted by the Applicant..			Data requirement addressed. The Applicant has submitted the required ECx calculations and these have been included in a revised DAR. However, the study was classified as unreliable during the experts' meeting.
Open point 5.15 RMS to include all relevant submitted information in the DAR. See reporting table 5(68)	Co-RMS: submitted ECx calculation has been included in the revised DAR. The suitability of the ECx presented can be discussed during the expert meeting (see experts' consultation 5.5)			See above.
Experts' consultation 5.5 Experts to discuss the chronic risk assessment	Co-RMS: noted.	<u>Pesticide Peer Review Meeting 12 (09 – 13 September 2019):</u>	Co-RMS (IT): LoEP and DAR have been revised according to open points reported in column C.	Open points fulfilled. The request from the experts in the meeting were appropriately translated in

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<p>for soil macro-organisms. In particular experts should discuss:</p> <ul style="list-style-type: none"> - the suitability for the tier 1 endpoint for earthworms (Patnaude, 2013). - the potential for recovery/recolonization of earthworms and other soil macro-organisms based on the available data. <p>See also points 5(70); 5(72); 5(74); 5(77); 5(80); 5(81); 5(82).</p> <p>See reporting table 5(69)</p>		<p>Overall, the experts agreed with the RMS that the risk to earthworms cannot be resolved with the available data.</p> <p>A high risk to soil macroorganisms is indicated.</p> <p>Open point RMS to update the DAR and remove the standard chronic endpoint for earthworms (Patnaude, 2013) and the related risk assessment from the LoEP.</p> <p>Open point RMS to check and ensure that it is clear in the LoEP that the two aged residue studies with earthworms (Patnaude, 2015 and Rodgers, 2009b) are not suitable for risk assessment.</p> <p>Open point RMS to highlight in the LoEP, e.g. by means of a footnote, the uncertainties with the tier 1 endpoint (Wainwright,</p>		amendments of the DAR.

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		<p>2004a) for <i>Folsomia</i>.</p> <p>Open point RMS to remove the endpoint and risk assessment performed using the endpoint from the aged residue study with <i>Hypoaspis</i> from the DAR and LoEP.</p> <p>Open point RMS to update the DAR to reflect the outcome of the discussion at the experts meeting indicating high risk for soil macroorganisms.</p>		
<p>Data requirement 5.10 Applicant to provide information about the permeability of film used in Patnaude (2013). See reporting table 5(73)</p>	Co-RMS: information submitted by the Applicant has been included in the revised DAR.			<p>The applicant has provided information on the film used in Patnaude (2013), although no data on permeability were available. The study was anyway considered unreliable by the experts during the peer-review meeting.</p>
<p>Open point 5.16 RMS to update the DAR by including</p>	Co-RMS: RMS consideration on contamination of off-field environment via run-off has been included in the			<p>Open point fulfilled. The RMS has provided some text to explain their evaluation due to contamination for off</p>

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consideration of contamination for off field environments via run-off. This is relevant for the assessment of effects off-field impacting on the analysis of possible re-colonisation. See reporting table 5(76)	revised DAR.			field environments via run-off.
Open point 5.17 RMS please amend the risk assessment by correcting the endpoint with the appropriate factor of 2. While the scientific limitations of this approach are well known to EFSA, we would like to note that this has been consistently applied. The assumption of the RMS that what is measured equals what is bioavailable is questionable.	Co-RMS: risk assessment has been amended considering the correction factor of 2.			Open point fulfilled. The risk assessment has been revised as requested, i.e. by correcting the endpoint with the appropriate factor of 2. It is noted that for earthworms no tier 1 risk assessment is currently available, due to the lack of a reliable endpoint.

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See reporting table 5(79)				
Data requirement 5.11 The Applicant is given the possibility to submit further data to address the risk to soil macro-organisms due to exposure to the metabolite DCNM. See reporting table 5(83)	Co-RMS: no further data has been submitted. The Applicant considers that recovery study(ies) covers the risk for the metabolite DCNM (see data requirement 5.8)			Data gap: No data are available for assessing the toxicity of the soil metabolite DCNM to any non-target soil organism.
Open point 5.18 Pending on the submitted information, the RMS is requested to update the DAR by highlighting that a low risk from DCNM cannot be concluded if relevant data are missing. See reporting table 5(83)	Co-RMS: DAR has been amended accordingly.			Open point fulfilled. The RMS has amended the DAR highlighting that, as no data are available, a conclusion of low risk for the metabolite DCNM cannot be achieved.
Open point 5.19	Co-RMS: LoEP has been			Open point fulfilled.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
RMS to update LoEP by clarifying the duration of the test and of the exposure for the earthworm chronic studies. See reporting table 5(84)	amended accordingly			The RMS has updated the LoEP clarifying the duration of the test and the exposure for the earthworm chronic studies.
Data requirement 5.12 Applicant to provide further information to address the risk to soil microflora. See reporting table 5(86)	Co-RMS: No new data has been submitted by the Applicant, a study from the public literature has been submitted instead. A summary of the study and its evaluation have been included in the revised DAR.			No new data have been submitted by the applicant, a study from the public literature has been submitted instead. A high risk to soil microflora has been identified.
Open point 5.20 RMS to add discussion on the uncertainty in study summary from Carter (2009). See reporting table 5(87)	Co-RMS: DAR has been amended accordingly.			Open point fulfilled. The DAR has been amended by including further discussion on the uncertainty in the study by Carter (2009).

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
Data requirement 5.13 The Applicant is given the possibility to submit further data to address the risk to soil micro-organisms due to exposure to the metabolite DCNM. See reporting table 5(88)	Co-RMS: No new data has been submitted by the Applicant, that commits to undertake a study of the effects of DCNM on nitrogen transformation processes in soil. A data gap is proposed to the Applicant to submit this study			Data gap: No data are available for assessing the toxicity of the soil metabolite DCNM to soil microflora.
Open point 5.21 Pending on the submitted information, the RMS is requested to update the DAR by highlighting that a low risk from DCNM cannot be concluded if relevant data are missing. See reporting table 5(88)	Co-RMS: No new data has been submitted by the Applicant. DAR has been amended accordingly.			Open point fulfilled. The RMS has amended the DAR highlighting that, as no data are available, a conclusion of low risk for the metabolite DCNM cannot be achieved.
Data requirement 5.14 Applicant to provide further information to	Co-RMS: further information has been submitted by the Applicant and included in the revised			Data gap: Further information has been submitted by the applicant, but this was not considered

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
address the risk to NTTPs. See reporting table 5(90)	DAR.			sufficient to address the concern related to the mismatch between the length of the exposure in the only available study and in the field.
Data requirement 5.15 Applicant to provide information to address effects of chloropicrin to seedling emergence when this reaches off-field areas via runoff. See reporting table 5(92)	Co-RMS: no new data has been submitted by the Applicant.			New data have not been submitted by the applicant. Nevertheless, this route of exposure is considered not as important as the other already evaluated.
Open point 5.22 RMS to consider providing a risk assessment addressing effects of chloropicrin to seedling emergence when this reaches off-field areas via runoff. See reporting table 5(92)	Co-RMS: a risk assessment for seedling emergence in the off-field for exposure via run-off is not a standard requirement. No agreed guidelines are available to address this point. No agreed methods to derive an exposure estimation <i>via</i> run-off is available. No EC ₅₀ is available to conduct the risk assessment. Consequently, to conduct a			Open point obsolete. See point above.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
	risk assessment in this condition is considered not adequate.			
Open point 5.23 RMS to make clear table with RA results for NTTPs. See reporting table 5(93)	Co-RMS: a table summarising the TER calculation has been included in the revised DAR.			Open point fulfilled. A table summarising the TER calculation for NTTPs has been included in the revised DAR.
Open point 5.24 It would be appreciated if the RMS could discuss the issues of the environmental risk assessment of the impurities in a more extensive form in the DAR. See reporting table 5(97)	Co-RMS: it is noted that no impurity has been considered as ecotoxicologically relevant. Please see Vol. 4			Open point obsolete. Consideration of representativeness of batches for what concern the impurities is present in Vol.4
Data requirement 5.16 Applicant to provide an updated literature search by including the	Co-RMS: the Applicant submitted the required literature search (included in the revised DAR).			Data requirement addressed. The applicant submitted the required literature search (included in the revised DAR).

