CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Blood meal is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

Blood meal was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Belgium being the designated rapporteur Member State submitted the DAR on blood meal in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 3 November 2006. The peer review was initiated on 12 June 2008 by dispatching the DAR to the notifier Gyllebo Gödning AB and on 16 December 2010 to the Member States for consultation. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on blood meal.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of blood meal as a repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00271, issued on 23 September 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p.19
[5] OJ L 309, 24.11.2009, p.1
[6] OJ L 153, 11.6.2011, p.1
[7] OJ L 153, 11.6.2011, p.187
[8] OJ L 37, 10.2.2010, p.12

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In the section for identity, physical, chemical and technical properties and methods of analysis data gaps were identified for a specification with supporting data, solubility in water, shelf-life, evidence that the formulation can form a useable solution and a method of analysis for the formulation.

No data gaps or critical areas of concern were identified in the mammalian toxicology section.

No data gaps or critical areas of concern were identified in the residue section.

The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary, with the exception of when application is made by less targeted spray application methods such as air-assisted broadcast spraying. In this situation the environmental exposure assessment to aquatic systems was not finalised.

A data gap was identified in the ecotoxicology section for the mandatory toxicity studies with aquatic organisms (acute toxicity test for fish, acute toxicity test for aquatic invertebrates and chronic study for algae) to fulfil the Annex II data requirements. In addition, due to a missing aquatic exposure assessment when less targeted spray application methods are employed, the risk assessment for aquatic organisms was not finalised.

KEY WORDS

Blood meal, peer review, risk assessment, pesticide, repellent

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BACKGROUND

Blood meal is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

Blood meal was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Belgium being the designated rapporteur Member State submitted the DAR on blood meal in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 3 November 2006 (Belgium, 2006). The peer review was initiated on 12 June 2008 by dispatching the DAR to the notifier Gyllebo Gödning AB and on 16 December 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments and the notifier's response were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 5 April 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and

[9] OJ L 379, 24.12.2004, p.13
[10] OJ L 246, 21.9.2007, p.19
[11] OJ L 309, 24.11.2009, p.1
[12] OJ L 153, 11.6.2011, p.1
[13] OJ L 153, 11.6.2011, p.187
[14] OJ L 37, 10.2.2010, p.12

address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (5 April 2011),
- the Evaluation Table (20 September 2011),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of June 2011 containing all individually submitted addenda (Belgium, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Blood meal is dried blood; it is of food grade quality and is collected in authorised slaughterhouses. It has been heat-treated to destroy microorganism contamination. The blood is only of porcine origin. The blood conforms with Commission Regulation (EU) No 142/2011[15], implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, that lays down provisions regarding the quality criteria of such material for use in feed material or in organic fertilizers and soil improvers (rules for process, microbiologic requirements, …). Regulation (EC) No 853/2004[16] lays down specific hygiene rules for food of animal origin too.

The representative formulated product for the evaluation was 'Certosan', a wettable powder (WP) containing 99.8 % blood meal.

The representative uses evaluated are as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants by direct application on the plants (brush, spray, or dipping of individual plants at plantation). Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The active substance is blood meal, however an analytical specification has not been proposed and is necessary so that the active substance can be identified and quantified in the plant protection product. The specification should be supported by batch data and validated methods of analysis. There is also a data gap identified for a method of analysis for the formulation.

The main data regarding the identity of blood meal and its physical and chemical properties are given in Appendix A.

A data gap was identified for solubility of the blood meal in water and for a shelf-life study including evidence to demonstrate that, when opened, the blood meal does not become contaminated with human pathogens or support their growth.

The formulation has persistent foam issues therefore it may be necessary to use an antifoaming agent. It was also shown that the formulation is difficult to wet and therefore evidence must be provided to demonstrate that a useable solution can be produced.

As there are no residue definitions proposed the need for methods of analysis for monitoring can be waived with the exception of a method for water, where data gaps need to be filled (see sections 4 and 5) before a conclusion on any water residue definition can be made.

2. Mammalian toxicity

Blood meal does not have a toxic mode of action and does not in itself present a toxicological concern. Since the manufacturing process ensures a food grade quality of the active substance by complete denaturation of the proteinaceous material and destruction of potential pathogens according to quality criteria for animal by-products, all toxicological data requirements are waived. Toxicological reference values are not required and no quantitative risk assessment for operators, workers and bystanders was conducted considering the risk, if any, to be negligible.

