Conclusion regarding the peer review of the pesticide risk assessment of the active substance

clomazone

finalised: 27 July 2007

(version of 3 August 2007 with a minor change related to the confidentiality of an impurity)

SUMMARY

Clomazone is one of the 79 substances of the third stage, part A, of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Denmark being the designated rapporteur Member State submitted the DAR on clomazone in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 16 March 2005. Following a quality check on the DAR, the peer review was initiated on 11 July 2005 by dispatching the DAR for consultation of the Member States and the sole applicant FMC. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in June – July 2006. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in January 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 26 June 2007 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative use as a herbicide on oilseed rape, for full details of the GAP please see the attached endpoints.
The representative formulated product for the evaluation was “Centium 36 CS", a capsule suspension (CS).

Residues in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For air there is a single method available that analysed for clomazone. Soil and water methods were provided however, they appear to contain a hydrolysis step and will therefore not be specific to clomazone. Several methods were provided for soil and water metabolites however, no conclusion was made on the acceptability of the validation data during the peer review process.

[1] OJ No L 224, 21.08.2002, p. 25

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Clomazone has a moderate acute toxicity by inhalation and if swallowed, it is not irritating to skin and eyes, and is not a skin sensitiser. In repeat dose studies, the liver was the target organ for all the species. The compound is not genotoxic, not carcinogenic, and has no reproductive or developmental effect. The acceptable daily intake (ADI) and the acceptable operator exposure level are both 0.133 mg/kg bw/day based on the 1-year dog study, and the acute reference dose (ARfD) was not considered necessary. The 100% default value for the dermal absorption was used, resulting in operator exposure estimates below the AOEL when gloves are used during mixing/loading and application.

Metabolism studies with pre-emergence treatment were conducted in tobacco, sweet potatoes and soy bean. In addition, there are two studies on cotton and alfalfa with post-emergence application, covering different plant parts. The metabolism is considered to be similar in the evaluated crops. It would therefore be possible, to propose a general residue definition for all plant products. However, the most abundant plant metabolite, 2-chlorobenzyl alcohol, was not found in rat metabolism, and it could not be demonstrated that it is of lower toxicity than clomazone. The latter was almost completely degraded and, if present, only at low levels. At current, i.e. with respect to the representative uses evaluated, the amount of neither, clomazone and 2-chlorobenzyl alcohol, will be significant in food and feed items (i.e. below the trigger values). Therefore, with respect to the representative uses the relevant residue should be defined by default as clomazone. Further data and information on 2-chlorobenzyl alcohol will be needed in order to render possible a generally applicable plant residue definition.
Metabolism studies in livestock animals are not necessary since residues in potential feedstuff is <0.1 mg/kg.
Studies in succeeding crops or rotational crops are not required. Based on the currently available information it was assessed that no residues in rotational crops are expected after treatment of the primary crops according to critical GAP.
A sufficient number of valid residue trials covering the relevant European growing areas allow for an MRL proposal for potato tubers and rape seed.
Independently of the model used, the chronic consumer intake form the representative uses is estimated to be well below the ADI. (<1%). No ARfD is proposed and therefore an acute risk to consumers is not expected.

Under laboratory aerobic conditions clomazone is moderate to high persistent in soil. Mineralisation to CO_2 accounted for 31.5% AR and unextracted soil residues accounted for 15.2% AR. No major metabolite exceeding 10% of the applied radioactivity was detected in the laboratory soil metabolism studies. Under anaerobic conditions, the major metabolite N-[(2-chlorobenzyl)]-3-hydroxy-2,2-

dimethyl propanamide was detected. In a laboratory soil batch adsorption/desorption study clomazone exhibited low to high mobility in soil.

The aquatic degradation of clomazone was studied in two water/sediment studies and was shown to degrade relatively slowly in both systems. Two major metabolites FMC 65317 (N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide) and FMC 55657 (N-[(2-chlorobenzyl)]-2-methyl propanamide were found in the water phase. The available aquatic exposure assessment is appropriate for addressing the spray drift, runoff and drainage routes of entry for clomazone.

The available FOCUS groundwater modelling is based on the longest degradation rate in soil as the recommended input value by FOCUS GW scenario guidance for PEC calculations with a number of 3 values for the parent compound. For the representative field uses applied for, the potential for groundwater exposure by clomazone above the drinking water limit of 0.1µg/L is low, except for regions with geoclimatic conditions represented by the Piacenza and Okehampton FOCUS groundwater scenarios.

Studies were available to asses the risk to non-target organisms. The risk to terrestrial vertebrates, aquatic organisms, bees, other non-target arthropods, earthworms, other soil macro- and micro-organisms and biological methods of sewage treatment was concluded to be low. Risk mitigation comparable to a 5 m buffer zone is required to protect non-target plants outside the treated field.

Key words: Clomazone peer review, risk assessment, pesticide, herbicide.

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Clomazone is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Sweden as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Denmark submitted the report of its initial evaluation of the dossier on clomazone hereafter referred to as the draft assessment report, to the EFSA on 16 March 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 11 July 2005 to the Member States and the main applicant FMC as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in June – July 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings in January 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 26 June 2007 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11(4) of the Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (rev. 1-1 of 7 August 2006)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (rev. 2-1 of 29 June 2007)

Given the importance of the draft assessment report including its addendum (compiled version of June 2007 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Vol. 3 B2, B5, B8, B9) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can basically be found in the original draft assessment report together with the peer review report which both is publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Clomazone is the ISO common name for 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one (IUPAC).

Clomazone is a isoxazolidinone herbicide, there are no other compounds currently in this class of herbicide. It inhibits carotenoid biosynthesis; the target enzyme is not known. It is a selective herbicide, absorbed by the roots and shoots and translocated upwards.

The representative formulated product for the evaluation was "Centium 36 CS", a capsule suspension (CS).

The evaluated representative uses are as a pre-emergence herbicide on potato and oilseed rape full details of the GAP can be found in the attached end points.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of clomazone as manufactured should not be less than 960 g/kg. At the moment no FAO specification exists. The technical material contains no relevant impurities.

The content of clomazone in the representative formulation is 360 g/L (pure).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of clomazone or the respective formulations.

The main data regarding the identity of clomazone and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of clomazone in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor clomazone in products of plant origin. Clomazone can be determined by the multi method DFG S19. An analytical method for food of animal origin is not required as no MRLs will be set. The method for air is by GC-MS with an LOQ of 0.025 µg/m^3. An LC-MS/MS method for soil and a GC-MS method for water were provided but they appeared to contain an acid hydrolysis step and the PhyChem meeting of experts (PRAPeR 16 March 2007) concluded that if there are conjugates of clomazone the methods would not be considered as specific to clomazone and therefore would not be accepted. A message was sent to Fate and Behaviour meeting however, as the Fate and Behaviour meeting took place before the PhysChem meeting the message was not considered by the Fate and Behaviour meeting of experts. However, an EFSA Fate and Behaviour expert has confirmed that there are conjugates (bound residues) in the environmental assessment which on acid hydrolysis produce clomazone. As this is the case the methods for soil and water can not be accepted and a data gap has been identified. It should be noted that the applicant in column 2 of the evaluation table stated that there is a position paper available to address this issue however it would appear that this position paper was not evaluated and therefore was not made available by the rapporteur during the peer review process. Several methods were provided for soil and water metabolites however, no conclusion was made on the acceptability of the validation data during the peer review process.

An analytical method for body fluids and tissues is not required as the active substance is nether toxic or very toxic.

2. Mammalian toxicology

Clomazone was discussed by the experts in mammalian toxicology in the PRAPeR meeting 14 (round 3, January 2007).

EFSA note: the toxicological batches were of lower purity than the technical specification, but no information on the levels of impurities was provided in the DAR. Therefore a data gap has to be set for additional information to confirm that the toxicological batches are representative of the technical specification with regard to the levels of impurities.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Clomazone is rapidly and extensively absorbed after oral administration (87-100% within 48h based on urinary excretion and intravenous study). Peak blood concentrations are seen 4 hours after dosing. Negligible residual tissue levels are detected 7 days after administration of a low dose (5 mg/kg bw). Clomazone is almost completely metabolised by hydroxylation and oxidation/opening of the 3-isoxazolidone ring. The majority of the excretion occurs within the first two days and is close to 100% after 7 days.

2.2. Acute toxicity

Clomazone is moderately toxic after oral administration (lowest rat LD_{50} = 1369 mg/kg bw in females) and after inhalation (rat LC_{50} = 4.85 mg/L), and is of low dermal toxicity (rabbit LD_{50} > 2000 mg/kg bw). It is not irritating to skin and eyes, and has no sensitizing properties according to a Buehler test presented in the original DAR and a Guinea Pig Maximisation Test summarised in the addendum (December 2006). Based on these results, the proposed classification is **Xn, R20/22 Harmful by inhalation and if swallowed.**

2.3. Short term toxicity

In the short term studies, the liver was the target organ for all the species (rat, mouse and dog) with increased absolute and/or relative weight, alterations in hepatocytes (megalocytosis), and related changes in clinical chemistry parameters (elevated cholesterol levels). Due to the limited study design of the three 28-day studies described (range-finding studies, low number of animals, and lack of histopathological examinations) no NOAELs were proposed in the DAR.

The proposed NOAELs for the 90-day studies in rats and mice, and the 1-year study in dogs were based on the use of a conversion factor (to convert ppm in feed to mg/kg bw/day). The experts agreed for the revised values presented in the addendum (December 2006) based on test article consumption data. The agreed NOAELs are 138 (m) – 163 (f) mg/kg bw/day for the 90-day rat study, 371 (m) – 522 (f) mg/kg bw/day for the 90-day mouse study, and 13.3 (m) – 14 (f) mg/kg bw/day for the 1-year dog study.

In the 28-day dermal study in rats, only local epidermal hyperplasia (indicative of skin irritation) was observed but no adverse systemic toxicity. The proposed NOAEL is 1000 mg/kg bw/day (the highest dose tested).

2.4. GENOTOXICITY

Three Ames tests were conducted with some weaknesses, but the overall evaluation of the three studies indicates that clomazone was not mutagenic in the tested species.

The *in vitro* tests investigating gene mutations in Chinese hamster ovary cells and DNA damage and repair gave negative results. No study investigating the clastogenic effects *in vitro* has been submitted. However, in the *in vivo* test, clomazone did not induce chromosome aberrations in the bone marrow of rats. The overall weight of evidence shows that clomazone is not of genotoxic concern.

2.5. LONG TERM TOXICITY

One 2-year study in the rat and one in the mouse have been submitted and presented in the DAR. The proposed NOAELs for these studies were initially based on the use of a conversion factor (to convert ppm in feed to mg/kg bw/day). The experts agreed for the revised values presented in the addendum (December 2006) based on test article consumption data.

In the 2-year rat study, the agreed NOAEL was 41 mg/kg bw/day (1000 ppm) based on liver changes (increased weight, hepatocytomegaly). In the 2-year mouse study, liver changes were also observed (increased weight, hepatocytomegaly) predominantly in males, and persistent thymus glands in females. These last findings were discussed by the experts. They were considered to be delayed normal thymic involution, but treatment-related, and taken into account for the setting of the NOAEL. In any case the reference values won't be affected. The agreed NOAEL was 142 (m) – 89 (f) mg/kg bw/day, based on thymus changes for the females and on liver effects for males.

In both species, there was no indication of a carcinogenic potential.

2.6. REPRODUCTIVE TOXICITY

The effects of clomazone on the reproductive system have been studied in a two-generation rat study, a rat teratogenicity study and a rabbit teratogenicity study.