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
RTECS database. See reporting table 5(98)				
Open point 5.25 RMS to update the DAR by including a proposal for the classification See also point 5(107) See reporting table 5(101)	Co-RMS: DAR has been amended accordingly.			The open point has been fulfilled by the RMS. However, following the invalidation of the studies with algae, providing the lowest endpoint for aquatic organisms, it is not possible to propose any reliable classification.
Open point 5.26 RMS please amend Vol.1 pending on the outcome of the peer-review. See reporting table 5(102)	Co-RMS: DAR amended accordingly.			Open point fulfilled. Vol. 1 has been amended according to the outcome of the peer-review.
Open point 5.27 RMS please amend the DAR pending on the outcome of the peer-review.	Co-RMS: DAR amended accordingly.			Open point fulfilled. The DAR has been amended according to the outcome of the peer-review.

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
See reporting table 5(104)				
Experts' consultation 5.6 added by EFSA to allow decision in line with the new ED criteria applicable from 10/11/2018. Experts to discuss the ED potential of chloropicrin	Co-RMS: noted.	<p><u>Pesticide Peer Review Meeting 12 (09 – 13 September 2019):</u></p> <p>Further investigation of the ED properties of the substance should be performed. In particular, level 3 tests should be conducted as follows:</p> <ul style="list-style-type: none"> • A test according to OECD TG 229 • A test according to OECD TG 231. <p>In case of positive result/s based on the level 3 tests, additional testing (OECD TG 241 and/or OECD TG 240) might be needed in order to further investigate the adversity.</p> <p>Open point: RMS to align the DAR with the outcome of the</p>	<p>Co-RMS (IT): the DAR has been revised according to outcome of the discussion.</p>	<p>With regard to the assessment of endocrine disruption (ED) potential according to ECHA/EFSA Guidance (2018), chloropicrin is not an endocrine disruptor for humans and this conclusion also applies to mammals as non-target organisms.</p> <p>For non-target organisms other than mammals, no relevant data for assessing the endocrine properties of chloropicrin through the EATS-modalities were available. Thus, the available evidence was not considered sufficient to draw a conclusion on the endocrine disrupting properties for non-target organisms (data gap).</p> <p>In line with the assessment strategy proposed in the ECHA/EFSA Guidance (2018), level 3 tests would be required to complete the current data package, i.e. a study in line</p>

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<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Rapporteur Member State comments (reference to addenda where necessary)	<u>Column C</u> Recommendations of the Pesticides Peer Review Meeting	<u>Column D</u> Rapporteur Member State homework (reference to addenda where necessary)	<u>Column E</u> EFSA conclusion
		discussion.		with OECD TG 231 (Amphibian Metamorphosis Assay (AMA)) ¹ and a study in line with the OECD TG 229 (Fish Short-Term Reproduction Assay (FSTRA)). In case of positive result/s based on any of these tests for at least one modality, additional testing (i.e. a test in line with OECD 241 and/or a test in line with OECD 240) might be needed in order to further investigate the adversity.

¹ See report of the Peer Review experts' meeting PREV 12 (September 2019) point 5.6. The experts discussed that considering the lack of T-mediated adversity in the mammalian data package, the XETA might also be a suitable test.

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Report of Pesticides Peer Review written procedure on additional information

CHLOROPICRIN

Rapporteur Member State: UK
Co-rapporteur Member State: IT

Comments on the assessment report are listed in the relevant reporting table. Comments submitted during the written procedure on the points for clarification are listed in Appendix 1.

Documents submitted for written procedure:

Date	Supplier	File Name
14-06-2018	RMS/EFSA	Chloropicrin reporting table 2018-06-14.doc
19-03-2019	RMS	Chloropicrin evaluation table section 1 2019-03-19.doc
10-02-2019	RMS	Chloropicrin evaluation table section 2 2019-10-02.doc
19-09-2019	RMS	Chloropicrin evaluation table section 3 2019-09-19.doc
02-10-2019	RMS	Chloropicrin evaluation table section 4 2019-10-02.doc
03-10-2019	RMS	Chloropicrin evaluation table section 5 2019-10-03.doc
31-07-2019	RMS	Chloropicrin DAR July 2019.zip
31-07-2019	RMS	Chloropicrin List of Endpoints July 2019.doc

Appendix 1: Discussion table written procedure: CHLOROPICRIN

Appendix 1: Discussion Table Written Procedure, Chloropicrin

1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	Data requirement 1.1 Accelerated storage stability study for 'Chloropicrin 99' in accordance with Regulation (EU) 545/2011 should be submitted See also 1(22) See reporting table 1(23)	DE: No data/study has been submitted by the applicant. The data requirement is still open.	Data gap Accelerated storage stability study for 'Chloropicrin 99' according to Regulation (EU) No 545/2011 should be submitted.
2	Data requirement 1.2 The surface tension of the preparation 'Chloropicrin EC' should be provided. According to Vol. 4, the co-formulant added indeed is a surfactant and therefore extrapolation from the surface tension of the technical material to the preparation is not acceptable. See also 1(29), 1(32)	DE: A new surface tension study, using the plant protection product, was submitted and accepted by the RMS. Data requirement is fulfilled.	Addressed A new surface tension study was provided and considered acceptable.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	See reporting table 1(24)		
3	Data requirement 1.3 Accelerated storage stability study for 'Chloropicrin EC' in accordance with Regulation (EU) 545/2011 should be submitted See also 1(32), 1(33) See reporting table 1(25)	DE: A study was submitted but found to be insufficient by the RMS. The data requirement is therefore still open.	Addressed. EFSA agrees that the study has some deficiency however could be considered as acceptable.
4	Data requirement 1.4 Applicant to submit the final report on the 2 years shelf life study including determination of the technical characteristics relevant for the EC formulation before and after storage. See also 1(31), 1(32), 1(33) See reporting table 1(26)	DE: A study was submitted but found to be insufficient by the RMS. The data requirement is therefore still open.	Data gap The study was provided, however for the part of the content of the active substance in the formulation before and after the storage, no technical characteristics relevant for the EC formulation were measured.
5	Data requirement 1.5 Applicant to provide information on the temperature of storage.	DE: Temperature requirements for storage have been added. Data requirement is fulfilled.	Addressed.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	See reporting table 1(42)		
6	<p>Data requirement 1.6</p> <p>Additional validation data according to SANCO/825/00/rev. 8.1 should be submitted for the method Gilberto, 2009 in order the method to be considered validated as a monitoring method for high water content matrices, in particular: additional samples at each fortification level for the confirmatory method and an ILV.</p> <p>See also 1(51), 1(57)</p> <p>See reporting table 1(44)</p>	<p>DE: Addressed with the study by Bruzzone (2018). Data requirement closed.</p>	<p>Addressed.</p> <p>A new ILV and additional validation data for the confirmatory method were submitted and considered acceptable.</p>
7	<p>Data requirement 1.7</p> <p>Monitoring methods for analysis of the residue definition in high oil content and dry matrices according to SANCO 825/00/rev. 8.1 are required.</p> <p>See also 1(52), 1(53), 1(54), 1(58)</p> <p>See reporting table 1(47)</p>	<p>DE: No additional data was provided. Data requirement still open.</p>	<p>Data gap</p> <p>Monitoring methods for analysis of the residue definition in dry and high oil content matrices are required.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
8	Data requirement 1.8 A confirmatory method is required for the monitoring method in high acid content matrices (strawberry) See data requirement in 1(44) See reporting table 1(51)	DE: To the understanding of DE, the validation in the ILV by Brown (2013) using a DB-5 MS can be considered as a confirmatory method. The validation at one level only is in agreement with SANCO/825/00 rev. 8.1 for confirmation by an independent analytical technique.	Addressed. The confirmatory method (Brown, D.C., 2013) using different chromatographic phase was already submitted and considered valid. Monitoring method in high acid content commodities is considered validated according to SANCO/825/00 rev. 8.1.