[15] OJ L 54, 26.02.2011, p.1
[16] OJ L 139, 30.04.2004, p.55

It is noted that depending on the outcome of the data gap identified in section 1 on the possible contamination of the product when used, further considerations might be required with regard to human pathogens.

3. Residues

Metabolism and residue studies were not considered relevant for evaluation due to the nature of the active substance and the representative uses.

As for the uses in forestry and on ornamental plants no exposure of food and feed items are usually expected. A quantitative consumer risk assessment is not required for these uses due to the unlikelihood of significant residues.

As for the use in orchards, the GAP would usually permit a treatment of the entire plant in any season. Hence, residues of blood meal on fruits, and consequently consumer and livestock exposure to blood meal residues cannot be excluded. To avoid potential risks for the food chain, the use in orchards strictly requires the use of blood meal of food grade quality in accordance with current EU legislation for animal by-products, as well as evidence that there will be no growth of human pathogens in the product when used (see data gap in section 1). If these conditions are met, consumer risk from the use of blood meal in orchards is likely to be negligible.

4. Environmental fate and behaviour

The environmental fate and behaviour assessment only considered uses via direct application on the plants (by brush, coating, dipping or targeted spraying to the tree base or trunks). Application via spray on the entire plant was not covered by the assessment in the DAR. Consequently, pertinent data gaps are indicated in section 7, resulting in the risk assessment not being finalised when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed.

The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. The degradation of organic N-combinations starts with mineralisation followed by nitrification. The application rate (ca. 20 kg/ha) is not expected to produce exposures to the terrestrial environment to this kind of material at levels above those that may occur by natural causes (e.g. arising from the death of mammals). The influence of an application of blood meal of ca. 20 kg/ha compared to the natural N-content in soils in 0-20 cm depth is considered to be negligible. Therefore, further data or considerations of the fate and behaviour in the environment of this active substance in soil are deemed to be unnecessary for all methods of application. However, in the situation where less targeted spray methods of application are employed, that do not preclude surface water exposure, an assessment of the potential for surface water exposure is not available and therefore a data gap has been identified. For the more direct application methods to the plants / trees (by brush, hand-held spraying directed to the tree base or trunk, or dipping of individual plants at planting), the potential for the exposure of aquatic systems can be considered negligible.

5. Ecotoxicology

The available data package is quite limited in this section. The mandatory toxicity studies with aquatic organisms (acute toxicity test for fish, acute toxicity test for aquatic invertebrates and chronic study for algae) were not submitted in the dossier. These studies are essential to fulfil the Annex II requirements for classification and labelling, therefore a data gap was identified.

Considering the nature and the use of blood meal and the low exposure levels of the terrestrial environmental compartment, the risk from blood meal to birds and mammals, bees, non-target arthropods, earthworms, soil macro- and micro-organisms, and biological methods for sewage treatment is considered as low for the representative use assessed (application by brush, coating, dipping or targeted spraying to the base of the trunks).

Where less targeted spray methods of application are employed, the contamination of food items for birds and mammals cannot be excluded. However, blood meal could be a food source for omnivorous birds and mammals or it acts as a repellent for herbivorous birds and mammals. Therefore, it can be concluded that the risk to birds and mammals is considered to be low for these application methods.

When applications are made by direct application on the plants (by brush, coating, dipping or targeted spraying to the base of the trunks) negligible exposure to the aquatic compartment was concluded (see section 4), therefore the risk to aquatic organisms can be concluded to be low. However, in the situation where less targeted spray methods of application are employed, that will not result in negligible surface water exposure, the risk to aquatic organisms remains to be addressed. A data gap has been identified for a risk assessment for aquatic organisms in relation to these application methods.

The exposure of bees and non-target arthropods where less targeted spray application techniques are employed cannot be excluded. However, the risk to bees and non-target arthropods was considered as low based on the toxicity data provided, which indicated a low concern.

It is noted that the application rate is not expected to produce exposures to the terrestrial environment at levels above those that may occur by natural causes even with spray applications. The risk to earthworms and soil macro- and micro-organisms is considered to be low for the representative uses where less targeted spray methods of application are employed.