In the DAR, the proposed NOAELs for the 2-generation study in rats were based on the use of a conversion factor (to convert ppm in feed to mg/kg bw/day). The experts agreed for the revised values presented in the addendum (December 2006) based on test article consumption data. The agreed parental NOAEL is 84 mg/kg bw/day, based on reduced maternal body weight, whereas the agreed NOAEL for the offspring and for the reproductive parameters is 354 mg/kg bw/day (highest dose tested).

In the rat teratogenicity study, the maternal toxicity was manifested by a decrease in food consumption and clinical signs, resulting in a NOAEL of 100 mg/kg bw/day. Foetal effects were a decreased body weight, an increased incidence of delayed ossifications and visceral abnormalities (hydroureter, within historical control data). The resulting developmental NOAEL was 100 mg/kg

bw/day. A re-evaluation of the maternal toxicity in relationship with the foetotoxic effects was presented in the addendum (December 2006), and the experts agreed that the minor effects in foetuses observed at maternal toxic doses do not warrant classification for developmental toxicity.
In the rabbit teratogenicity study, there was no relevant increased incidence of malformations, developmental variations or abnormalities. The high dose produced maternal toxicity manifested by decreased body weight, 3 deaths, 4 abortions, red vaginal discharge (most often in animals which aborted). The proposed NOAELs were 240 mg/kg bw/day for maternal toxicity and 700 mg/kg bw/day for developmental toxicity.

2.7. NEUROTOXICITY

No studies were available. Based on the toxicological profile, no specific neurotoxicity studies were considered necessary.

2.8. FURTHER STUDIES

The major metabolite in plants is 2-chlorobenzyl alcohol (OCB-alcohol or FMC 61569).
In the DAR, information from published literature has been summarized. This metabolite is the major metabolite of 2-chlorotoluene, is rapidly eliminated in rats, and could be an intermediate in the rat metabolism of clomazone.

EFSA notes: in an addendum provided after the experts' meeting (May 2007) and not peer-reviewed, the acute oral toxicity of OCB-alcohol is assumed to be comparable to clomazone based on toxicological results with a family of chemical analogues.
Four other minor plant metabolites were considered in the DAR, but results of toxicological studies were only given for isoxazolidine (FMC 57091). It was not irritating to skin in a test considered only as supportive, and there was no evidence of mutagenic activity in an Ames test. As it is proposed as an intermediate in the rat metabolism and highly instable, it was not assumed to be of toxicological significance.

2.9. MEDICAL DATA

No clinically relevant health problems associated with clomazone production have ever been observed. No data are available concerning reported incidents of clinical cases of poisoning with clomazone.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARfD)

Acceptable daily intake (ADI)

The target organ in the long term toxicity studies is the liver. The dog is the most sensitive species. The agreed ADI is 0.133 mg/kg bw/day, based on the 1-year dog study, with the use of a safety factor of 100.

Acceptable operator exposure level (AOEL)

As clomazone is not carcinogenic, not toxic to reproduction or a developmental toxicant the most relevant study to consider was the 1-year dog study, since no 90-day dog study was available. The agreed AOEL is 0.133 mg/kg bw/day with the use of a safety factor of 100.

Acute reference dose (ARfD)

The need of an ARfD has been discussed by the experts in light of the toxicity seen in the rabbit developmental study, where a non statistical significant body weight loss was observed in the mothers at 240 mg/kg bw/day. The meeting agreed that no ARfD is needed based on this result.

2.11. DERMAL ABSORPTION

No dermal study has been performed with the formulated product Centium 36CS (water based liquid containing a suspension of microcapsules) or the active substance.

According to the Guidance Document on Dermal Absorption, the default dermal absorption value of 100% should be used according to the physico-chemical properties of the compound (molecular weight < 500 and log Pow <4). The reduction of this default value was discussed by the experts on the basis of the data available in the addendum (December 2006). The micro-encapsulated formulation type is expected to reduce the potential for dermal absorption as the active substance remains exclusively within the capsules in the concentrated product and is released into the spray solution up to 36% after 1 day (50% after 7 days). However great uncertainties remain on the extent of chemical release from the microcapsules (in the spray tank before use, when hitting the skin, in hot and occluded conditions inside a glove …). As a result, it was agreed the use the conservative 100% default value, without requiring additional data.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Centium 36 SC is a micro-encapsulated formulation containing 360 g clomazone/kg, for use on potatoes and oilseed rape by downward spray using conventional tractor mounted hydraulic sprayer.

Operator exposure

According to the intended uses submitted by the applicant, the maximum applied dose is 120 g a.s./ha for oilseed rape, and the minimum volume 200 L.

The estimated operator exposure for Centium 36CS is below the AOEL when gloves are used during mixing/loading and application, according to both models (German and UK POEM).

Estimated exposure presented as % of AOEL (0.133 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Model	No PPE	With PPE
German	114	45
UK POEM	1076	86

PPE (personal protective equipment): gloves during mixing/loading and application

Worker exposure

No significant level of exposure is expected since Centium 36CS is applied to the soil just after planting/sowing as a pre-emergence herbicide treatment, therefore workers are not required to re-enter the field during the weeks following treatment.

Bystander exposure

The worst case estimate of bystander exposure is using data based on Lloyd and Bell[2] (1983), taking into account dermal and inhalation exposure. Assuming no protection from clothing, the estimated acute exposure of a bystander is approximately 0.8% of the AOEL.

3. Residues

Clomazone was discussed by the residues experts in the PRAPeR meeting 15 (round 3, January 2007).

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Metabolism of clomazone was investigated upon pre-emergence treatment of tobacco (leafy vegetables group), sweet potatoes (root and tuber crops) and soybeans (oil seed crops) with radio-labelled material. Application rates were exaggerated (*ca* 10N to 40N) compared to the maximum recommended rate for the representative uses. In addition, studies on cotton and alfalfa with post-emergence application were submitted and evaluated to complete the picture of clomazone metabolism in plants. An available study in maize was judged inappropriate to be used for the evaluation of clomazone and was therefore not further considered.

In the study on sweet **potatoes** total radioactive residues (TRR) were low in tubers (<0.15 mg/kg) and foliage (<0.5 mg/kg), given the exaggerated amount applied (nearly 40 N). Samples with the highest TRR levels were extracted to study the metabolic profile of clomazone. Only small amounts of clomazone were found (<2% TRR). Various hydroxylated clomazone metabolites (3-11% TRR) could be identified. Moreover a metabolic cleavage of the clomazone structure occurs and leads to

[2] Lloyd and Bell, 1983. Hydraulic nozzles: comparative spray drift study.

metabolites derived from the chlorphenyl- and isoxazolidinone moiety, respectively. So was 2-chlorobenzyl alcohol the major metabolite in both vine (25% TRR) and tuber (15% TRR) after treatment with (phenyl-^{14}C)-clomazone. Results from ^{14}C-carbonyl-clomazone treated potato plants suggest that the most abundant compound in vines (30% TRR) and tubers (11% TRR) existed as an amino acid conjugate derived from the isoxazolidinone moiety of clomazone. Sequential enzymatic and chemical fractionation of the material containing unextractable radioactivity (23-47% TRR) indicated also an association of residues with cell wall components, starch, cellulose and lignin.

In the studies on **soybeans** TRRs decreased until harvest of the mature soybeans and were at 0.1 mg/kg in a test with an application rate equal to *ca* 18 fold the recommended rate for oilseeds.
In the immature plants the predominant metabolite was 2-chlorobenzyl alcohol (up to 54% TRR) while parent clomazone was not detected. Other metabolites identified were 5-keto-clomazone (5% TRR) and hydroxy-and hydroymethyl clomazone compounds (together 22% TRR).
In mature soybeans residues of clomazone were negligible (<2% TRR i.e. <0.002 mg/kg). The majority of the residues was either of polar nature or non-extractable from plant solids. Three metabolites were identified in beans as 2-chlorobenzyl alcohol, hydroxy-2-chlorobenzyl alcohol and 2-chlorobenzoic acid.

In the study on **tobacco** uptake of residues from the treated soil into the leaves was limited and therefore the rate of characterisation and identification of residues was low. Nevertheless, the major metabolic pathway in tobacco plants could be detected. Metabolites identified as either non-conjugated material or aglycones included various hydroxylated compounds derived from clomazone, moreover isoxazolidinone, 2-chlorobenzoic acid and 2-chlorobenzyl alcohol were detected.

The studies on **alfalfa** and **cotton** with post-emergence application support the findings of the studies reported above. The immature whole plant and different plant parts of the mature crop (leaves and forage, cotton seeds and lint) were analysed. Upon a foliar application clomazone was readily taken up by the plants and extensively metabolised. While on cotton plants significant amounts of parent compound (up to 22% TRR) could still be found at 21 days after application, clomazone was not detectable on alfalfa forage at 3 days after application. All metabolites identified in alfalfa forage and immature cotton plants appeared to be identical to those found in the soybean metabolism study. The major metabolites were 2-chlorobenzyl alcohol and monohydroxylated derivates of clomazone (the exact position of hydroxylation on the aromatic ring could not always be confirmed.)

The metabolic pathways in all the investigated crops are similar and involve hydroxylation of the methylene bridge carbon of the clomazone molecule, to generate carbinolamide. This unstable intermediate would then decompose to yield isoxazolidinone and 2-chloro-benzaldehyde. The aldehyde may be further reduced to yield the corresponding alcohol or oxidised to the carboxylic acid. The degradation products can then be further conjugated to yield glucosides and/or amino acid conjugates. The isoxazolidinone may undergo hydrolysis/oxidation/reduction to yield related products, followed by conjugation with glycosides and amino acid. Another important metabolic

pathway, especially considered being of relevance in cotton and soybeans, included hydroxylation of clomazone to yield various hydroxylated metabolites.

As for pre-emergence treatments, it was considered that there are sufficient metabolism studies to cover all plant crops after pre-emergence treatment. There are two studies on cotton and alfalfa with post-emergence application, covering only one crop groups (oilseeds and pulses), but covering different plant parts (seeds and foliage). Since the pathway identified in these studies was very similar to the pathway identified in the pre-emergence studies, the experts of PRAPeR 15 concluded that this information would be sufficient to cover also post-emergence treatments. It was therefore considered possible, with the available metabolism studies, to propose a residue definition for all plant products for both pre-emergence and post-emergence treatments.

It has been concluded by the RMS that the only residue of toxicological significance is clomazone, and that the residue definition in plants for both monitoring and risk assessment should be proposed as clomazone.

However, in plants only 2-chlorobenzyl alcohol and hydroxy derivates of clomazone were found in significant amounts. 2-chlorobenzyl alcohol was even found to be the major metabolite in nearly all plant parts (10% TRR in tobacco, 15% and 25% TRR in sweet potato tubers and leaves respectively, 16% TRR in cotton seed and 48% in soybean plants) and it occurred in an order of magnitude higher than clomazone (3% TRR in tobacco, 1.6 and 0.4% TRR in sweet potato tubers and leaves respectively, 0.8 % TRR in cotton seed and not detected in soybean plants). Moreover it is noted that, even if its formation as an intermediate was considered likely by the RMS, the metabolite 2-chlorobenzyl alcohol was not identified in rat metabolism. Therefore the experts discussed the relevance of 2-chlorobenzyl alcohol for the consumer risk assessment and the possibility of including this metabolite in the plant residues definition. The experts acknowledged that 2-chlorobenzyl alcohol is not expected to have higher toxicity than clomazone and that, with respect to the representative uses, the metabolite is not expected to be present at levels higher than 0.01 mg/kg in food items and 0.1 mg/kg in feed items.