2. Mammalian toxicology

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	Data requirement 2.1 Applicant to provide revised tables of tissue residues (including conversions as percentage of administered radioactivity) for the ADME study in rats by oral route, in order to reflect clearly the calculation of the oral absorption value. See reporting table 2(1)	DE: Data requirement fulfilled. Please note that the revised table of tissue residues (Table B.6.1.1-2a) is provided twice (one duplicate) in the revised DAR.	Data requirement fulfilled. Comment noted.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
2	<p>Data requirement 2.2</p> <p>Applicant to provide the full study reports and robust study summaries for the missing acute toxicity studies with chloropicrin (i.e. acute oral and dermal toxicity studies, skin irritation, eye irritation), including data on human cases if available (for consideration of C&L).</p> <p>See also comments 2(5), 2(6), 2(7), 2(8), 2(10), 2(11), 2(12), 2(16), 2(17), 2(19).</p> <p>See reporting table 2(4)</p>	<p>DE: Data requirement partially fulfilled.</p> <p>Additional study summaries were provided by the applicant/RMS in the revised DAR, but access to the full reports of these additional studies is missing.</p> <p>The revised report is in an older format, so the level of reporting for the study summaries is limited.</p>	<p>Data requirement is considered fulfilled. The level of reporting is considered sufficient to allow an expert judgement on the results of the acute toxicity studies.</p>
3	<p>Data requirement 2.3</p> <p>Applicant to provide further assessment/data on the <i>in vivo</i> gene mutation potential of chloropicrin, as follow-up for a positive Ames test.</p> <p>See also experts' consultation in 2(21).</p>	<p>DE: Data requirement not fulfilled.</p> <p>The <i>in vivo</i> gene mutation potential of chloropicrin was evaluated only with the outcomes of the rat liver unscheduled DNA synthesis test, which is considered as a test of low sensitivity by EFSA and other experts. Also, the test did not reflect the relevant route of exposure (inhalation) and assessment of the target tissue (e.g. respiratory tract). An <i>in vivo</i> Comet assay from inhalation exposure to chloropicrin with assessment of the respiratory tract would be more appropriate for the evaluation.</p> <p>Taking this into consideration, there is currently a lack of understanding of the mutagenic mode of action of chloropicrin <i>in vivo</i>.</p> <p>Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	<p>Data gap</p> <p>Further assessment/data on the gene mutation potential of chloropicrin, as follow up for a positive Ames test, should be provided (e.g. transgenic rodent mutation assay or rodent comet assay, including inhalation exposure and adequate target tissues could be an appropriate follow up).</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	See reporting table 2(23)		
4	Data requirement 2.4 Applicant to provide summary tables of results for the organ weight changes and non-neoplastic lesions observed in the respiratory tract during the long term mouse study with chloropicrin. See reporting table 2(32)	DE: Data requirement fulfilled.	Data requirement fulfilled.
5	Data requirement 2.5 Applicant to provide further assessment of the potential of chloropicrin for neurotoxicity. See reporting table 2(38)	DE: Data requirement partially fulfilled. The applicant provided further assessment of the neurotoxic potential of chloropicrin and concluded that there is no evidence of neurotoxicity due to lack of consistent findings in histopathological assessment or clinical observations. We do not completely agree with this conclusion. Most of the repeated dose toxicity studies conducted observations to note any clinical signs, which is one component for assessing neurotoxicity. However, none of the mentioned studies performed functional tests, e.g. sensory reactivity, limb grip strength and assessment of motor activity. Some of the studies did report evidence of reduced motor activity (████ (1996b) with dogs at 10 and 30 mg/kg bw/day; █████ (1987) with rats at 0.37 ppm onwards). Although histopathology of the nervous system was performed, it is not clear if brain morphometry was conducted. For example, reduced motor activity could be effects occurring in the motor cortex or cerebellum of the brain, and details on the histopathology of the affected brain regions would have been informative.	Data requirement is considered fulfilled. The neurotoxic potential of chloropicrin was discussed during the Pesticide Peer Review Meeting PREV 13 (16-20 September 2019). Based on the available toxicological data, the experts agreed that further specific investigation of neurotoxicity is not considered necessary and that chloropicrin is unlikely to be neurotoxic.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
6	<p>Data requirement 2.6</p> <p>Applicant to provide additional details on how the BMCL₁₀ was derived in the use of human sensory irritation data in exposure standard setting for chloropicrin.</p> <p>See also experts' consultation in 2(39).</p> <p>See reporting table 2(40)</p>	<p>DE: Data requirement partially fulfilled.</p> <p>The applicant provided limited additional data on the BMD (or BMC) modelling approach. Without further presentation of the BMC modelling, such as data fitted in the various models, AIC, p-values, in the DAR, it cannot be clearly determined whether the BMCL₁₀ was correctly calculated or can be considered as reliable.</p> <p>Nevertheless, it was discussed in the PREV 13 meeting that the use of human volunteer sensory irritation study should not be allowed for the derivation of reference values (see Art. 13 of the Regulation (EC) No 1107/2009) such as (A)AOEC. Therefore, this data requirement is no longer considered as critical for the evaluation.</p> <p>Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	<p>Data requirement obsolete.</p> <p>Since it is not allowed to use human volunteer studies for the derivation of toxicological reference values, this data requirement is not considered critical anymore and can be waived.</p>
7	<p>Data requirement 2.7</p> <p>Applicant to provide an additional scientific assessment of the potential ED properties of chloropicrin, following the OECD Conceptual Framework (as analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors, 2013).</p> <p>See reporting table 2(41)</p>	<p>DE: Data requirement partially fulfilled.</p> <p>The ED assessment from the applicant/RMS provided in Appendix 1 of the revised DAR is not totally in line with the ECHA/EFSA's ED guidance template format and the evaluation is difficult to follow.</p> <p>The T modality seems sufficiently investigated, but it is not clear if there were effects in the thyroid weight as this information was not included in the Appendix E, Excel table. Also, the ToxCast models for ER and AR are available but were not included in the assessment.</p>	<p>Addressed.</p> <p>It is acknowledged that the data requirement is partially fulfilled, but can be closed since, given the mode of action of chloropicrin, i.e. local irritant with minimal systemic effects, no further testing is necessary (data waiver) to conclude on the ED potential.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
8	<p>Data requirement 2.8</p> <p>Applicant to provide further assessment of the levels of DCNM (as % of the administered parent) identified in the rat metabolism study.</p> <p>See also comments 2(2), 2(44).</p> <p>See also experts' consultation in 2(43).</p> <p>See reporting table 2(42)</p>	<p>DE: Data requirement partially fulfilled.</p> <p>The applicant provided further explanation about the formation of DCNM after oral exposure to chloropicrin from the study of Kidd & Davidson (2005). Based on this explanation, it is clear that the assessment of the level of DCNM (i.e. 20 % of parent compound) was made by subtracting the total amount by the amount of excreted chloropicrin as CO₂ (up to ~60 % of administered dose) and dividing the remaining 40 % by 2 to account for the 2 metabolites, DCNM and chloronitromethane. There is no scientific data to demonstrate the levels of DCNM after exposure to chloropicrin from this study.</p> <p>The explanation is not scientifically convincing. In particular, what is the basis of assuming that 20 % of the parent compound would be DCNM or chloronitromethane? Without further understanding of the kinetics or conversion rate of these 2 metabolites, it is not appropriate to simply assign an equivalent conversion of 20 % for each of these metabolites.</p> <p>Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	<p>In the absence of clear identification of the polar metabolism resulting from the metabolic pathway of chloropicrin, DCNM and MCNM cannot be concluded to be major rat metabolites of the active substance.</p> <p>(this should be addressed with the toxicological assessment of the metabolite, see data gap identified at the expert consultation 2.8 below)</p>
9	<p>Data requirement 2.9</p> <p>Applicant to provide a more detailed assessment of the available toxicological information/data for the metabolite DCNM (including an assessment of the relevance and reliability of the public data).</p> <p>See also experts' consultation in 2(43).</p> <p>See reporting table 2(45)</p>	<p>DE: Data requirement not fulfilled.</p> <p>The assessment of DCNM is currently presented in Vol. 4 as one of the impurities. Considering DCNM is presumably a major metabolite of chloropicrin, the assessment should be provided also in Vol. 3, B.6. Nevertheless, the provided information in the assessment is currently insufficient to conclude on the toxicity of DCNM. As the <i>in vivo</i> genotoxic potential of chloropicrin cannot be fully evaluated as mentioned above, the same data gap applies for DCNM (i.e. unknown genotoxic potential <i>in vivo</i>).</p> <p>Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	<p>A data gap has been identified for a more extensive toxicological assessment of the metabolite DCNM during the experts' consultation 2.8.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
10	<p>Data requirement 2.10</p> <p>Applicant to provide more detailed summary tables for exposure scenarios for each representative use (shank and drip). They should also reflect the number of monitored individuals by task, and the number of monitoring points by study and by analysed substance (chloropicrin and phosgene).</p> <p>See also experts' consultation in 2(64).</p> <p>See reporting table 2(63)</p>	<p>DE: Data requirement fulfilled. Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	Data requirement fulfilled.
11	<p>Data requirement 2.11</p> <p>Applicant to provide further information on the phosgene generation by photodegradation of chloropicrin (by visible and UV light).</p> <p>See also experts' consultation in 2(64).</p> <p>See reporting table 2(76)</p>	<p>DE: Data requirement not fulfilled. Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	<p>Data requirement obsolete. The lack of night-time sampling for phosgene was discussed by the experts. They agreed that phosgene will not be formed during the night since it results from photolysis of chloropicrin.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
12	<p>Data requirement 2.12</p> <p>Applicant to provide further information on the use of fan system and robust evidence (e.g. supported by analytical data) supporting its adoption as a suitable engineering control.</p> <p>See also experts' consultation in 2(64).</p> <p>See reporting table 2(77)</p>	<p>DE: Data requirement fulfilled.</p>	<p>Data requirement fulfilled.</p> <p>The fan system described in the DAR and used in the field studies is based on the specification set out in the California EPA guidance and is expected to be applicable by a limited number of specialist application companies.</p>
13	<p>Data requirement 2.13</p> <p>Applicant to provide the additional monitoring study including measurements of chloropicrin at sampling heights of 1.5 and 1m (in order to address the concerns raised in relationship with the exposure of child residents).</p> <p>See also experts' consultation in 2(64).</p> <p>See also comment 2(86).</p> <p>See also data requirement in 4(52).</p>	<p>DE: Data requirement fulfilled.</p> <p>Data requirement discussed in Pesticide Peer Review Meeting PREV 13 (16-20 September 2019).</p>	<p>Data requirement fulfilled.</p> <p>For this additional monitoring study, the 1h concentration exceeds the AOEC at 50m several times until first third of the second day after treatment.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	See reporting table 2(91)		
14	<p>Data requirement 2.14</p> <p>Applicant to provide further assessment of the toxicological relevance of the impurities (Table C.1.2.3.2). It is noted that impurities below 1 g/kg might also need to be included in the technical specification if their toxicological profile is such that they might contribute significantly to the toxicological properties of the parent.</p> <p>Therefore as a first step, the hazardous properties of the identified impurities have to be further assessed (in comparison with the parent's).</p> <p>Pending on the conclusion about the toxicological relevance of the impurities (and the need to include them in the technical specification), it will have to be considered if the</p>	<p>DE: Data requirement fulfilled. The assessment of the toxicological relevance of the various impurities was provided by the applicant/RMS in Vol. 4.</p>	<p>Data gap The toxicological relevance of one impurity in the technical specification has not been sufficiently investigated.</p> <p>Nevertheless, considering the high purity of the active substance, the material tested in the toxicity studies can be considered as representative of the technical specification.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>composition of the batches used for the toxicity studies (including the levels of impurities) is sufficiently representative of the proposed technical specification.</p> <p>See also data requirement in 2(45).</p> <p>See also data requirement in 4(66).</p> <p>See reporting table 2(101)</p>		
15	<p>Data requirement 2.15</p> <p>Applicant to provide a revised report for the literature review, including a clear description for the search terms, the selection criteria (to identify relevant articles) and the reliability criteria that have been applied to each selected article for weight of evidence considerations in comparison with regulatory studies.</p> <p>See reporting table 2(102)</p>	<p>DE: Data requirement partially fulfilled.</p> <p>The selection criteria to identify relevant articles are missing. Even though the reliability criteria (according to Klimisch et al., 1997) are mentioned, it is not clear if they were applied to each relevant article (except for the ED assessment).</p>	<p>Data requirement considered fulfilled.</p>