No exposure for sewage treatment plants would be expected for all representative uses, therefore no data were necessary. The risk needs to be further considered if any contamination of sewage treatment plants may occur.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Not applicable Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for blood meal.	Not applicable	-

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Not applicable Considering the nature of the substance and the estimated exposure from the representative uses a definition of residue in the environment for groundwater exposure assessment is deemed to be unnecessary for blood meal.	Not applicable	Not applicable	-	-	-

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Blood meal, when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed. For the other methods of application assessed, considering the nature of the substance and the limited exposure from these representative uses, a definition of residue in the environment for risk assessment by other disciplines can be considered unnecessary.	Data gap -

6.4. Air

Compound (name and/or code)	Toxicology
Not applicable Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for blood meal.	-

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Specification with supporting batch data and validated methods of analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Solubility in water (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Shelf-life study including evidence to demonstrate that, when opened, the blood meal does not become contaminated with human pathogens or support their growth (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Evidence in the form of data should be provided to demonstrate how the product can be wetted to form a useable solution (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Method of analysis for the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Information regarding exposure of aquatic systems when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed was not available (relevant for the representative uses employing these application techniques, submission date proposed by the notifier: unknown; see section 4)
- The mandatory toxicity studies with aquatic organisms (acute toxicity test for fish, acute toxicity test for aquatic invertebrates and chronic study for algae) should be provided (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)
- A risk assessment for aquatic organisms was not provided for the representative uses where less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed (relevant for the representative uses employing these application techniques; submission date proposed by the notifier: unknown; see section 5)

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- The formulation has persistent foam issues therefore it may be necessary to use an antifoaming agent.
- Direct application on the plants (by brush, coating, dipping or targeted spraying to the tree base or trunks) was the only use considered with respect to the fate and behaviour and environmental risk assessment in the dossier and RMS evaluation. Application via spray on the entire plant is not covered by the assessment available.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such

importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. A risk assessment for aquatic organisms was not finalised, that covers the situations when less targeted spraying application techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

- None.

10. Overview of the assessments for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		Repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants by direct application on the plants (brush, spraying to the tree base or trunk or dipping of individual plants at planting).	Repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants by spraying entire trees using less targeted spraying techniques such as air-assisted broadcast spraying.
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		X[1]
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated as concerns

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

Belgium, 2006. Draft Assessment Report (DAR) on the active substance blood meal prepared by the rapporteur Member State Belgium in the framework of Directive 91/414/EEC, July 2006.

Belgium, 2011. Final Addendum to the Draft Assessment Report on blood meal, compiled by EFSA, June 2011.

EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance blood meal.

European Commission, 2008. Review Report for the active substance blood meal finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of blood meal in Annex I of Directive 91/414/EEC. SANCO/2604/08 – rev. 1, 06 August 2008.

APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Blood meal
Function (*e.g.* fungicide)	Repellent
Rapporteur Member State	Belgium

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Not applicable
Chemical name (CA) ‡	Not applicable
CIPAC No ‡	909
CAS No ‡	90989-74-5
EEC No (EINECS or ELINCS) ‡	292-731-9
FAO Specification (including year of publication)‡	No FAO specification exists
Minimum purity of the active substance as manufactured (g/kg) ‡	The following quality criteria are applied: - Food grade quality blood collected in authorised slaughterhouses, - Destruction of pathogens and protein denaturation occur during blood processing - Blood of porcine origin. Commission Regulation 142/2011, implementing Regulation 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, lays down provisions regarding to the quality criteria of such material for use in feed material or in organic fertilizers and soil improvers (rules for process, microbiologic requirements, …). Regulation 853/2004 lays down specific hygiene rules for food of animal origin too. Open for specification.
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula ‡	Not applicable
Molecular mass ‡	Not applicable
Structural formula ‡	Not applicable

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Not relevant. Blood meal is a well known widely traded commodity, used as food additive, organic fertilizer etc.
Boiling point (state purity) ‡	Not relevant (see melting point)
Temperature of decomposition	Not relevant (see melting point)
Appearance (state purity) ‡	Red brownish powder with vaguely sugar like smell
Vapour pressure (in Pa, state temperature) ‡	Not relevant (see melting point)
Henry's law constant (Pa m^3 mol^{-1}) ‡	Not relevant (see melting point)
Solubility in water (g/l or mg/l, state temperature) ‡	Open
Solubility in organic solvents (in g/l or mg/l, state temperature) ‡	Not relevant (see melting point)
Surface tension ‡	Not relevant (see melting point)
Partition co-efficient (log P_{OW}) (state pH and temperature) ‡	Not relevant (see melting point)
Dissociation constant ‡	Not relevant (see melting point)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡	Not relevant (see melting point)
Flammability ‡	Not considered as highly flammable, not considered as auto-flammable
Explosive properties ‡	Not relevant (see melting point)
Oxidising properties ‡:	Not relevant (see melting point)