The experts in the meeting PRAPeR 15 aimed to establish a plant residue definition that can be applied in general to all crops, independent of a particular GAP. However as insufficient toxicological data and information on 2-chlorobenzyl alcohol was available, the experts suggested that the applicant may submit further data on the relative toxicity of 2-chlorobenzyl alcohol compared to clomazone. If it could be demonstrated that 2-chlorobenzyl alcohol is of much lower toxicity than clomazone, it would be possible to conclude that, regardless of being the predominant residue, the contribution of 2-chlorobenzyl alcohol to the toxicological burden of the total residue is minor.

Since with respect to the residue levels in the representative uses further data on 2-chlorobenzyl alcohol were not necessary, the proposed data gap should be considered a potential requirement on Member State level, if uses and/or GAPs other than that currently evaluated become relevant. Information presented by the RMS in the addendum of May 2007 (for more details refer to point 2.8 above) was not peer reviewed.

As a consequence the EFSA propose to limit the residue definition "Clomazone" to the evaluated representative uses, i.e. pre-emergence application to oil seeds and potatoes at the requested application rate.

Residue trials were performed in potatoes and rapeseed at the critical GAP in both the Northern and Southern region of Europe. Clomazone was the residue analysed for in these trials. All residues in potato tubers and different parts of rapeseed were ≤0.01 mg/kg (at harvest), independently of the PHI considered. The trial results are supported by validated analytical methods and sufficient storage stability data of clomazone in starch-containing and oil-containing matrices.

As residues of clomazone are below 0.01 mg/kg in all samples of potato tuber and rapeseed no studies concerning the effects of industrial processing and/or household preparation on the nature of the residues are required.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

No studies of residues in rotational crops have been submitted.
Even though the DT_{90} of clomazone has been calculated to be in the range of 86 to 297 days in field studies, PRAPeR 15 concluded that a rotational crop study was at current not necessary. In the supervised residue trials with pre-emergence application no residues exceeding the LOQ were observed in immature leaves and stems of oil seed rape and in potatoes tubers at around 30 days after application, neither at later sampling stages. It is therefore not expected that residues of clomazone exceeding 0.01 mg/kg would occur in any rotational crop growing after crop failure of the primary crop.
It should be noted that this conclusion is only applicable for the evaluated representative uses. If in the future uses with a higher application rate should be requested, the requirement for rotational crop data would need to be reconsidered.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Metabolism and feeding studies in livestock are not required since no residues above 0.01 mg clomazone/kg are expected in potential feeding items when clomazone is used in potato and rape according to the cGAP.
However, studies in goat and hen have been submitted and evaluated by the RMS, and the following is noted: In the goat metabolism study only the total radioactive residues were determined. In poultry the metabolism was only investigated with material radio-labelled in the phenyl ring. Therefore the RMS considered the available data insufficient to reach a conclusion about the metabolism in livestock and propose a residue definition for products of animal origin.

3.3. CONSUMER RISK ASSESSMENT

The TMDI was estimated with the proposed MRLs for potatoes and oilseed rape, and with consumption data from the WHO GEMS/Food European diet, with German consumption data for

children and with UK consumption data including more subgroups such as adults, vegetarian, elderly. In all cases the chronic intake from the representative crops has been estimated to amount to <0.5% of the ADI of 0.13 mg/kg.
An ARD is not required and therefore an acute risk to consumers is not expected.

3.4. PROPOSED MRLS

An MRL of 0.01* mg/kg is proposed for both potatoes and oilseed rape based on the fact that all residues from trials conducted in accordance with critical GAP are below LOQ (0.01 mg/kg).

4. Environmental fate and behaviour

Clomazone was discussed at the PRAPeR experts' meeting on environmental fate and behaviour (PRAPeR 12) in January 2007.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The route of degradation under dark aerobic conditions was investigated in several laboratory trials with 5 different soils. However, in the course of the EU evaluation process, concerns raised on the validity of these studies due to low recoveries or lack of information. The original reports of the aerobic metabolism studies were re-considered and discussed by the MS experts at the PRAPeR meeting on fate and behaviour. It was concluded (see addendum 2, May 2007) that there is only one trial (Dunkirk silt loam soil) performed with ring-^{14}C-radiolabelled clomazone that can be considered valid and may be used as the acceptable route study. Degradation of clomazone was moderate (from 94.8% AR at time 0 to 30.6% AR after 9 months), with a corresponding increase of $^{14}CO_2$ to 31.5% AR after 120 days) and bound residues reaching a maximum of 17% AR after 6 months. Seven unidentified metabolites were noted, never exceeding in total 3.1% AR of organic fractions.

Under anaerobic conditions, the major metabolite **N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide**, was detected (max 37.9% AR after 60 days). Clomazone degraded more rapidly under anaerobic conditions (mineralization ranged between 25.6 and 51.0% AR) and unextractable soil bound residues amounted to 10.5-14.5% AR after 60 days in the two soils.

Sunlight irradiation of ^{14}C labelled clomazone applied to one soil did not result in any appreciable degradation of the parent, without forming any metabolites exceeding 5% AR.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The rate of degradation of clomazone in soil was calculated from soil metabolism studies and 2 additional laboratory experiments aimed at determining the DT_{50} and DT_{90} values. However, the PRAPeR peer review meeting had reservations over the validity of the data submitted originally by

the applicant and re-evaluated the degradation rates in laboratory soils. The outcome of the discussion was reported by RMS in addendum 2 (B.1.1 and B.8.1.2). It was agreed that six of the available DT_{50} values were not acceptable because of few sampling dates or low recoveries and/or due to the too high experimental temperature. The remaining three degradation rates were therefore recalculated during the meeting using SFO kinetics, following the recommendations of FOCUS degradation kinetic report (not normalised DT_{50} ranged from 26.7 to 152.8 days). Although only 3 reliable rate degradation studies are available, despite the 4 required under Annex II, point 7.1, the experts concluded that in this case the information is sufficient as a number of field studies are available to clarify the fate of clomazone in soil. As a consequence, it was agreed that the longest DT_{50} value of 167.6 days (normalised to 20 ºC and soil moisture content of pF2) is the recommended input value by FOCUS GW scenario guidance for PEC calculations with a number of 3 values for the parent compound.

Field dissipation studies with clomazone formulated as either capsule suspension (Command 36 CS; 360 g a.s./L, 10 field trials) or wettable powder (Command 50 WP; 500 g a.s./kg, 5 field trials) have been carried out in five European countries, mainly in northern Europe (Belgium, Germany, The Netherlands and United Kingdom), plus a study in southern Europe (Spain). In all cases, clomazone was applied pre-emergence, i.e. onto bare soil, either in the spring (May/June) or in the autumn (August/September). Application rates ranged from 88 g a.s./ha to 360 g a.s./ha.
The DT_{50} values calculated using (pseudo) first order kinetics or, for some of the older studies, a graphical estimation, were in the range of 15-90 days, while the DT_{90} values in the 86-297 days interval. No overall systematic differences in dissipation pattern were observed between the two different locations where the filed trials were conducted, between spring and autumn application trials or between the different clomazone formulations applied. However it was noticed that the worst case rates were observed in the field dissipation study conducted in United Kingdom with spring application (loam soil, 91 g a.s./ha) using the Command 36 CS formulation.
In general, clomazone residues were only found in the upper 0-15 or 0-20 cm of the soil but in a few cases low concentrations, i.e. just above the LOQ of 0.005 mg/kg, were observed in the 15-30 cm layer.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Soil adsorption/desorption study on clomazone using 4 different soil types (pH: 4.8 – 6.9; clay content: 3.6-35.0%) is available. The results indicated that clomazone is low to high mobile in soil (K_{foc} = 139-562 mL/g). Freundlich exponents (1/n values) for adsorption (0.81-0.96, mean = 0.88) demonstrated a non-linear sorption.

Three laboratory studies were conducted to investigate the column leaching of clomazone. In each trial clomazone was applied to 3 soils, ranging from sand to loamy sand. In a trial performed with ^{14}C-clomazone, 0.56-1.62% of the applied radioactivity was detected in the leachate. The nature of the leached substances could not be identified, but was excluded to be clomazone or the metabolite

N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide. In the other trials trace amounts (0.022-0.07 µg/L) of parent clomazone were analytically determined in the leachates.

The leaching behaviour of aged (30 to 34 days) residues of clomazone was investigated with ^{14}C-clomazone. Between 2.0 and 3.1% of the applied radioactivity was determined in the leachate. The nature of the residues was not identified, but were excluded to be clomazone or the metabolite N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide. The majority of the radioactivity (87.1-94.1% AR) remained in the top 28 cm of the soil core. In a second trial performed with unlabelled clomazone, trace amounts of the parent compound (0.061 µg/L) and the metabolites N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide (0.020 µg/L) and N-[(2-chlorobenzyl)]-2-methyl propanamide (0.041 µg/L) were detected in the leachate.

No reliable lysimeter studies are available.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In a hydrolytic degradation study in the dark (see addendum 1) clomazone was found to be stable under neutral, acidic and alkaline conditions.

The molar decadic absorption coefficient of clomazone for wavelengths at and above 290 nm is < 10. Nevertheless three studies on the aqueous photochemical degradation were available and reported in addendum 1. Results confirmed that clomazone is not likely to undergo direct phtototransformation in water under sunlight conditions.

Clomazone is not readily biodegradable in water according to the available study.

A study to investigate the dissipation of clomazone in two water/sediment systems (sediment organic carbon content: 0.1% and 6.7%) were performed with radiolabelled clomazone. Clomazone degraded to concentrations of approximately 18% AR and 37% AR, with negligible amounts detected in sediment (< 3.0% AR). A maximum mineralisation of 7.2% AR was measured at the end of the study (100 days). One major metabolite was detected in the water phases, identified as **FMC 65317 (N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide)** and reaching a maximum amounts of 24.9% AR and 28.1% AR at day 61. In the sediment phase FMC 65317 was measured at levels < 4.5% AR. A second metabolite, **FMC 55657 (N-[(2-chlorobenzyl)]-2-methyl propanamide**, was shown to occur at maximum concentrations of 11.6-11.8% AR (100d) in the water phase and < 4% AR in sediment. In view of the very low amounts of clomazone dissipated to sediment, 1st order DT_{50} were calculated only for the whole systems (40.4 days and 66.9 days).

In line with the FOCUS Work Group on Degradation Kinetics, the experts agreed on the use of the mean value of 52.5 days for $DT_{50water}$ and a worst-case half-life of 1000 days for $DT_{50sediment}$ as input parameters in the modelling.

Predicted Environmental Concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) were re-calculated following the MS experts discussion on the appropriate soil DT_{50} for clomazone to be used in the modelling (see section 4.1.2). The calculations were performed for different and representative drainage and run-off scenarios at 6 locations in Europe relevant for potatoes, winter and summer

oilseed rape. FOCUSsw Step 1-3 modelling for clomazone was evaluated by RMS and reported in addendum 2. Although the results are not peer reviewed, EFSA agrees with the RMS that the new PEC_{SW} and PEC_{SED} values can be considered valid as they are derived with the appropriate model input parameters for the parent compound (longest laboratory soil DT_{50}, Koc = 287 mL/g, and 1/n = 0.88, DT_{50} for water = 52.5 days and DT_{50} for sediment = 1000 days). It should be noted that in addendum 2 additional "Tier 2" simulations were included. As they use not agreed input parameters (arithmetic mean soil DT_{50lab} value of 88.2 days), they can not be considered acceptable.