3. Residues

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	<p>Data requirement 3.1</p> <p>Applicant to provide further data/information not yet presented in the DAR to support his claim that the metabolism study with strawberries, green beans, and red beets is sufficiently addressing the data requirement.</p> <p>See reporting table 3(8)</p>	DE: Discussed in Pesticide Peer Review Meeting TC 08 (12 September 2019).	<p>Data gap:</p> <p>A data gap has been identified to further investigate the metabolism of chloropicrin in plants considering the chemical structure of chloropicrin, the overall data available on the metabolism in plants, residue trials, the degradation pathway of chloropicrin in soil (as the representative uses consist of a soil application) (see section 4), the potential toxicological relevance of the metabolites identified in soil (see section 2) and any relevant literature search on the parent and the soil metabolites.</p>
2	<p>Data requirement 3.2</p> <p>Applicant is invited to submit "the further 22 supervised residue trials conducted in 2016 (two trials (one drip and one shank) in the central-EU on tomatoes, peppers, zucchini, melons, and lettuce, two trials (one drip and one shank) in the southern-EU on tomatoes, peppers, zucchini, melons, strawberries and lettuce)."</p>	DE: Addressed in revised DAR.	<p>The applicant submitted "a supplementary document summarising two reports. The first contains the further supervised residue trials conducted in 2016 to quantify residues of chloropicrin in strawberries, zucchini, melons, tomatoes, peppers and lettuce. The second includes additional analyses of samples produced by the same residue trials in the first report to determine the magnitude of residues of the potential metabolite dichlorodinitrimethane (DCDNM) in zucchini, melons, tomatoes, peppers and lettuce."</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>See also 3(21)-3(25)</p> <p>See reporting table 3(29) Estimation of the potential exposure through diet and other sources</p>		<p>For the evaluation of the residue trials and for the identified data gap, see experts consultation 3.3.</p>
3	<p>Data requirement 3.3</p> <p>Applicant to provide formally justification for choosing the databases for the literature search and information on the main focus of the searched database.</p> <p>See reporting table 3(29) Other comments</p>	<p>DE: Addressed in revised DAR.</p>	<p>Addressed.</p> <p>The applicant used the database provider STN international and RTECS (Registry of Toxic Effects of Chemical Substances) for the literature search. The argument for using these databases was that these provided access to more than 220 relevant databases (STN international). Three relevant DB (Chemical Abstracts Plus, Toxicology Center Database and the Registry of Toxic Effects of Chemical Substances) were used for the search.</p>
4	<p>Data requirement 3.4</p> <p>Applicant to provide the details of the analytical methods including the details of the validation used to determine the impurities B, C, D and F in tomato and strawberries whenever available.</p> <p>See reporting table 3(30)</p>	<p>DE: Addressed in revised DAR.</p>	<p>Addressed.</p> <p>Method validation data for the analytical method to determine impurities B and F in tomato and strawberries are available and demonstrated that the method is meeting the data requirements of SANCO/3029/99 rev.4. These two impurities (DCNM as breakdown product of B) were measured in tomatoes. For impurities C and D, no method validation data are available as no measurements of these impurities were</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	Other comments		performed in any crop.
5	Data requirement 3.5 Applicant to formally submit information on stability of the eight impurities in food matrices. See reporting table 3(31) Other comments	DE: Addressed in revised DAR.	Addressed. Despite the fact that no information on the stability of the eight impurities in food matrices is provided, the argumentation of the applicant is acceptable that the impurities would be of similar very limited storage stability and considering the fact that analysis took place in very short time intervals.