Summary of uses supported by available data (Blood meal)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled I	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. Of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Deciduous and coniferous trees in forestry	Germany	Certosan	F	Game repellent	WP	998 g/kg	coating with brush, spraying or dipping individual plants; entire plants	all-season	1	n. a.	n. a.	80-400	19.8	Not required	-
Trees in orchards	Germany	Certosan	F	Game repellent	WP	998 g/kg	coating with brush, spraying or dipping individual plants; entire plants	all-season	1	n. a.	n. a.	80-400	19.8	Not required	-
Ornamental plants	Germany	Certosan	F	Game repellent	WP	998 g/kg	coating with brush, spraying or dipping individual plants ; entire plants	all-season	1	n. a.	n. a.	80-400	19.8	Not required	-

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical a.s. (principle of method)	Open
Impurities in technical a.s. (principle of method)	Open
Plant protection product (principle of method)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required (no residue definition)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required (no residue definition)
Soil (principle of method and LOQ)	Not required (blood meal is a natural non-toxic compound)
Water (principle of method and LOQ)	Data gaps need to be filled before a residue definition and need for a method can be concluded on.
Air (principle of method and LOQ)	Not required (blood meal is a natural non-toxic compound)
Body fluids and tissues (principle of method and LOQ)	Not required (blood meal is a natural non-toxic compound)

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None

Impact on Human and Animal Health

Blood meal has a non-toxic mode of action and is non-toxic by itself.

In order to ensure that the active substance is of low risk to humans, the following quality criteria are applied:

- *Food grade quality blood collected in authorized slaughterhouses*
- *Destruction of pathogens and protein denaturation occur during blood processing*
- *Blood of porcine origin*

Blood meal is produced in accordance with current feed and food EU legislations.

Based upon these statements, and taking into account that the substance does not in itself present a toxicological concern, the waiver for toxicological studies was deemed acceptable.

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	No data - not required
Distribution ‡	No data - not required
Potential for accumulation ‡	No data - not required
Rate and extent of excretion ‡	No data - not required
Metabolism in animals ‡	No data - not required
Toxicologically relevant compounds ‡ (animals and plants)	No data - not required
Toxicologically relevant compounds ‡ (environment)	No data – not required

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	No data - not required	
Rat LD_{50} dermal ‡	No data - not required	
Rat LC_{50} inhalation ‡	No data - not required	
Skin irritation ‡	No data - not required	
Eye irritation ‡	No data - not required	
Skin sensitisation ‡	No data - not required	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data - not required	
Relevant oral NOAEL ‡	No data - not required	
Relevant dermal NOAEL ‡	No data - not required	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

No data - not required	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data - not required	
Relevant NOAEL ‡	No data - not required	
Carcinogenicity ‡	No data - not required	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data - not required	
Relevant parental NOAEL ‡	No data - not required	
Relevant reproductive NOAEL ‡	No data - not required	
Relevant offspring NOAEL ‡	No data - not required	

Developmental toxicity

Developmental target / critical effect ‡	No data - not required	
Relevant maternal NOAEL ‡	No data - not required	
Relevant developmental NOAEL ‡	No data - not required	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data - not required	
Repeated neurotoxicity ‡	No data - not required	
Delayed neurotoxicity ‡	No data - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
Studies performed on metabolites or impurities ‡	No data

Medical data ‡ (Annex IIA, point 5.9)

No data - not required

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not required*	-	-
AOEL ‡	Not required*	-	-
ARfD ‡	Not required*	-	-

* The setting of reference values was not deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as blood meal is food-grade, and used as a food additive.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Certosan® (> 99% WP blood meal)	No data, not necessary

Exposure scenarios (Annex IIIA, point 7.2)

Operator	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as blood meal is food-grade, and used as a food additive.
Workers	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as blood meal is food-grade, and used as a food additive.
Bystanders	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as blood meal is food-grade, and used as a food additive.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Blood meal	No classification required

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	The formulation is applied on fruit trees by coating with brush, spraying or dipping of individual plants (at plantation). Exposure of the fruit is possible but might be negligible. However, to avoid any potential risks for the food chain, the use in orchards strictly requires the use of blood meal of food grade quality in accordance with current EU legislation, and evidence that there will be no growth of human pathogens in the product when used (see data gap in section 1). Toxicological end points were not set (ADI, ARfD). A quantitative risk assessment for the consumer is therefore not required. No data required
Rotational crops	No data required
Plant residue definition for monitoring	None
Plant residue definition for risk assessment	None
Conversion factor (monitoring to risk assessment)	-

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not required.
Animal residue definition for monitoring	Not required.
Animal residue definition for risk assessment	Not required.
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	Not required.
Fat soluble residue: (yes/no)	Not required.