The need for PEC_{SW} calculations for the major metabolites FMC 65317 and FMC 556657 was discussed at the meeting of experts. It was concluded that since these metabolites are less toxic to aquatic organisms than the parent, a surface water exposure assessment is not required.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

New FOCUS PEC_{GW} calculations were provided by the applicant after the discussion on the appropriate soil DT_{50}lab for modelling took place at the PRAPeR meeting of experts (see section 4.1.2). The new modelling is evaluated by RMS in addendum 2 but has not been peer reviewed. However, EFSA confirms that worst case soil DT_{50}lab of 167.6 days, of Koc value of 287 mL/g and 1/n of 0.88 agreed by the experts were considered in the calculations. Following yearly application of clomazone at a rate of 120 g a.s./ha pre-emergent to oilseed rape the trigger of 0.1 µg/L was never exceeded in the 3 summer oilseed rape scenarios, whereas for winter oil seed rape the trigger was exceeded in 2 out of 6 scenarios (0.144 µg/L in Okehampton and 0.294 µg/L in Piacenza). Annual application of clomazone at a rate of 90 g a.s./ha pre-emergent to potatoes resulted in an 80th percentile annual average concentrations < 0.1 µg/L in 8 of the 9 investigated FOCUS scenarios (0.168 µg/L in Piacenza scenarios). During the final discussion on clomazone (evaluation meeting on 26-27 June 2007), it was agreed that at Member State level a second model might be considered to calculate PEC_{GW}. This confirmatory data gap is in line with the opinion of EFSA Panel on PPR of 14 September 2004 (the EFSA Journal (2004) 93, 1-20) on the FOCUS groundwater models comparability and the consistency of the risk assessment of ground water contamination.

It should be noted that the additional "higher tier" simulations included in addendum 2 can not be considered acceptable as they deviate from the FOCUS recommendations for the use of the soil DT50 or from the GAP applied for (a clomazone application every third year is not in line with the representative uses applied for).

4.3. FATE AND BEHAVIOUR IN AIR

The evaporation of clomazone from soil was studied using the BBA standard test. The sum of evaporated radio-labelled clomazone was 6.9%, which is below the 20% limit recommended by the guideline to require an estimation of a photochemical-oxidative degradation in air.

A comparison of clomazone volatility over time using 2 formulated products in an environmental chamber showed that the encapsulated formulation is less volatile than the emulsifiable concentrate formulation and therefore is more effective at restricting volatility, and affection of none-target vegetation is less likely. In another study, the comparative volatility of clomazone between the 2

formulation types was examined in a semi-field study. Mustard seedlings (*Sinapis alba*) placed in a glasshouse were used as representative for sensitive plant species. However, the applicant did not submit the vegetative vigour test conducted to demonstrate that mustard is highly sensitive to clomazone symptoms. The phytotoxicity differences between the 2 formulations indicated that the CS formulation has less foliar activity than the EC formulation.

5. Ecotoxicology

Clomazone was discussed at the experts' meeting for ecotoxicology (PRAPeR 13) in January 2007. The batches used in the ecotoxicological studies were in the majority of the studies of lower purity than the technical specification, but no information on the levels of impurities was provided in the DAR. Therefore, a data gap was proposed by EFSA for additional information to confirm that the batches used are representative of the technical specification with regard to the levels of impurities.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals was assessed for the use of 1 × 0.12 kg/ha clomazone in oilseed rape (generic species for the leafy crop scenario) in accordance with the Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000). The first tier assessment resulted in TER values well above the relevant Annex VI triggers for all time scales thus indicating a low acute and long-term risk. This assessment also covers the use in potato.

The acute risk from exposure via contaminated drinking water was calculated in line with the guidance in SANCO/4145/2000 and presented in addendum 1 of December 2006. The result indicates a low risk. The risk for secondary poisoning of earthworm- and fish-eating birds and mammals is expected to be low since the log P_{ow} or clomazone was determined as 2.54. The plant metabolites 2-chlorobenzyl alcohol and hydroxyl derivatives of clomazone (only detected as conjugates) are more polar and more water soluble than clomazone. They are expected to be excreted quickly and will therefore be less toxic than clomazone. Therefore the risk assessment for clomazone should also cover that for the plant metabolites.

5.2. RISK TO AQUATIC ORGANISMS

Clomazone is proposed to be classified as very toxic to aquatic organisms (R50/53). The most sensitive organism tested was the diatom algae *Navicula pelliculosa* with an E_bC_{50} of 0.136 mg a.s./L. With FOCUS Step 3 global maximum PEC values the Annex VI triggers are met for all relevant scenarios and the risk to aquatic organisms from exposure to clomazone is therefore considered to be low for the evaluated uses. The formulated product showed lower toxicity than clomazone alone. A general concern was raised in the PRAPeR meeting with regard to the appropriateness of *Lemna* sp. as test organisms for selective herbicides since *Lemna* seemed to be non sensitive.

Two metabolites (FMC 63517 and FMC 55657) were detected >10% of applied amount of clomazone in the water phase in the water/sediment study. Toxicity studies with fish, daphnids and algae show that these metabolites are less toxic than clomazone. The toxicity study with algae was conducted with *Selenastrum capricornatum* and the experts' meeting discussed whether studies with the most sensitive algae *N. pelliculosa* should be required. It was agreed that the margin of safety was large and no further studies are necessary.

Clomazone and the two metabolites were not detected in sediment >10% and therefore no studies with sediment dwelling organisms are required.

The bioconcentration factor for whole fish was determined to 40 and the clearance was rapid with a CT_{50} >24 hours.

5.3. RISK TO BEES

The acute toxicity to bees is low and the HQ values obtained from the first tier oral and contact toxicity studies with clomazone are >1.2 and <1.4. These values are clearly below the Annex VI trigger of 50 and hence the risk to bees is considered to be low. No studies are available with the formulated product. It was however agreed by Member State experts that since the toxicity of the formulated product to other non target arthropods is low no further data is required.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The in-field and off-field risk to non-target arthropods from the use of clomazone formulated as 'Centium 36 CS' is considered to be low based on effects below 30% from studies on inert substrate with the two standard species *Typhlodromus pyri* and *Aphidius rhopalosiph* and the soil dwelling *Poecilius cupreus* and *Aleochara bilineata* at a field rate of 0.32 kg a.s./ha.

5.5. RISK TO EARTHWORMS

Acute toxicity studies are available with clomazone, and the formulation 'Command 50 WP'. A study on sub-lethal/reproduction effects used the formulation 'Centium 36 CS'. In the reproduction study no significant effects were observed at 1 × and 5 × the proposed field rate. TER values for both acute and long-term are well above the Annex VI trigger indicating a low risk.

There were no metabolites detected > 10% of applied clomazone in the aerobic soil degradation studies.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The $DT_{90field}$ in soil is between 100 and 360 days. However, since the toxicity to non-target arthropods, earthworms and soil micro-organisms is low no studies are required and the risk is considered to be low.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects on soil respiration and nitrification were tested in two studies, one using a WP formulation and the other Command 36 CS. The only significant effect observed was an increase in dehydrogenase activity on day 32 in the study with Clomazone 50 WP. The effect had disappeared at day 60. No effects >25% were observed in the other study at a dose rate of 720 g a.s./ha. The risk to soil micro-organisms was therefore concluded to be low.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Four laboratory studies and two field studies on toxicity of Centium (or Command) 36 CS to terrestrial non-target plants were evaluated in the DAR. The most sensitive species tested was common chickweed, *Stellaria media*, with an ER_{50} for phytotoxicity (biomass) of 4.4 g a.s./ha derived in a glasshouse study with post emergence application. The TER based on the drift at 1 m from the treated field was calculated to 1.4. With a 5 m buffer zone the TER becomes 6.6 which are above the Annex VI trigger of 5.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Data from a test with clomazone technical on effects on activated sludge respiration rate indicate that the risk to biological methods of sewage treatment is low should clomazone reach sewage treatment plants.

6. Residue definitions

Soil

Definitions for risk assessment: clomazone

Definitions for monitoring: clomazone

Water

Ground water

Definitions for exposure assessment: clomazone

Definitions for monitoring: clomazone

Surface water

Definitions for risk assessment: clomazone (water phase), N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide (FMC 65317) (water phase), N-[(2-chlorobenzyl)]-2-methyl propanamide (FMC 55657) (water phase)

Definitions for monitoring: clomazone

Air

Definitions for risk assessment: clomazone

Definitions for monitoring: clomazone

Food of plant origin

Definitions for risk assessment: clomazone (proposed to be currently restricted to the evaluated representative uses) [3]

Definitions for monitoring: clomazone (recommended to be currently applied to the evaluated representative uses only)[4]

Food of animal origin

Definitions for risk assessment: none proposed (see 3.2 above)

Definitions for monitoring: none required for representative uses

[3] As residue levels in rape and potato were not significant following application of clomazone conform to GAP, parent compound clomazone was proposed as a default definition. The conclusion of whether or not for other crops or different agricultural practices the most abundant residue, the metabolite 2-chlorophenyl alcohol, should be included in a general residue definition was not finalised during the peer review procedure. For details refer to point 3.1.1 of this document.

[4] Same remark as above applies

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

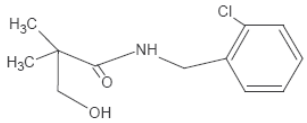
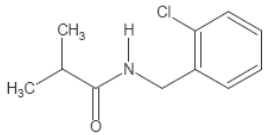
Soil

Compound (name and/or code)	Persistence	Ecotoxicology
clomazone	moderate to high persistence (first order $DT_{50\ lab}$ = 26.7-167.5 d, 20°C and pF2 soil moisture);	Risk to soil organisms is low

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 relevance
clomazone	low to high mobile (K_{foc} = 139-562 mL/g)	FOCUS-PELMO 3.3.2: yes in 2 out of 9 scenarios for winter oilseed rape (0.144 and 0.294 µg/L in Okehampton and Piacenza) and in 1 of 9 scenarios for potatoes (0.168 µg/L in Piacenza) Lysimeter: no	Yes	Yes	Yes

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
clomazone	Classified as very toxic to algae and aquatic invertebrates. No risk mitigation measures required
N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethyl propanamide (FMC 65317) 	Less toxic than clomazone. Low risk.
N-[(2-chlorobenzyl)]-2-methyl propanamide (FMC 55657) 	Less toxic than clomazone. Low risk.

Air

Compound (name and/or code)	Toxicology
clomazone	Xn R20 Harmful by inhalation (rat LC_{50} 4.85 mg/L air/4h)

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Methods of analysis for clomazone in soil and water are required (relevant for all uses evaluated; data gap identified by EFSA in June 2007 which is supported by the conclusion of the Meeting of Experts PRAPeR 16 March 2007; date of submission unknown, refer to chapter 1)
- Applicant to submit information in order to confirm that the toxicological batches are representative of the technical specification with regard to the levels of impurities (relevant for all uses evaluated; data gap identified by EFSA in June 2007; information submitted but not peer reviewed, refer to chapter 2).
- Applicant to submit information on the composition of the batches used in the ecotoxicological studies and to assess the equivalence with the technical specification with regard to levels of impurities (relevant for all uses evaluated; data gap identified by EFSA in June 2007; information submitted but not peer reviewed; refer to chapter 5).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions
The conclusion was reached on the basis of the evaluation of the representative use as a herbicide on oilseed rape, for full details of the GAP please see the attached endpoints.
The representative formulated product for the evaluation was “Centium 36 CS", a capsule suspension (CS).