4. Environmental fate and behaviour

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	Data requirement 4.1 Applicant to provide data or studies to identify the presumed volatile metabolite formed by the aerobic degradation in soil of DCNM. See reporting table 4(13)	DE: No comment. EL: We agree. Further identification is required, since another metabolite is presumed.	Data gap Data gap identified for reliable soil degradation studies under aerobic conditions with mass balance closed, reliable kinetic analysis of the degradation of chloropicrin and formation and degradation of metabolites (including DCNM) and adequate identification of volatiles. In particular, to identify the presumed metabolite formed by aerobic degradation of DCNM.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
2	<p>Data requirement 4.2</p> <p>Due to the serious doubts on the acceptability of the water sediment study McLaughlin, 2013c, the applicant is given the opportunity to provide a new fully reliable water sediment study.</p> <p>See reporting table 4(26)</p>	<p>DE: No comment.</p> <p>EL: Considering the nature of chloropicrin, it is rather questionable whether better recoveries will be obtained in a new study, we would propose the provisional acceptance of the current endpoints in a worst case basis and possibly the submission of a new study to verify the actual behaviour of chloropicrin and its metabolites in water/sediment systems.</p>	<p>Data gap</p> <p>A data gap is identified for a water/sediment investigation with a closed mass balance, to enable the characterisation of the route of degradation of chloropicrin in the aquatic environment.</p> <p>(see experts' consultation 4.4)</p>
3	<p>Data requirement 4.3</p> <p>Applicant to provide further data, or a more elaborated and substantiated case, on the possible impact of water treatment procedures on the residues of chloropicrin.</p> <p>See reporting table 4(29)</p>	<p>DE: No comment.</p> <p>EL: We agree on that point. Further details regarding the fate and behaviour of Chloropicrin for the various water treatment plant found in EU countries (chlorination, ozonation, UV, sedimentation, filtration etc) shall be provided.</p>	<p>Data gap</p> <p>Data gap identified on the possible impact of water treatment procedures on the residues of chloropicrin as required in Regulation (EC) No 1107/2009 under the approval criteria.</p> <p>(see experts' consultation 4.5)</p>
4	<p>Data requirement 4.4</p> <p>Due to the serious doubts on the acceptability of the degradation studies in soil Völkel (2004) and McLaughlin (2013a), applicant is given the opportunity to provide new</p>	<p>DE: No comment.</p> <p>EL: From our point of view and considering the dataset provided in the DAR, the comments by EFSA and MS as well as the nature of the molecule and the documentation submitted by the notifier, we are of the opinion that the study by McLaughlin (2013a) can give some useful results regarding the degradation of chloropicrin in soil. In more detail, since in the vast majority of soils, the recovery reduces in a sampling after the one that determines the DT50, the respective DegT50 endpoints may be used provisionally for</p>	<p>See data gap at point 4.1</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>fully reliable degradation in soil studies under aerobic conditions.</p> <p>See also experts consultations in 4(6) and 4(8)</p> <p>See also open points in 4(7) and 4(8)</p> <p>See also 4(9), 4(120), 4(36), 4(37) and 4(55).</p> <p>See reporting table 4(34)</p>	<p>the finalization of the risk assessment. The performance of a new route and rate of degradation study is in any case the best possible approach, however, considering the nature of chloropicrin, it is rather questionable whether better recoveries will be obtained following the OECD 307 Guideline.</p>	
5	<p>Data requirement 4.5</p> <p>In the lack of adequate model to simulate volatilization / deposition of a substance with the properties of chloropicrin experimental data at 10 and 20 m is needed (in addition to the available data at 1m and 50 m) for the consideration of adequate risk management measures for the protection of surface water.</p>	<p>DE: No comment.</p> <p>EL: Indeed FOCUS models are not adequate to estimate PECs for such volatile compounds (relevant issues have been identified also for other disinfectants). A wind tunnel study could give some useful information. In any case, since results are available for 50m a relevant RMM may be utilized.</p>	<p>Data requirement addressed.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>See also 4(42), 4(45) and 4(46).</p> <p>See reporting table 4(52)</p>		
6	<p>Data requirement 4.6</p> <p>Applicant to propose more realistic distribution of chloropicrin over the soil horizons during the time the soil is covered to be considered for the PEC GW calculations.</p> <p>In order to identify a realistic worst case for the distribution of chloropicrin over the soil horizons it is suggested that results of the study Gao S., Trout, T., Schneider, S., Parlier, C.A., Ajwa, H., and Browne G. 2004 (Distribution and Dissipation of 1,3-D and Chloropicrin After Shank and Drip Applications in a Clay Loam Soil. In: Annual International Research Conference on Methyl Bromide Alternatives and Emissions Reductions) presented in the ecotox</p>	<p>DE: No comment.</p> <p>EL: Since it seems that the PECgw of Chloropicrin exceeds the parametric trigger value of 0.1 ug/L in several scenarios and higher tier studies (monitoring study in US and Italy as well) have been submitted, it is rather questionable if further PECgw calculations are deemed necessary. In any case we agree with this proposal as it will make the PECgw clearer and more robust.</p>	<p>See experts 'consultation at 4.6</p> <p>The available groundwater modelling (and surface water modelling) cannot be relied upon and has been maintained for illustrative purposes only to show the relevance of the concern.</p> <p>The RMS produced new surface water calculations assuming no reduced dose rate accounting for the time the tarpaulin is in place (i.e. considering there was no degradation in this period) to illustrate the potential concern from surface water exposure.</p> <p>Consequently, the RMS removed the groundwater modelling results for drip irrigation application from the LoEP.</p> <p>The RMS removed lab soil dissipation from the LoEP main entries. They remained there in the illustrative modelling section.</p> <p>The RMS removed the metabolites assessment and modelling results for the</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>section are considered.</p> <p>Other studies produced by the applicant or found in the open peer reviewed scientific literature may also be considered.</p> <p>See open point in 4(58) and expert consultation in 4(57).</p> <p>See also 4(38), 4(48), 4(53) and 4(56)</p> <p>See reporting table 4(54)</p>		metabolites from the LoEP.
7	<p>Data requirement 4.7</p> <p>Applicant to address potential GW contamination by relevant toxicological impurities.</p> <p>See reporting table 4(61)</p>	<p>DE: Similar to the active substance chloropicrin under tarp also the impurity [REDACTED] might not partition into the atmosphere but instead get evenly distributed into the soil column while the soil is covered with the tarp. Thus, a groundwater contamination with [REDACTED] should not automatically be excluded on basis of its high vapour pressure.</p> <p>EL: It seems that this point has already been addressed in Volume 4 or the DAR. The respective PECgw values for the relevant impurities were <<0.1 ug/L.</p>	<p>Groundwater exposure assessments of the impurity of the active substance for which the toxicological relevance assessment could not be done, may be needed, depending on the final result of that assessment since this impurity has the potential to be applied to soil in significant amounts.</p>
8	<p>Data requirement 4.8</p> <p>Applicant to provide an updated review of peer reviewed open scientific literature in relation to the metabolites of chloropicrin</p>	<p>DE: No comment.</p> <p>EL: We agree.</p>	<p>Data requirement addressed.</p> <p>See updated DAR.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>identified in the environment. Especially surface water metabolites, chloronitromethane, nitromethane, iminodimethanethiol thiocianic acid should be considered with respect to its fate and behaviour, toxicological and ecotoxicological properties.</p> <p>See also 4(2)</p> <p>See reporting table 4(66)</p>		