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	No data provided.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Not required.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle	-		
Liver	-		
Kidney	-		
Fat	-		
Milk	-		
Eggs	-		

Studies not required.

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Southern Europe	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL (mg/kg)	STMR (mg/kg) (b)
Not required					

(a) : Number of trials in which particular residue levels were reported.
(b) :Supervised Trials Median Residue: The median residue level estimated on the basis of supervised trials relating to the critical GAP

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not required.
TMDI (European Diet) (% ADI)	Not required.
NEDI (% ADI)	Not required.
Factors included in NEDI	Not required.
ARfD	Not required.
Acute exposure (% ARfD)	Not required.

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Not required			

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Not required.

Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡ Non-extractable residues after 100 days ‡ Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	The degradation of organic N-combinations starts with mineralisation followed by nitrification. The speed of this process depends on the soil temperature. The influence of an application of blood meal of ca.20 kg/ha compared to the natural N-content in soils of 900 – 9000 kg/ha in 0-20 cm depth is negligible. Further studies investigating the fate and behaviour in soil are not required.

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	Not required
Soil photolysis ‡	Not required

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	
Laboratory studies (range or median, with n value, with r^2 value) ‡	DT_{50lab} (20°C, aerobic): ‡ Not required
	DT_{90lab} (20°C, aerobic): ‡ Not required
	DT_{50lab} (10°C, aerobic): ‡ Not required
	DT_{50lab} (20°C, anaerobic): ‡ Not required
	degradation in the saturated zone: ‡ Not required
Field studies (state location, range or median with n value) ‡	DT_{50f}: ‡ Not required
	DT_{90f}: ‡ Not required
Soil accumulation and plateau concentration ‡	Not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence (yes / no) (if yes type of dependence) ‡	Not required

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Not required
Aged residues leaching ‡	Not required
Lysimeter/ field leaching studies ‡	Not required The notifier submitted a 12-year lysimeter study showing that the leaching of N depends on the vegetation and precipitation. The study is designed to evaluate the balance of fertilizing agents.

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	Not required
Application rate	

PEC$_{(s)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	-	-
Short term 24h	-	-	-	-
2d				
4d				
Long term 7d	-	-	-	-
28d				
50d				
100d				

Route and rate of degradation in water (Annex IIA, point 7.2.1)

The degradation of blood meal follows the normal route of organic N-combinations in nature.
The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. Exposure of surface water is expected to be negligible, when spray is targeted to the base of trees or the trunk. Further studies investigating the fate in water are not required when brushing, dipping or targeted spraying to the base of trees or trunks is employed as an application method. However, further information may be required if application is made to entire plants by less targeted spraying techniques such as air-assisted broadcast spraying.

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature) ‡	No information provided but blood meal is expected to be stable to hydrolysis for periods of days at ca. pH 7.3-7.5.
Photolytic degradation of active substance and relevant metabolites ‡	Not required
Readily biodegradable (yes/no) ‡	No information available
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	Not required in respect of brush, base or trunk spraying, or dipping applications to individual plants. There is a data gap in relation to air-assisted broadcast spraying to entire plants.
Mineralization	
Non-extractable residues	
Distribution in water / sediment systems (active substance) ‡	
Distribution in water / sediment systems (metabolites) ‡	

PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation	Not required in respect of brush, base or trunk spraying, or dipping applications to individual plants. Data gap in respect of air-assisted broadcast spraying to entire plants.
Application rate	
Main routes of entry	

PEC$_{(sw)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	-	-
Short term 24h 2d 4d	-	-	-	-
Long term 7d 14d 21d 28d 42d	-	-	-	-

PEC (sediment)

Method of calculation	Not required in respect of brush, base or trunk spraying, or dipping applications to individual plants. Data gap in respect of air-assisted broadcast spraying to entire plants.
Application rate	

PEC$_{(sed)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	-	-
Short term	-	-	-	-
Long term	-	-	-	-

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Not required.
Application rate	

PEC$_{(gw)}$

Maximum concentration	-
Average annual concentration	

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡ Quantum yield of direct phototransformation Photochemical oxidative degradation in air ‡ Volatilization ‡	When the formulation is applied on trees by coating with brush, or dipping of individual plants, no exposure of air is expected. No study investigating the fate and behaviour in air is required in relation to these application methods.