Residues in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For air there is a single method available that analysed for clomazone. Soil and water methods were provided however, they appear to contain a hydrolysis step and will therefore not be specific to clomazone. Several methods were provided for soil and water metabolites however, no conclusion was made on the acceptability of the validation data during the peer review process.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Clomazone is rapidly and extensively absorbed and metabolised. The acute toxicity by oral administration and inhalation is moderate (Xn, R 20/22 Harmful by inhalation and if swallowed), it is not irritating to skin and eyes, and is not a skin sensitiser. In repeat dose studies, the liver was the target organ for all the tested species. The compound is not genotoxic, not carcinogenic, and has no reproductive or developmental effect. The data available for the major plant metabolites 2-chlorobenzyl alcohol do not allow concluding with certainty on its relative toxicity in comparison with the parent compound. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) are both 0.133 mg/kg bw/day based on the 1-year dog study, and the acute reference

dose (ARfD) was not considered necessary. The 100% default value for the dermal absorption was used even though the micro-encapsulated formulation type is expected to reduce the potential for dermal absorption to negligible levels. The operator exposure estimates are below the AOEL when gloves are used during mixing/loading and application. No significant exposure of the worker is expected, and the bystander exposure estimate is negligible.

Metabolism studies with pre-emergence treatment were conducted in tobacco, sweet potatoes and soy bean. In addition, there are two studies on cotton and alfalfa with post-emergence application, covering different plant parts. The metabolism is considered to be similar in the evaluated crops. It would therefore be possible, to propose a general residue definition for all plant products. However, the most abundant plant metabolite, 2-chlorobenzyl alcohol, was not found in rat metabolism, and it could not be demonstrated that it is of lower toxicity than clomazone. The latter was almost completely degraded and, if present, only at low levels. At current, i.e. with respect to the representative uses evaluated, the amount of neither, clomazone and 2-chlorobenzyl alcohol, will be significant in food and feed items (i.e. below the trigger values). Therefore, with respect to the representative uses the relevant residue should be defined by default as clomazone. Further data and information on 2-chlorobenzyl alcohol will be needed in order to render possible a generally applicable plant residue definition.
Metabolism studies in livestock animals are not necessary since residues in potential feedstuff is <0.1 mg/kg.
Studies in succeeding crops or rotational crops are not required. Based on the currently available information it was assessed that no residues in rotational crops are expected after treatment of the primary crops according to critical GAP.
A sufficient number of valid residue trials covering the relevant European growing areas allow for an MRL proposal for potato tubers and rape seed.
Independently of the model used, the chronic consumer intake form the representative uses is estimated to be well below the ADI (<1%). No ARfD is proposed and therefore an acute risk to consumers is not expected.

The information submitted on the fate and behaviour in the environment is generally sufficient to enable the required environmental exposure concentrations to be estimated that are required for environmental risk assessment at EU level. For the representative filed uses applied for, the potential for groundwater exposure by clomazone above the drinking water limit of 0.1µg/L is low except for regions with geoclimatic conditions represented by the Piacenza and Okehampton FOCUS groundwater scenarios. A refinement of the assessment using a more realistic dissipation rate in soil for clomazone may be necessary if the appropriate number of the required degradation rates will be available at Member State level.

Studies were available to asses the risk to non-target organisms. The risk to terrestrial vertebrates, aquatic organisms, bees, other non-target arthropods, earthworms, other soil macro- and micro-

organisms and biological methods of sewage treatment was concluded to be low. Risk mitigation comparable to a 5 m buffer zone is required to protect non-target plants outside the treated field.

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

- Use of gloves during mixing/loading and application in order to have an operator exposure estimate below the AOEL (refer to point 2.12).
- Risk mitigation comparable to 5 m buffer zones are required to protect non-target plants outside the treated field (refer to point 5.8).

Critical areas of concern

- There is no acceptable monitoring method available for water.
- Risk mitigation comparable to 5 m buffer zones are required to protect non-target plants outside the treated field.

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

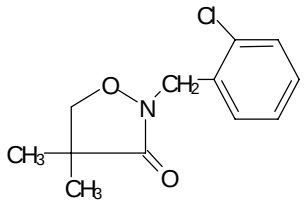
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Clomazone
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	Denmark
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one
Chemical name (CA) ‡	2-(2-chlorophenyl) methyl-4,4-dimethyl-3-isoxazolidinone
CIPAC No ‡	509
CAS No ‡	81777-89-1
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	960 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	$C_{12}H_{14}ClNO_2$
Molecular mass ‡	239.7 g/mol
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	33.0 - 34.7 °C (99.7 %)
Boiling point (state purity) ‡	281.7 °C (99.1 %)
Temperature of decomposition (state purity)	Not relevant as melting and boiling point are stated.
Appearance (state purity) ‡	Pure material: white solid (99.7%)
	Technical material: weak yellow liquid (96 %)
Vapour pressure (state temperature, state purity) ‡	1.92×10^{-2} Pa (97.5 %, 25 °C) (extrapolated)
Henry's law constant ‡	4.2×10^{-3} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	1102 mg/L (23 °C, 97.5 %)
Solubility in organic solvents ‡ (state temperature, state purity)	The solubility has not been carried out at different pHs as the molecule does not dissociate in water at acidic or basic pH
	Purity: 89.4-92.7 %
	acetone >1000 g/L at 22 °C
	acetonitrile >1000 g/L at 22 °C
	dichloroethane 955 g/L at 25 °C
	ethylacetate 940 g/L at 25 °C
	n-heptane 192 g/L at 20 °C
	methanol 969 g/L at 25 °C
	toluene >1000 g/L at 22 °C
Surface tension ‡ (state concentration and temperature, state purity)	σ = 43.5 mN/m measured at 90% saturated solution at 19.8°C, purity: 90.8%
	Clomazone has to be regarded as a surface active substance.
Partition co-efficient ‡ (state temperature, pH and purity)	log Pow = 2.54 (23 °C, neutral pH) purity 97.5%
	log Pow = 2.17 (calculated value)
	Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range
Dissociation constant (state purity) ‡	Not required since there is no dissociation in water in the environmentally relevant pH-range
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Purity: 99.7%
	solution wavelength [nm] molar extinction coefficient [L / mol · cm]
	ACN 211 12800
	No ε for absorbency > 290 nm, but this is acceptable as quantum yield is determined
Flammability ‡ (state purity)	Not applicable to liquids
	Auto flammability: 376 °C (90.8 %)

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

Explosive properties ‡ (state purity)	Not explosive (90.8 %)
Oxidising properties ‡ (state purity)	Not oxidising (statement)

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

Summary of representative uses evaluated *

Crop and/ or situation (a)	Member State, Country or Region	Product name	F, G, or I (b)	Pests or group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	Kg a.s./Hl (l) min – max	water L/ha min – max	Kg a.s./ha (l) min – max		
Potato SOLTU	EU	Centium 36 CS	F	*Galium aparine Stellaria media*	CS	360 g/L	Spraying	Pre-emergence 7 d before cracking	1	Not applicable	0.0225-0.045	200-400	0.09	Not applicable. Pre-mergence treatment and all residues <0.01	Early and ware potatoes
Oilseed rape BRSNN	EU	Centium 36CS	F	*Galium aparine Stellaria media*	CS	360 g/L	Spraying	Pre-emergence max. 5 d after sowing	1	Not applicable	0.030-0.060	200-400	0.12	Not applicable. Pre-mergence treatment; >100 days from treat. to harvest	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	RP-HPLC-UV or NP-HPLC-UV
Impurities in technical as (analytical technique)	RP-HPLC-UV
Plant protection product (analytical technique)	RP-HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Clomazone
Food of animal origin		None. Not necessary as intakes by livestock ≤ 0.1 mg/kg diey/day and since no detectable residues are expected.
Soil		Clomazone
Water	surface	Clomazone
	drinking/ground	Clomazone
Air		Clomazone

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	DFG method S19 has been independently validated to determine clomazone in food of plant origin for matrices with a high content of water and acid as well as oily and dry matrices. . GC-MSD with an LOQ of 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No methods are necessary since no MRLs are proposed. Residues in feeding are <0.1 mg/kg.
Soil (analytical technique and LOQ)	LC-MS-MS 0.2 µg/kg. Open: current method is not specific for clomazone
Water (analytical technique and LOQ)	GC-MS 0.1 µg/L (drinking water) GC-MS 0.1 µg/L (surface water) Open: current method is not specific for clomazone
Air (analytical technique and LOQ)	GC-MS 0.025 µg/m³
Body fluids and tissues (analytical technique and LOQ)	Not required [substance is not classified as toxic (T) or very toxic (T+)]

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

	RMS/peer review proposal
Active substance	None

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of absorption ‡	Rapidly and extensively absorbed (87-100% within 48h based on urinary excretion and iv study). Peak blood concentrations were seen 4 hours after dosing.
Distribution ‡	Low levels of residues in liver, kidneys, blood, hair and carcass.
Potential for accumulation‡	No evidence for accumulation.
Rate and extent of excretion ‡	Majority of the excretion within 2 days, close to 100% after 7 days (~70% in urine and ~30% in faeces).
Metabolism in animals ‡	Extensively metabolised (> 95 %) by oxidation reactions and cleavage reactions.
Toxicologically relevant compounds ‡ (animals and plants)	Clomazone
Toxicologically relevant compounds ‡ (environment)	Clomazone

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	2077 mg/kg bw (males) 1369 mg/kg bw (females) **R22**
Rabbit LD_{50} dermal ‡	> 2000 mg/kg bw
Rat LC_{50} inhalation ‡	4.85 mg/L air/4 hr **R20** (whole body, combined sexes)
Skin irritation ‡	Not irritating
Eye irritation ‡	Not irritating
Skin sensitization (test method used and result) ‡	Non-sensitiser (M&K and Buehler test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver (rats, dogs and mice), with increased weight, alterations in hepatocytes, gross pathological findings and changes in clinical chemistry parameters.
Relevant oral NOAEL ‡	13.3 mg/kg bw/day (12 months dog study)
Relevant dermal NOAEL ‡	1000 mg/kg bw/day (28 day rat study)
Relevant inhalation NOAEL ‡	No data/ Not required

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

Genotoxicity ‡ (Annex IIA, point 5.4)

……..	No genotoxic concern	

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

Target/critical effect ‡	Liver
Relevant NOAEL ‡	41 mg/kg bw/day (2-year, rat) 89 mg/kg bw/day (2-year, mouse)
Carcinogenicity ‡	No carcinogenic potential in rats or mice

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	No adverse effect on reproduction.
Relevant reproductive NOAEL ‡	84 mg/kg bw/day for parental 354 mg/kg bw/day for offspring 354 mg/kg bw/day for reproduction
Developmental target / critical effect ‡	Foetal effects in the rat study at maternal toxic doses: decreased litter body weight, delayed ossifications, increased incidence of hydroureter (but within historical control data).
Relevant maternal NOAEL ‡	100 mg/kg bw/day (rat) 240 mg/kg bw/day (rabbit
Relevant developmental NOAEL ‡	100 mg/kg bw/day (rat) 700 mg/kg bw/day (rabbit)

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7) ‡

…….....	No data available – no concern from other studies

Other toxicological studies (Annex IIA, point 5.8) ‡

Isoxazolidine (plant metabolite, FMC 57091)	Negative skin irritation/dermal toxicity study and Ames test

Medical data ‡ (Annex IIA, point 5.9)

No evidence of toxicological concern from medical surveillance of manufacturing plant personnel.