5. Ecotoxicology

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	<p>Data requirement 5.1</p> <p>Applicant please provide information on the term "Virtually Impermeable Plastic"</p> <p>See reporting table 5(1)</p>	<p>DE: No comment.</p>	<p>Data requirement fulfilled.</p> <p>The Applicant submitted further information on the term "Virtually Impermeable Plastic", which has been included in the revised DAR.</p>
2	Data requirement 5.2	<p>DE: We do not agree with the applicant's statement "<i>As local irritation effects are primarily driven by concentration, exposure duration is less</i></p>	<p>Data gap</p> <p>The applicant provided some information</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>Applicant to provide further information to address the reproductive risk to birds and wild mammals via inhalation exposure.</p> <p>See points 5(22); 5(25).</p> <p>In addition, see expert discussion 5(5).</p> <p>See reporting table 5(8)</p>	<p><i>important and it is considered valid to use a short-term endpoint to cover long-term exposure. Accordingly, the surrogate reproductive NOAEC of 0.645 mg/m³ is applied in the following long-term reproductive risk assessment."</i></p> <p>In contrast, the studies with mammals show that the reproductive endpoint is much lower than the NOEC found in the acute study. Therefore it is inadequate to base the risk for birds on the acute NOAEC.</p>	<p>that was included in the DAR. Nevertheless, following the agreement at the expert meeting, the avian short-term inhalation endpoint was not considered suitable to cover for long-term exposure. Hence, a data gap is identified and the long-term avian inhalation risk assessment cannot be finalised.</p>
3	<p>Data requirement 5.3</p> <p>Applicant to submit ECx calculations or an argumentation for not calculating ECx values.</p> <p>See reporting table 5(26)</p>	DE: No comment.	<p>Data requirement addressed.</p> <p>ECx calculations or an argumentation for not calculating ECx values were submitted by the applicant and included in the DAR under the summary of study 8.2.4/01</p>
4	<p>Data requirement 5.4</p> <p>Applicant to provide a valid study with algae for chloropicrin.</p> <p>We agree that a study on a second species is not needed. Nevertheless, following the information provided by the RMS under point 5(30), none of the two</p>	DE: No comment.	<p>Data gap</p> <p>No valid studies with algae are available for chloropicrin.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	available studies (Wilby, 2009a; Flatman 2004) is considered sufficiently reliable for the risk assessment. Hence, a new valid study is needed. See reporting table 5(33)		
5	Data requirement 5.5 Applicant to include additional QSAR calculations. See reporting table 5(41)	DE: Given the data for dichloronitromethane (DCNM), LC ₅₀ for <i>O. mykiss</i> the calculated values by VEGA (DCNM:133 mg/L) and OECD Toolbox (DCNM: 13700 mg/L) do not seem to be reliable with respect to measured values (DCNM: 0.084 mg/L). Also, reliability of risk assessment based only on calculated data for algae remain questionable due to lack or unreliable QSAR-data and lack of valid parent endpoint.	Data have been submitted by the Applicant. The QSAR estimations are not considered reliable, but the RMS used this information as indications that the metabolites are not more toxic than the active substance chloropicrin. This argument may be considered further when reliable exposure estimates become available.
6	Data requirement 5.6 The applicant is being given the opportunity to submit further data to address the risk for scenarios/crop combinations for which a high risk is still predicted despite the application of mitigation measures. See reporting table 5(42)	DE: No such data available.	Data gap No sufficient data have been submitted by the Applicant to resolve the aquatic risk assessment.
7	Data requirement 5.7 Applicant to provide toxicity	DE: No further data submitted. Extended laboratory data has been submitted for three soil dwelling species but not for any foliar dwelling species. For the off-field risk assessment in Tier II extended laboratory data	Data gap No sufficient information was submitted to address the toxicity of chloropicrin to

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	<p>data on foliar dwelling arthropods.</p> <p>See also points 5(54); 5(55).</p> <p>See reporting table 5(45)</p>	<p>on four species are needed. Additionally, considering recolonisation in the off-field is inadequate since no adverse effects are accepted there. Also, it is questionable that in-field recolonisation from off-field area is realistic considering the size of the fields.</p>	foliar dwelling arthropods.
8	<p>Data requirement 5.8</p> <p>Applicant to provide further information to address the risk to earthworms.</p> <p>See reporting table 5(66)</p>	<p>DE: The risk to earthworms remains unresolved. Once eliminated, recolonisation from adjacent areas is very slow and very limited in spatial range.</p> <p>When for run-off risk assessment a vegetated strip is considered, this needs to be applied as a mandatory risk mitigation measure in-field.</p>	<p>Data gap</p> <p>No sufficient data have been submitted. No reliable data are available to carry out the risk assessment for earthworms.</p>
9	<p>Data requirement 5.9</p> <p>Applicant to submit ECx calculations or an argumentation for not calculating ECx values.</p> <p>See reporting table 5(68)</p>	DE: No comment.	<p>Data requirement addressed.</p> <p>The Applicant has submitted the required ECx calculations and these have been included in a revised DAR. However, the study was classified as unreliable during the expert meeting.</p>
10	<p>Data requirement 5.10</p> <p>Applicant to provide information about the permeability of film used in Patnaude (2013).</p> <p>See reporting table 5(73)</p>	DE: No comment.	<p>The applicant has provided information on the film used in Patnaude (2013), although no data on permeability were available. The study was anyway considered unreliable by the experts during the peer-review meeting.</p>

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
11	Data requirement 5.11 The Applicant is given the possibility to submit further data to address the risk to soil macro-organisms due to exposure to the metabolite DCNM. See reporting table 5(83)	DE: No comment.	Data gap No data are available for assessing the toxicity of the soil metabolite DCNM to any non-target soil organism.
12	Data requirement 5.12 Applicant to provide further information to address the risk to soil microflora. See reporting table 5(86)	DE: No comment.	No new data have been submitted by the Applicant, a study from the public literature has been submitted instead. A high risk to soil microflora has been identified.
13	Data requirement 5.13 The Applicant is given the possibility to submit further data to address the risk to soil micro-organisms due to exposure to the metabolite DCNM. See reporting table 5(88)	DE: No comment.	Data gap No data are available for assessing the toxicity of the soil metabolite DCNM to soil microflora.
14	Data requirement 5.14 Applicant to provide further	DE: No comment.	Data gap Further information has been submitted by the Applicant, but this was not considered sufficient to address the

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	information to address the risk to NTTPs. See reporting table 5(90)		concern related to the mismatch between the length of the exposure in the only available study and in the field.
15	Data requirement 5.15 Applicant to provide information to address effects of chloropicrin to seedling emergence when this reaches off-field areas via runoff. See reporting table 5(92)	DE: No further data on seedling emergence or monitoring data provided. Also run-off has not been addressed. Please refer also to considerations in the aquatic section about run-off in vegetated area and mind that this area should be restricted to the in-field in order to avoid effects in the off-field.	New data have not been submitted by the Applicant. Nevertheless, this route of exposure is considered not as important as the other already evaluated.
16	Data requirement 5.16 Applicant to provide an updated literature search by including the RTECS database. See reporting table 5(98)	DE: No comment.	Data requirement addressed. The Applicant submitted the required literature search (included in the revised DAR).