PEC (air)

Method of calculation	Not required

$PEC_{(a)}$

Maximum concentration	Not required

Residues requiring further assessment

(Annex IIA, point 7.3)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology), or for which a groundwater exposure assessment is triggered.	Generally not applicable, considering the nature of the substance and the limited exposure from the representative uses. The degradation of blood meal follows the normal route of organic N-combinations in nature. However, for the exception where application is made by air-assisted broadcast spraying to entire plants, blood meal requires further consideration by ecotoxicology.

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R 53 (in the absence of information having been made available on ready biodegradability)

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡	Not required.
Reproductive toxicity to mammals ‡	Not required.
Acute toxicity to birds ‡	Not required.
Dietary toxicity to birds ‡	Not required.
Reproductive toxicity to birds ‡	Not required.

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg a.s./ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
- The risk to birds and mammals is considered to be low based on the following arguments: - Blood meal is a mammal repellent - Blood meal is an important ingredient in foodstuffs.					

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2) ‡

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Data gap				

Microcosm or mesocosm tests
Not required.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg a.s./ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
• When applications are made by direct application on the plants (by brush, coating, dipping or targeted spraying to the base of the trunks) negligible exposure to the aquatic compartment was concluded (see section on fate and behaviour), therefore the risk to aquatic organisms can be concluded to be low. • However, in the situation where less targeted spray methods of application are employed, that will not result in negligible surface water exposure, the risk to aquatic organisms remains to be addressed. A data gap has been identified for a risk assessment for aquatic organisms in relation to these application methods.						

Bioconcentration

Bioconcentration factor (BCF) ‡	Not required.
Annex VI Trigger for the bioconcentration factor	Not required.
Clearance time (CT_{50}) (CT_{90})	Not required. Not required.
Level of residues (%) in organisms after the 14 day depuration phase	Not required.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	LD_{50} > 198 µg Certosan/bee
Acute contact toxicity ‡	LD_{50} > 200 µg Certosan/bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
The use pattern involves applications on deciduous and coniferous trees in forestry, trees in orchards and ornamental plants by coating with brush, spraying or dipping of individual plants at a single application rate of 19.8 kg a.s./ha. • When applications are made by direct application on the plants (by brush, coating, dipping or targeted spraying to the base of the trunks) negligible exposure of bees is expected and therefore low risk to bees is expected. • Where less targeted spray methods of application are employed, the exposure of bees cannot be excluded. However, the risk to bees was considered as low based on the toxicity data provided, which indicated a low concern.				
Field or semi-field tests				
Not required.				

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5) ‡

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
‡ *Poecilus cupreus*	adults	Certosan	40 kg/ha in 400 L water/ha	Reduction of beneficial capacity	- 4.7 %	30 %
‡ *Pardosa spp.*	adults	Certosan	40 kg/ha in 400 L water/ha	Reduction of beneficial capacity	- 4.3 %	30 %

Field or semi-field tests
Not required.

The use pattern involves applications on deciduous and coniferous trees in forestry, trees in orchards and ornamental plants by coating with brush, spraying or dipping of individual plants at a single application rate of 19.8 kg a.s./ha.

The exposure of non-target arthropods where less targeted spray methods of application are employed cannot be excluded.

No effects of the formulation Certosan were observed up to a dose of 40 kg/ha (equivalent to 39.96 kg a.s./ha) for the soil-dwelling arthropods *Poecilus cupreus* and *Pardosa spp*. In conclusion, the risk from blood meal and the formulation Certosan to non-target arthropods is low.

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	Not required.
Reproductive toxicity ‡	Not required.

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg a.s./ha)	Crop	Time-scale	TER	Annex VI Trigger
Blood meal is a fertiliser in organic farming. No negative effects on earthworms are reported.				

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	Not required.
Carbon mineralization ‡	Not required.

Blood meal is a fertiliser in organic farming. No negative effects on soil microbial activity are reported.

Effects on other non-target organisms (flora and fauna) (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Blood meal is a fertiliser in organic farming. No negative effects on other non-target organisms are reported.

Effects on biological methods of sewage treatment (Annex IIA, point 8.7)

An environmental toxicology study of dried blood has been waived for the following reason:

- The use pattern involves applications on deciduous and coniferous trees in forestry, trees in orchards and ornamental plants by coating with brush, spraying or dipping of individual plants and, therefore, exposure of activated sludge is considered negligible.

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Not required
water	Data gap needs to be filled before this can be concluded.
sediment	Data gap needs to be filled before this can be concluded.
groundwater	Not required

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	Data gap

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
WP	wettable powder
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year