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

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.133 mg/kg bw/day	1-year dog study.	100
AOEL ‡	0.133 mg/kg bw/day	1-year dog study.	100
ARfD (acute reference dose) ‡	Not necessary		

Dermal absorption (Annex IIIA, point 7.3) ‡

Centium 36 CS	No data, 100% default value

Exposure scenarios (including method of calculation)

Operator	Tractor mounted equipment Without PPE (% AOEL) : 1076% UK POEM 114% German Model With PPE*(% AOEL): 86% UK POEM model 45% German Model
Workers	Not relevant since re-entry is not considered necessary shortly after spraying.
Bystanders	Exposure considered to be negligible.

* PPE: gloves during mixing/loading and application

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

	RMS/peer review proposal	
Active substance	Xn, R20/22	Harmful Harmful by inhalation and if swallowed

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

Appendix 1.4: Residues

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

Plant groups covered	Data available to cover all plant groups for both pre- and post-emergence treatments Studies on pre- emergence treatments of tobacco (L), sweet potatoes (R) and soybeans (P/O) and post-emergence treatments of cotton, alfalfa (P/O)
Rotational crops	No studies submitted. Not necessary as residues ≥ 0.01 mg/kg are not expected.
Metabolism in rotational crops similar to metabolism in primary crops?	No studies submitted. Not necessary as residues ≥ 0.01 mg/kg are not expected.
Processed commodities	Not required, since no significant residues (all residues <0.01 mg/kg) occur in the plant or plant product for further processing and TMDI <10% of ADI.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not required, since no significant residues (all residues <0.01 mg/kg) occur in the plant or plant product for further processing and TMDI <10% of ADI.
Plant residue definition for monitoring	Clomazone[5]
Plant residue definition for risk assessment	Clomazone[6]
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Not relevant for representative uses
Time needed to reach a plateau concentration in milk and eggs	Not applicable.
Animal residue definition for monitoring	None. Not necessary as intakes by livestock ≤0.1 mg/kg diet/day since no detectable residues are expected.
Animal residue definition for risk assessment	None. Not necessary as intakes by livestock ≤0.1 mg/kg diet/day since no detectable residues are expected.
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Not applicable.
Fat soluble residue: (yes/no)	No, log P_{ow} < 3

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

…….	No studies submitted. Not necessary as residues ≥ 0.01 mg/kg are not expected.

[5] Even though data is available to cover all plant groups for both pre- and post-emergence treatments, the residue definition should currently be restricted to the evaluated representative uses. For details refer to point 3.1.1 of this document.
[6] Same remark as above apply

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

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

……..	Storage stability of clomazone residues was examined in corn (starch-containing crop) tobacco, soybean and cottonseed (oil-containing crops). Clomazone residues were found to be stable in crops stored at approximately -20°C for up to at least 1 year for corn and cottonseed, 6 months for soybean and 40 months for tobacco

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No studies required	No studies required	No studies required
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

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

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the representative uses (a)	Recommendation/ comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Potatoes	North and south	17 x <0.01 mg/kg		0.01 mg/kg	0.01 mg/kg	0.01 mg/kg
Rapeseed	North and south	25 x <0.01 mg/kg		0.01 mg/kg	0.01 mg/kg	0.01 mg/kg

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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

ADI	0.125
TMDI (% ADI) according to WHO European diet	<0.5 %
TMDI (% ADI) according to national (to be specified) diets	<0.5 % (UK and German model)
IEDI (WHO European Diet) (% ADI)	Not necessary
NEDI (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not necessary
ARfD	No value proposed
IESTI (% ARfD)	Not necessary
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not necessary
Factors included in IESTI and NESTI	Not necessary

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

Not required, since no significant residues (all residues <0.01 mg/kg) occur in the plant or plant product for further processing and TMDI <10% of ADI.

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

MRL in plant and animal products must be proposed in all cases where residue trials and feeding studies respectively are required (Residue trials are required if the PPP is applied to plant/plant products used as food or feedingstuffs or where residues from soil or other substrates can be taken up by such plants except extrapolation cases; feeding studies are required when significant residues (≥ 0.1 mg/kg diet (dry weight basis) except special case e.g. a.s. which accumulate) occur in crops or part of the crop fed to animals, and when metabolism studies indicate that significant residues (0.01 mg/kg or above the LOQ if this would be higher than 0.01 mg/kg) may occur in any edible animal tissue at expected rate of exposure.

Potatoes, early and ware	0.01* mg/kg
Rapeseed	0.01* mg/kg

* LOQ

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

Appendix 1.5: Fate and bahaviour in the Environment

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

Mineralization after 100 days ‡	31.5 % AR after 120 d, [^{14}C-ring] (n= 1*)
Non-extractable residues after 100 days ‡	15.2 % AR after 120 d, [^{14}C-ring] (n= 1*)
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	None relevant

* Due to low recovery, only one acceptable route study.

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

Anaerobic degradation ‡	
Mineralization after 100 days	25.6-51.0 % after 60 d (n= 2)
Non-extractable residues after 100 days	10.3-12.5 % after 60 d (n= 2)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	N-[(2-chlorobenzyl)]-3-hydroxy-2,2-dimethylpropanamide - 19.3-37.9 % at 60 d
Soil photolysis ‡	
Mineralisation	< 4 % after 30 d
Non-extractable residues	1.5-2.1 % after 30 d
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None greater than 5%

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

Method of calculation	Laboratory: 1st order kinetics (Excel curvefitting or, for FOCUS modelling, ModelManager 1.1)
Laboratory studies (range or median, with n value, with r^2 value) ‡	DT_{50lab} (20-25°C, aerobic): Silt loam = 64.1 d Sandy loam = 152.8 d Loamy sand = 26.7 d (all passed Chi2 test) Normalised DT_{50lab} (20°C and pF2) = 26.7-167.5 d (n=3). Arithmetic normalised mean = 88.8 d (n = 3) Geomean normalised = 68.0 d (n = 3) Metabolites: No data available For FOCUS gw modelling -

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

	Parent DT_{50lab} (aerobic, 1st order kinetics): 167.5 d* (normalised to 20°C and 100% FC) Metabolites: No data submitted * Only 3 acceptable laboratory studies on the rate of degradation in soil are available, although studies with 4 soils are required. The expert meeting considered the information sufficient, as a number of field studies are available to clarify fate in the field situation. However for groundwater assessment the experts agreed that the longest DT_{50} of 167.6 days should be applied to be in accordance with the FOCUS scenario guidance.
	DT_{50lab} (10°C, aerobic): 27.1 d (n=1, r^2=0.952)
	DT_{50lab} (20°C, anaerobic): No data, justification given
	Degradation in the saturated zone: No data submitted
Field studies (state location, range or median with n value) ‡	Application in May/June, pre-emergence, bare soil: (all rates calculated using (pseudo) 1st order kinetics, except where another is stated specifically) Belgium, St. Amand (loam soil; 88 g a.s./ha; date of app: 13-05-1996); DT_{50f} (Command 50 WP): 53 days (n=1; r^2=0.97) DT_{90f} (Command 50 WP): 175 days (n=1; r^2=0.97) DT_{50f} (Command 36 CS): 59 days (n=1; r^2=0.96) DT_{90f} (Command 36 CS): 197 days (n=1; r^2=0.96) Netherlands, Wijnandsrade (loess soil; 110 g a.s./ha; date of app: 17-05-1996): DT_{50f} (Command 50 WP): 74 days (n=1; r^2=0.95) DT_{90f} (Command 50 WP): 246 days (n=1; r^2=0.95) DT_{50f} (Command 36 CS): 57 days (n=1; r^2=0.90) DT_{90f} (Command 36 CS): 191 days (n=1; r^2=0.90) Germany, Pleidelsheim/Murr (loess loam; 90 g a.s./ha; date of app: 22-05-1997): DT_{50f} (Command 36 CS): 51 days (n=1; r^2=0.95) DT_{90f} (Command 36 CS): 168 days (n=1; r^2=0.95) Germany, Sandelsbronn (loess clay; 90 g a.s./ha; date of app: 21-05-1997): DT_{50f} (Command 36 CS): 32 days (n=1; r^2=0.87) DT_{90f} (Command 36 CS): 105 days (n=1; r^2=0.87) Germany, Pleidelsheim (silt loam; 115 g a.s./ha; date of

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app: 14-05-1998):
DT_{50f} (Command 36 CS): 26 days (n=1; r^2=0.93)
DT_{90f} (Command 36 CS): 86 days (n=1; r^2=0.93)

Spain, Sevilla (silty loam; 360 g a.s./ha; date of app: 02-06-1999):
DT_{50f} (Command 36 CS): 34 days (n=1; r^2=0.94)
DT_{90f} (Command 36 CS): 178 days (n=1; r^2=0.94)
NB! 1.5 order kinetics used for calculation

Spain, Sevilla (silty loam; 360 g a.s./ha; date of app: 29-05-1998):
DT_{50f} (Command 36 CS): 16 days (n=1; r^2=0.93)
DT_{90f} (Command 36 CS): 179 days (n=1; r^2=0.93)
NB! Sq.-root 1st order kinetics used for calculation

United Kingdom, Wilson (loam; 91 g a.s./ha; date of app: 24-06-1998):
DT_{50f} (Command 36 CS): 90 days (n=1; r^2=0.88)
DT_{90f} (Command 36 CS): 297 days (n=1; r^2=0.88)

Application in August/September, pre-emergence, bare soil:
(all rates calculated using (pseudo) 1st order kinetics, except where another is stated specifically)

Germany, Grebin (loamy sand; 120 g a.s./ha; date of app: 09-09-1992):
DT_{50f} (Command 50 WP): 30 days (n=1)
DT_{90f} (Command 50 WP): 160 days (n=1)
NB! DT-values graphically estimated

Germany, Heiligkreuz (clay silt; 120 g a.s./ha; date of app: 21-08-1992):
DT_{50f} (Command 50 WP): 15 days (n=1)
DT_{90f} (Command 50 WP): 210 days (n=1)
NB! DT-values graphically estimated

Germany, Herford (loamy sand; 120 g a.s./ha; date of app: 10-09-1991):
DT_{50f} (Command 50 WP): 45 days (n=1)
DT_{90f} (Command 50 WP): 250 days (n=1)
NB! DT-values graphically estimated

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

	Germany, Blaufelden (silty clay; 118 g a.s./ha; date of app: 25-08-1997): DT_{50f} (Command 36 CS): 54 days (n=1; r^2=0.95) DT_{90f} (Command 36 CS): 179 days (n=1; r^2=0.95) United Kingdom, Wilson (sandy silt loam;121 g a.s./ha; date of app: 10-09-1997): DT_{50f} (Command 36 CS): 56 days (n=1; r^2=0.98) DT_{90f} (Command 36 CS): 186 days (n=1; r^2=0.98) Germany, Ismaning (silty clay; 120 g a.s./ha; date of app: 28-09-1991): DT_{50f} (Command 50 WP): 30 days (n=1) DT_{90f} (Command 50 WP): 160 days (n=1) NB! DT-values graphically estimated
pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	In field trials at a total of 9 locations in Germany, no residues could be observed in soil 301-338 days after application of clomazone. LOQ = 0.01 mg/kg.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡	K_{foc}: 139-562 (mL/gl) (mean 286.5, 1/n= 0.81-0.96, mean = 0.88, 4 soils) Metabolites: No data submitted
pH dependence (yes / no) (if yes type of dependence) ‡	K_f: 1.54 - 6.85 (mean 3.44, 4 soils) Metabolites: No data submitted No apparent pH dependence of adsorption For FOCUS gw modelling - K_{foc}: parent, mean 286.5, 1/n = 0.88 Metabolites: No data submitted