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06	Comments on the draft EFSA conclusion

List of documents

Date	Document
16.12.2019	<u>Chloropicrin RMS IT comments on draft EFSA Conclusion with EFSA response.doc</u>
21.01.2020	<u>Chloropicrin MSs comments on draft EFSA Conclusion.doc</u>

Rapporteur Member States' comments on the draft EFSA Conclusion on chloropicrin
Pesticides Peer Review Written Procedure: December 2019

(16.12.2019) 1/6

Background			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
1	Written procedure – Mammalian Toxicology - all document	IT: The RMS notes the comments provided by MS-DE. Since no issues having a significant impact on the assessment have been raised, the RMS has no relevant comment to provide; overall, the RMS is in line with the EFSA's answers.	Noted.

Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
1	EFSA conclusion – Section 2, genotoxicity paragraph, page 8	IT: The RMS would propose an amendment since it appears that from available <i>in vivo</i> studies, MN assay and UDS assay, are sufficient to exclude the clastogenic potential of chloropicrin. However, the UDS assay is an indicator test detecting DNA damage, not stable genetic alterations, and it was one of the two assays, together with the mouse spot test, indicated in the Regulation (EC) 544/2011 as a follow up for positive <i>in vitro</i> gene mutation results.	Since the EFSA Opinion of the Scientific Committee on genotoxicity testing strategies (2011), it is acknowledged that the UDS has a low sensitivity in detecting rodent carcinogens and/or <i>in vivo</i> genotoxins and therefore is not included any more in the recommended test methods. In the EFSA Scientific Opinion on aspects related to genotoxicity assessment (EFSA,

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Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
		<p>The RMS acknowledges that Reg. 544/2011 was repealed by Regulation (EU) 283/2013 setting new data requirements for active substances. However, it should be specified that a complete dossier was submitted according to the legislation in force at the time of the application, and that the data gap identified for the gene mutation potential shall be read in conjunction with point 2.2 "Submission of further information" in the Annex II of Regulation (EC) 1107/2009.</p>	<p>2017), is noted that for the cases where UDS data as a follow-up to a positive <i>in vitro</i> mutation test already exists, there might be positive or negative results. Only positive results may be considered as adequate to assess the genotoxic potential.</p> <p>Based on these updated scientific considerations, UDS test is not recommended any more as a follow up for positive <i>in vitro</i> gene mutation results, and consequently the mutagenic potential of chloropicrin cannot be concluded.</p>
2	EFSA conclusion – Section 8, Data gaps, page 18	<p>IT: The RMS acknowledges the high level of performance of the <i>in vivo</i> Comet assay and the recommendations as a suitable follow up for positive <i>in vitro</i> gene mutation results. However, chloropicrin is a corrosive substance. Therefore, the RMS considers that, given the physico-chemical properties and the hazard profile of chloropicrin, the results of the Comet assay may be difficult to interpret in presence of local damage at the site of contact and suggests that the indication to perform a Comet assay may be omitted in the EFSA conclusion.</p> <p>In addition, the Comet assay is an indicator test to detect damages to the DNA and, according to the EFSA</p>	<p>According to the EFSA Scientific opinion on genotoxicity testing strategies (EFSA, 2011), appropriate <i>in vivo</i> tests to follow-up a bacterial reverse mutation test would be to conduct a transgenic rodent mutation assay or a rodent Comet assay, including adequate target tissues and exposure route.</p> <p>The data gap has been reworded accordingly.</p>

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Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
		<p>"Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment", does not give information on the mode of genotoxic action and should therefore not be included in the core set for hazard identification. The RMS fully agrees with that sentence and would prefer, instead of suggesting an assay that the applicant follows the indications laid down in Regulation (EU) 283/2013 for positive <i>in vitro</i> gene mutation results.</p> <p>The RMS agrees with the necessity to investigate gene mutation by inhalation route as pointed out in the EFSA conclusion.</p>	
3	EFSA conclusion – Section 2, Toxicological reference values paragraph, pages 8-9	<p>IT: The RMS position regarding the use of the human voluntary data has been already expressed during the expert meeting and in the assessment report, and still remains the same. However, the RMS have really appreciated the EFSA promptness after the meeting in replying and clarifying by email the EU approach and the view of EFSA in the use of human data for pesticides assessment. The RMS would like to clarify that, although the positions remain divergent, does understand the EFSA position in the application of EU legislation.</p> <p>Finally, the RMS would propose to slightly amend the following sentence of the EFSA conclusion "<i>Consequently,</i></p>	<p>Noted. The text of the conclusion has been amended accordingly.</p> <p>Since these human data are not used to finalise the risk assessment, they will be mentioned only in the list of end points.</p>

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Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
		<p><i>the human sensory irritation study was not further considered for the assessment of chloropicrin." with "Consequently, the human sensory irritation study was not further considered for the setting of the reference values of chloropicrin."</i></p> <p>The RMS also considers that the human voluntary study gives very useful indications for risk managers, at least, and, considering that the results of this study are also presented in the LoEP, the addition of a sentence or a mention to the results in the core text of the EFSA conclusion may be considered.</p>	
4	EFSA conclusion – Section 2, Non-dietary exposure paragraph, page 9	IT: The RMS agrees that the non-dietary exposure assessment for operators, workers, residents and bystanders to chloropicrin cannot be conducted since the reference values were not established.	Noted. Thank you.
5	Volume 1 – Table at page 39	IT: There is a typo in the cell located in the first column and last row. The referenced study is not a 90-d mouse study, as indicated, but a 78-w mouse study.	This is not a comment for the EFSA conclusion. RMS to consider providing a revised Vol. 1 with correction of the typo.
6	Volume 3 CA B-6 - 90-d rat Inhalation [REDACTED] (1993) – pages [REDACTED]	IT: The 90-d rat study of [REDACTED] (1993) was not discussed during the meeting. However, since it is the study used to derive the AOEC and AAOEC values, the	During the first expert meeting for the mammalian toxicity of chloropicrin (TC 44, 16 th November 2010), the 90-day rat study ([REDACTED],

Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
	48-60	<p>RMS is available to discuss the study since the effect level established for rat may be debatable and the RMS does not share to set the local LOAEC at the lowest dose tested (please to refer also to the RMS position at pages 59-60).</p> <p>The RMS wants to express its availability for a TC, however, it recognizes that, a discussion on the 90-d rat study may be postponed until the genotoxicity issues are clarified.</p>	<p>1993) was discussed.</p> <p>The agreed systemic NOAEL was 0.3 ppm based on adverse effects in the lung, but a local LOAEL of 0.3 ppm was also identified on the basis of the histopathological findings in the nasal epithelium.</p> <p>For the derivation of the AOEL, it was agreed to use this local LOAEL and to apply an increased uncertainty factor of 300 (for the use of this local LOAEL and to provide a sufficient margin of safety for the effect of mortality in the rabbit developmental study).</p> <p>On the basis of the available data (no additional scientific data were provided to revise the assessment of the adversity of this local effect, and no comments were provided during the peer review by other MSs), this conclusion should not be changed.</p>

Endocrine disruption properties			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
1	EFSA conclusion – Section 6, Endocrine disruption properties, page 15	IT: The RMS agrees with the draft EFSA conclusion related to humans.	Noted. Thank you.