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

Column leaching ‡	Guideline: BBA Guideline part IV, 4-2 Precipitation (mm): 200 mm Time period (d): 2 d Leachate: 0.56-1.62% radioactivity in leachate (2 replicates, 3 soils)

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

	Metabolites: No data available >88% retained in top 35 cm Guideline: BBA Guideline part IV, 4-2 Precipitation (mm): 200 mm Time period (d): 2 d Leachate: 0.00-0.012% of applied clomazone (2 replicates, 3 soils) Metabolites: No data available Soil residues: No data available Guideline: BBA Guideline part IV, 4-2 Precipitation (mm): 200 mm Time period (d): 2 d Leachate: 0.10-0.13% of applied clomazone (2 replicates, 3 soils) Metabolites: No data available Soil residues: No data available
Aged residues leaching ‡	Guideline: BBA Guideline part IV, 4-2 Aged for (d): 34 d Time period (d): 2 d Precipitation (mm): 200 mm Leachate: 2.0-3.1% radioactivity in leachate (2 tests, 2 replicates, 1 soil) Metabolites: No data available 87.1-94.1% radioactivity retained in top 28 cm Guideline: BBA Guideline part IV, 4-2 Aged for (d): 30 d Time period (d): 2 d Precipitation (mm): 200 mm Leachate: 0.073-0.194% active substance (average = 0.061 µg/L), 0.075-0.106% N-(2-chlorobenzyl)-2-methylpropanamide (average = 0.041 µg/L), 0.028-0.049% N-(2-chlorobenzyl)-3-hydroxy-2,2-dimethylpropanamide (average = 0.020 µg/L) Soil residues: No data available
Lysimeter/ field leaching studies ‡	Data submitted considered insufficient. Justification for not submitting a 'state of the art' study given.

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

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	DT_{50} (d): 90 days Kinetics: 1st order Field or lab: longest DT_{50} from field studies (loam from Wilsom in UK).
Application rate	Crops: Oilseed rape (worst case) Depth of soil layer: 5 cm % plant interception: Pre-emergence, therefore no crop interception (0%) Number of applications: 1 per year Interval (d): 365 Application rate: 120 g a.s./ha

PEC(s) (mg/kg)		Single Application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		160	160	Not relevant	Not relevant
Short term	24h	158.77	159.39	Not relevant	Not relevant
	2d	157.55	158.77		
	4d	155.15	157.56		
Long term	7d	151.60	155.76	Not relevant	Not relevant
	28d	128.96	143.92		
	50d	108.86	132.79		
	100d	74.07	111.57		

Metabolite

Method of calculation	No calculations done due to lack of data
Application rate	Not relevant

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		Not relevant	Not relevant	Not relevant	Not relevant
Short term	24h	Not relevant	Not relevant	Not relevant	Not relevant
	2d				
	4d				

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

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d 28d 50d 100d	Not relevant	Not relevant	Not relevant	Not relevant

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature) ‡	Clomazone is not degraded by hydrolysis (<10% degraded hydrolytically in 41 days)
	pH___5___: Stable (25 °C)
	pH___7___: Stable (25 °C)
	pH___9___: Stable (25 °C)
Photolytic degradation of active substance and relevant metabolites ‡	Data available, no photochemical degradation of clomazone occurred in water irradiated with monochromatic light of 304 nm
Readily biodegradable (yes/no) ‡	No
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	Only calculation for whole system due to <3.5% in sediment. Calculations based on mean of two replicates. [^{14}C-Clomazone uniformly labelled in phenyl ring] The DT-values were calculated from the linear regression lines constructed on the degradation plots (log (% radioactivity) against time). Hence, no coefficients of variations were determined. High organic sediment (n=1): DT_{50} whole system = 40.4 days DT_{90} whole system = 139 days Low organic sediment (n=1): DT_{50} whole system = 66.9 days DT_{90} whole system = 221 days
Mineralization	0.65% to 7.2% from day 30 to day 100 (high OC) 0.18% to 3.6% from day 30 to day 100 (low OC) Calculations based on mean of two replicates. [^{14}C-Clomazone uniformly labelled in phenyl ring]

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

Non-extractable residues	0.26% to 15.1% from day 7 to day 100 (high OC) 0.27% to 3.4% from day 14 to day 100 (low OC) Calculations based on mean of two replicates. [^{14}C-Clomazone uniformly labelled in phenyl ring]
Distribution in water / sediment systems (active substance) ‡	96.75% (6h) / 0.89% (30 d) (High OC at day 100) 93.5% (2 d) / 2.7% (1 d) (Low OC at day 100) Calculations based on mean of two replicates. [^{14}C-Clomazone uniformly labelled in phenyl ring]
Distribution in water / sediment systems (metabolites) ‡	Two metabolites were identified. In the high organic matter water/sediment system a maximum of 15-24.9% N-(2-chlorobenzyl)-3-hydroxy-2,2-di-methylpropanamide was detected at day 30 and 61 respectively in water, and 4.3 and 3.6 in sediment at the same days. A maximum of 10.4-11.6% N-(2-chlorobenzyl)-2-methylpropanamide was detected at day 61 and 100 respectively in water, and 3.9 in sediment at day 61. In the low organic matter water/sediment system a maximum of 28.1 and 19.5% N-(2-chlorobenzyl)-3-hydroxy-2,2-di-methylpropanamide was detected at day 61 and 100 respectively in water, and 2.5 and 3.3% in sediment at day 1 and 61 respectively. A maximum of 5.1 and 11.8% N-(2-chlorobenzyl)-2-methylpropanamide was detected at day 61 and 100 respectively in water and 0.4% in sediment at day 61. 3 miner unknown metabolites (M1, M2 and M4) were detected in both phases of both systems (individual concentration < 2.6%) Calculations based on mean of two replicates. [^{14}C-Clomazone uniformly labelled in phenyl ring]

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

Parent Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 239.7 Water solubility (mg/L): 1102 Koc (L/kg): 286.5 DT_{50} soil (d): 167.5 days (In accordance with FOCUS SFO; maximum of n = 3 DT_{50}lab, 20°C, 100% FC) DT_{50} water/sediment system (d): 52.53 days (geometric mean of n = 2 DT_{50} in the whole system, 20°C)

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

	DT_{50} sediment (d): 1000 days (default value) Crop interception (%): x% partitioning to top x cm layer of sediment, entry route as for surface water, pattern of decline reflecting that measured in the sediment/water study
Parameters used in FOCUSsw step 3	Vapour pressure: 0.0094 Pa measured at 25°C; extrapolated to 20°C Kom: 162.41 L/kg calculation by SWASH based on KOC 1/n: 0.88 (Freundlich exponent general or for soil ,susp. solids or sediment respectively)
Application rate	Crop: Winter oil seed rape Crop interception: Pre-emergence, therefore no crop interception (0%) Number of applications: 1 per year Interval (d): 365 Application rate(s): 120 g a.s./ha Depth of water body: 30 cm
Main routes of entry	2.77 % drift from 1 meter 10 % runoff/drainage (at FOCUSsw Step 1 and 2)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	30.03		83.03	
	24 h	29.34	29.69	84.20	83.61
	2 d	28.95	29.42	83.10	83.63
	4 d	28.20	28.99	80.93	82.82
	7 d	27.10	28.42	77.79	81.33
	14 d	24.71	27.15	70.92	77.82
	21 d	22.53	25.97	64.66	74.46
	28 d	20.54	24.86	58.95	71.28
	42 d	17.07	22.82	49.00	65.46

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				
Southern EU*	0 h	9.38		26.68	
	24 h	9.18	9.28	26.42	26.55
	2 d	9.09	9.21	26.16	26.42
	4 d	8.92	9.10	25.66	26.16
	7 d	8.66	8.97	24.92	25.79
	14 d	8.09	8.67	23.28	24.94
	21 d	7.56	8.39	21.75	24.13
	28 d	7.06	8.12	20.32	23.35
	42 d	6.16	7.61	17.73	21.90

* South Europe gave highest concentration

Metabolite

Not calculated. Reason given in volume 3, Annex B8.6.2.

Method of calculation	Not applicable (not sufficient data to allow such calculation)
Application rate	--
Main routes of entry	--

PEC(sw) (µg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				
Short term				
Long term				

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

Application to winter oilseed rape

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2	Ditch	0 h	4.560	-	17.380	-
		24 h	2.536	3.067	17.361	17.369
		2 d	4.439	2.723	17.319	17.361
		4 d	1.857	2.591	17.292	17.333
		7 d	1.872	2.437	17.185	17.300
		14 d	1.520	2.311	16.945	17.206
		21d	2.697	2.161	16.667	17.116
		28 d	2.047	2.093	n.c.	17.008
		42 d	2.156	2.019	n.c.	16.774
D2	Stream	0 h	2.853	-	10.509	-
		24 h	1.417	1.794	10.482	10.502
		2 d	2.706	1.585	10.485	10.499
		4 d	1.100	1.527	10.458	10.489
		7 d	1.103	1.482	10.395	10.474
		14 d	0.894	1.410	10.227	10.414
		21 d	1.388	1.327	10.124	10.357
		28 d	1.215	1.281	n.c.	10.299
		42 d	1.239	1.202	n.c.	10.145
D3	Ditch	0 h	0.766	-	0.607	-
		24 h	0.652	0.703	0.590	0.605
		2 d	0.565	0.656	0.553	0.600
		4 d	0.327	0.553	0.468	0.582
		7 d	0.088	0.397	0.375	0.542
		14 d	0.008	0.213	0.273	0.454
		21 d	0.002	0.144	0.226	0.393
		28 d	0.001	0.108	0.198	0.351
		42 d	0.000	0.072	0.165	0.297

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4	Pond	0 h	1.011	-	4.507	-
		24 h	1.011	1.012	4.507	4.507
		2 d	1.007	1.012	4.506	4.507
		4 d	0.996	1.010	4.505	4.507
		7 d	0.974	1.007	4.502	4.506
		14 d	0.915	0.995	4.490	4.505
		21 d	0.857	0.978	4.473	4.504
		28 d	0.827	0.958	4.453	4.501
		42 d	0.739	0.917	n.c.	4.495
D4	Stream	0 h	1.451	-	2.132	-
		24 h	0.931	1.203	2.128	2.131
		2 d	1.320	1.107	2.118	2.130
		4 d	0.933	1.076	2.115	2.126
		7 d	0.889	0.993	2.070	2.121
		14 d	0.741	0.899	1.883	2.090
		21 d	0.452	0.804	1.693	2.041
		28 d	0.248	0.698	1.618	1.985
		42 d	0.120	0.524	1.630	1.878
D5	Pond	0 h	0.771	-	3.904	-
		24 h	0.770	0.771	n.c.	3.903
		2 d	0.765	0.770	n.c.	3.903
		4 d	0.753	0.768	n.c.	3.902
		7 d	0.733	0.763	n.c.	3.900
		14 d	0.685	0.745	n.c.	3.893
		21 d	0.639	0.725	n.c.	3.882
		28 d	0.599	0.704	n.c.	3.866
		42 d	0.530	0.665	n.c.	3.818