Other			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Rapporteur Member State comment	EFSA response to comment
1	List of Endpoints – Short-term toxicity – page 25	IT: The hazard statement "H335" shall be added below "STOT SE 3".	The text has been amended accordingly.
2	List of Endpoints – Long-term toxicity and carcinogenicity – page 26	IT: There is some little inconsistency in the reporting of the mouse study. It is sometime reported as either a 2-yr study or a 18-mo study. To be consistent the RMS proposes to use the "78-w inhal" or the "18-mo inhal" caption.	The reporting of the long-term mouse study has been amended as "18-mo inhal".
3	List of Endpoints	IT: Overall, the RMS agrees with the proposed LoEP.	Noted. Thank you.

MSs' comments on the draft EFSA Conclusion on chloropicrin (new RMS: IT)
Pesticides Peer Review Written Procedure: January 2020

(21.01.2020) 1/6

Identity, physical/chemical/technical properties and methods of analysis			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1.	Conclusion text, analytical method, phosgene	DK: there is no mention of analytical methods for the metabolites phosgene and DCNM.	A data gap for monitoring method for phosgene in air was set. DCNM is currently not included in any residue definition for monitoring, therefore a monitoring method is not needed. As it is reported in the Conclusion, pending on the conclusion on the residue definition for monitoring in soil and water, new monitoring methods might be required.

Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
2.	Conclusion text, phosgene	DK: no information on toxicity only the occupational limits are mentioned. These limits must be based on some data? Think it would be relevant to indicate the toxicity of phosgene.	Since harmonised occupational exposure limits at EU level have been recommended by the EU Scientific Committee on Occupational Exposure Limits (SCOEL), the report of this EU Committee is the main reference to the assessment of phosgene (as mentioned in Volume 1 of the DAR).
3.	Conclusion text, phosgene	DK: usually the AOEL (which would correspond to the AOEC) is used for residents as well. The AAOEL (which would correspond to the AAOEC) is usually used for acute exposure for operators	The 8h-hour TWA value of 0.4 mg/m ³ (0.1 ppm) was considered most relevant for the human occupational exposure risk assessment (operator

MSs' comments on the draft EFSA Conclusion on chloropicrin (new RMS: IT)
Pesticides Peer Review Written Procedure: January 2020

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Mammalian toxicity			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		as well. This is not clear from the text.	and worker) since the SCOEL values are intended for a healthy worker population. For the general population (bystanders and residents), an uncertainty factor of 10 has been applied to the STEL (15 min) value (for intra-species variation), resulting in an AAOEC of 0.2 mg/m ³ .
4.	Conclusion text, phosgene	DK: it is mentioned that the measured values in the field studies were below the LOQ for air. It would be relevant to state the LOQ to show that it is below the occupational limit values. Was a validated analytical method used, since no validated method is mentioned in the method of analysis section of the conclusion text.	The LOQ value has been added in the conclusion text. It is confirmed that a validated analytical method has been provided and is described in Vol. 3 for the PPP (Appendix 2).
5.	Conclusion text, phosgene, line 9-12 of the phosgene paragraph	DK: the 50 and 200 m please add "from the treatment area" if that is the case.	It has been added in the conclusion text that these distances were measured from field edges.
6.	EFSA conclusion – Section 2	IT: the RMS agrees with the draft EFSA conclusion. There are no further comments on the EFSA responses provided on December 2019.	Noted, thank you.

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Residues			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		-	-

Environmental fate and behaviour			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
7.	EFSA Conclusion General	EL: We overall agree with the draft EFSA Conclusion.	Noted.
8.	Groundwater	EL: Higher tier studies (groundwater monitoring in the US and Italy) are available by the applicant providing supportive evidence for minimal groundwater risk. The EU study by Ferrari, 2019 (not initially submitted) was conducted in 2018 and its results support a conclusion that use of chloropicrin does not pose a risk to groundwater. A reference to these results and a possible submission as post-approval confirmatory data could be included in the EFSA conclusion, as there seems to be positive intention by the applicant to cover the groundwater contamination potential issue.	The EFSA conclusion refers only to studies available in the dossier, assessed by the RMS and peer reviewed by MSs and EFSA. The claims or conclusions of studies not independently assessed by RMS, MSs and EFSA cannot be presented in the conclusion.
9.	General	PL agrees with draft EFSA conclusion	Noted.

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Environmental fate and behaviour			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
10.	List of endpoints and Chloropicrin_DAR_10_Volume_3CA_B-8_revised_October_2019	PL: For consistency PECs values included in both documents should be the same: in LoEP (p. 49) the PECs values are the same as in Table B.8.23-4 in DAR_10_Chloropicrin_DAR_10_Volume_3CA_B-8_revised_October_2019 (p.76 of 197). In Vol_3CA_B-8 these values were calculated for DT50=8.8 d which was not agreed and were crossed out in Vol_3CA_B-8.	The Volume_3CA_B-8_revised_October_2019 presents the results of the experts' consultation and replaces Vol_3CA_B-8.
11.	List of endpoints and Chloropicrin_DAR_10_Volume_3CA_B-8_revised_October_2019	PL: In PECgw assessment in LoEP (p. 50) the DT50 in soil for active substance is missing (the former is crossed out); in Chloropicrin_DAR_10_Volume_3CA_B-8_revised_October_2019 (p. 128) the DT50 value of 4.2 d is reported.	Correctly. The experts' consultation agreed that reliable DegT50 could not be derived from the available information in the dossier. Dissipation values derived from the laboratory studies could not be used to represent dissipation under realistic conditions of use. Therefore, this was crossed out in the LoEP and only initial PECs are reported.

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		-	-

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Other			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
12.	Conclusion text, 9. Particular conditions proposed to be taken into account to manage the risk(s) identified	<p>DK: At the expert meeting the conditions of the field trials were discussed and the conditions of use that would be covered by the assessment:</p> <ol style="list-style-type: none"> 1) Shank application – application restricted to less than 1 ha. As risk assessment is based on data from 7500-9200 m². 2) The area for dry irrigation was even less. Only up to 3000 m². Only used on areas of up to 3000 m². 3) Special equipment to apply. Only allowed for trained professionals not the farmer themselves. 	Since the exposure assessment for chloropicrin have not been finalised in the absence of toxicological reference values (critical area of concern), no particular conditions could be proposed to manage the risk (not completely identified for the active substance).
13.	Conclusion text, 9. Particular conditions proposed to be taken into account to manage the risk(s) identified	DK: From the field studies conditions of minimum bufferzones to residents could be set based on the phosgene measurements. (refer to conclusion text on phosgene in chapter 2 Mammalian toxicity)	Since the exposure assessment for chloropicrin have not been finalised in the absence of toxicological reference values (critical area of concern), no particular conditions could be proposed to manage the risk (not completely identified for the active substance).
14.	Conclusion text, 9. Particular conditions proposed to be taken into account to manage the risk(s) identified	DK: A minimum „Re-entry“ time could also be set based on how long the film should stay and how long the area should be ventilated after the film was removed before establishing a tunnel above.	Since the exposure assessment for chloropicrin have not been finalised in the absence of toxicological reference values (critical area of concern), no particular conditions could be proposed to manage the risk (not completely identified for the active

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Other			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
			substance).
15.	List of Endpoints – Long-term toxicity and carcinogenicity – page 28	IT: in the section "Relevant NOAEL for carcinogenicity", for consistency reasons, the caption used for the long-term mouse study should be "18-mo inhal" and not "2-yr inhal". Overall, the RMS agrees with the proposed LoEP.	Thank you, the box has been amended.