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5	Stream	0 h	0.792	-	1.311	-
		24 h	0.598	0.589	1.303	1.309
		2 d	0.357	0.570	1.285	1.306
		4 d	0.482	0.541	1.243	1.297
		7 d	0.268	0.494	1.185	1.278
		14 d	0.167	0.394	1.080	1.227
		21 d	0.104	0.317	1.007	1.180
		28 d	0.113	0.263	0.958	1.139
		42 d	0.085	0.202	1.010	1.084
R1	Pond	0 h	0.026	-	0.105	-
		24 h	0.025	0.026	0.105	0.105
		2 d	0.024	0.025	0.105	0.105
		4 d	0.023	0.025	0.105	0.105
		7 d	0.022	0.024	0.105	0.105
		14 d	0.019	0.022	0.105	0.105
		21 d	0.017	0.021	0.104	0.105
		28 d	0.015	0.019	0.103	0.105
		42 d	0.012	0.017	0.101	0.104
R1	Stream	0 h	0.503	-	0.103	-
		24 h	0.000	0.146	0.069	0.089
		2 d	0.000	0.073	0.055	0.077
		4 d	0.000	0.037	0.044	0.064
		7 d	0.000	0.021	0.037	0.054
		14 d	0.000	0.011	0.034	0.044
		21 d	0.000	0.007	0.029	0.039
		28 d	0.000	0.007	0.025	0.036
		42 d	0.000	0.007	0.028	0.034

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3	Stream	0 h	2.265	-	0.840	-
		24 h	0.645	1.188	0.779	0.817
		2 d	0.004	0.793	0.633	0.797
		4 d	0.001	0.454	0.515	0.739
		7 d	0.584	0.359	0.439	0.650
		14 d	0.001	0.245	0.347	0.544
		21 d	0.000	0.173	0.300	0.495
		28 d	0.000	0.131	0.273	0.453
		42 d	0.000	0.088	0.238	0.395

Application to summer oilseed rape

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	Ditch	0 h	3.806	-	19.009	-
		24 h	3.781	3.790	n.c.	18.996
		2 d	3.745	3.774	n.c.	18.990
		4 d	3.663	3.748	n.c.	18.978
		7 d	3.509	3.687	n.c.	18.952
		14 d	3.097	3.526	n.c.	18.835
		21 d	2.852	3.378	n.c.	18.751
		28 d	3.080	3.257	n.c.	18.685
		42 d	2.526	3.130	n.c.	18.506
D1	Stream	0 h	2.380	-	11.249	-
		24 h	2.358	2.369	n.c.	11.231
		2 d	2.335	2.357	n.c.	11.223
		4 d	2.296	2.338	n.c.	11.214
		7 d	2.170	2.298	n.c.	11.195
		14 d	1.903	2.190	n.c.	11.108
		21 d	1.755	2.098	n.c.	11.041
		28 d	1.920	2.025	n.c.	10.988
		42 d	1.535	1.944	n.c.	10.841

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4	Pond	0 h	0.653	-	3.023	-
		24 h	0.652	0.653	3.023	3.023
		2 d	0.650	0.653	3.023	3.023
		4 d	0.642	0.652	3.022	3.023
		7 d	0.628	0.650	3.020	3.023
		14 d	0.590	0.643	3.012	3.022
		21 d	0.552	0.632	3.000	3.021
		28 d	0.530	0.618	2.985	3.019
		42 d	0.474	0.592	n.c.	3.015
D4	Stream	0 h	0.778	-	1.355	-
		24 h	0.585	0.663	1.352	1.354
		2 d	0.522	0.622	1.346	1.354
		4 d	0.489	0.601	1.341	1.351
		7 d	0.485	0.583	1.312	1.347
		14 d	0.358	0.531	1.195	1.327
		21 d	0.223	0.483	1.077	1.297
		28 d	0.125	0.425	1.034	1.263
		42 d	0.129	0.320	1.048	1.196
D5	Pond	0 h	0.334	-	1.883	-
		24 h	0.333	0.333	n.c.	1.883
		2 d	0.331	0.333	n.c.	1.882
		4 d	0.326	0.332	n.c.	1.881
		7 d	0.318	0.330	n.c.	1.880
		14 d	0.298	0.323	n.c.	1.875
		21 d	0.279	0.314	n.c.	1.867
		28 d	0.261	0.306	n.c.	1.857
		42 d	0.241	0.290	n.c.	1.829

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5	Stream	0 h	0.639	-	0.648	-
		24 h	0.051	0.234	0.645	0.648
		2 d	0.050	0.228	0.639	0.647
		4 d	0.049	0.219	0.623	0.643
		7 d	0.046	0.202	0.602	0.636
		14 d	0.046	0.167	0.563	0.617
		21 d	0.054	0.137	0.534	0.599
		28 d	0.050	0.116	0.516	0.584
		42 d	0.040	0.093	0.563	0.567
R1	Pond	0 h	0.103	-	0.388	-
		24 h	0.101	0.102	0.388	0.388
		2 d	0.099	0.101	0.388	0.388
		4 d	0.095	0.099	0.387	0.388
		7 d	0.090	0.097	0.386	0.388
		14 d	0.079	0.091	0.383	0.387
		21 d	0.070	0.086	0.378	0.387
		28 d	0.077	0.084	0.371	0.386
		42 d	0.060	0.081	0.356	0.383
R1	Stream	0 h	1.355	-	0.435	-
		24 h	0.003	0.732	0.256	0.365
		2 d	0.001	0.367	0.193	0.305
		4 d	0.003	0.184	0.159	0.241
		7 d	0.001	0.151	0.217	0.227
		14 d	0.010	0.097	0.207	0.217
		21 d	0.000	0.067	0.141	0.201
		28 d	0.000	0.050	0.119	0.183
		42 d	0.000	0.038	0.116	0.167

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

Application to potatoes

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	Ditch	0 h	0.471	-	0.194	-
		24 h	0.213	0.361	0.153	0.187
		2 d	0.029	0.231	0.118	0.172
		4 d	0.002	0.120	0.087	0.143
		7 d	0.001	0.069	0.068	0.117
		14 d	0.000	0.035	0.050	0.089
		21 d	0.000	0.023	0.042	0.075
		28 d	0.000	0.018	0.037	0.066
		42 d	0.000	0.012	0.031	0.056
D4	Pond	0 h	0.478	-	2.679	-
		24 h	0.477	0.478	2.679	2.679
		2 d	0.476	0.478	2.678	2.679
		4 d	0.471	0.477	2.678	2.679
		7 d	0.461	0.476	2.677	2.678
		14 d	0.434	0.471	2.671	2.678
		21 d	0.409	0.464	2.661	2.677
		28 d	0.404	0.454	2.649	2.676
		42 d	0.368	0.438	n.c.	2.672
D4	Stream	0 h	0.492	-	1.260	-
		24 h	0.378	0.425	1.260	1.260
		2 d	0.340	0.401	1.256	1.260
		4 d	0.322	0.388	1.258	1.258
		7 d	0.328	0.381	1.241	1.258
		14 d	0.257	0.351	1.165	1.246
		21 d	0.173	0.327	1.082	1.226
		28 d	0.105	0.293	1.072	1.203
		42 d	0.125	0.227	1.095	1.164

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	Ditch	0 h	0.509	-	0.747	-
		24 h	0.053	0.236	0.746	0.747
		2 d	0.042	0.211	0.745	0.746
		4 d	0.039	0.172	0.743	0.746
		7 d	0.035	0.153	0.738	0.745
		14 d	0.039	0.137	0.729	0.743
		21 d	0.049	0.122	0.737	0.742
		28 d	0.038	0.107	n.c.	0.739
		42 d	0.036	0.087	n.c.	0.736
R1	Pond	0 h	0.074	-	0.279	-
		24 h	0.073	0.073	0.279	0.279
		2 d	0.071	0.073	0.279	0.279
		4 d	0.069	0.071	0.279	0.279
		7 d	0.065	0.069	0.278	0.279
		14 d	0.057	0.065	0.275	0.279
		21 d	0.051	0.062	0.271	0.278
		28 d	0.052	0.060	0.267	0.277
		42 d	0.041	0.057	0.255	0.276
R1	Stream	0 h	0.981	-	0.336	-
		24 h	0.001	0.447	0.218	0.288
		2 d	0.000	0.224	0.176	0.249
		4 d	0.000	0.112	0.173	0.206
		7 d	0.102	0.097	0.188	0.196
		14 d	0.001	0.069	0.175	0.189
		21 d	0.000	0.057	0.126	0.174
		28 d	0.000	0.051	0.109	0.160
		42 d	0.000	0.035	0.103	0.146

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R2	Stream	0 h	0.703	-	3.815	-
		24 h	0.637	0.414	3.546	3.687
		2 d	0.003	0.343	3.482	3.594
		4 d	0.001	0.200	3.243	3.484
		7 d	0.002	0.151	3.124	3.376
		14 d	0.001	0.078	2.762	3.162
		21 d	0.000	0.054	2.487	2.990
		28 d	0.001	0.060	2.402	2.869
		42 d	0.000	0.041	2.059	2.658
R3	Stream	0 h	2.638	-	0.775	-
		24 h	0.021	1.076	0.600	0.727
		2 d	0.004	0.580	0.495	0.655
		4 d	0.001	0.292	0.412	0.563
		7 d	0.007	0.197	0.356	0.490
		14 d	0.000	0.109	0.295	0.409
		21 d	0.003	0.122	0.262	0.366
		28 d	0.000	0.097	0.287	0.363
		42 d	0.002	0.065	0.250	0.337

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

Method of calculation and type of study (e.g. modelling, monitoring, lysimeter)	The leaching of clomazone to groundwater at 9 European locations was modelled using the FOCUS groundwater scenarios and the pesticide leaching model FOCUS PELMO 3.3.2.
	Molecular weight 239.7 g/mol
	DT_{50}lab (days) 167.5
	Koc (mL/g) 286.5
	Average pH of soils 6.17
	Freundlich exponent 0.88
	Water solubility (g/L) 1.1
	Vapour pressure (Pa) 1.94×10-3 (at 25ºC)
	Pka 20
Application rate	Winter oilseed rape: 120 g/ha Potatoes: 90 g/ha

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

$PEC_{(gw)}$

Maximum concentration	No data submitted
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Annual average concentration (80th percentile) according to FOCUS guidance, see results in table below.

PEC(gw) –FOCUS modelling results expressed as 80th percentile annual average concentrations following a pre-emergent application annually to winter and summer oilseed rape and potatoes.

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
FOCUS PELMO 3.3.2 / Winter oilseed rape	Chateaudun, no irrigation	0.008	No data submitted, justification given		
	Hamburg	0.088			
	Kremsmünster	0.059			
	Okehampton	0.144			
	Piacenza, no irrigation	0.294			
	Porto	0.000			

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
FOCUS PELMO 3.3.2/ summer oilseed rape	Jokioinen	0.000	No data submitted, justification given		
	Okehampton	0.042			
	Porto	0.000			

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
FOCUS PELMO 3.3.2/ Potatoes	Chateaudun, irrigated	0.001	No data submitted, justification given		
	Hamburg	0.007			
	Jokioinen	0.000			
	Kremsmünster	0.000			
	Okehampton	0.008			
	Piacenza, irrigated	0.168			
	Porto	0.000			
	Sevilla, irrigated	0.000			
	Thiva, irrigated	0.000			

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

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

Direct photolysis in air ‡	No data – no significant degradation by photolysis is expected (notifier's statement)..
Quantum yield of direct phototransformation	The quantum yield not required as the molar decadic extinction coefficient at wavelength > 290 is <10. And since no degradation has been observed quantum yield cannot be calculated
Photochemical oxidative degradation in air ‡	DT_{50} in the atmosphere is 0.567 days ($1.5 \cdot 10^6$ OH-radicals / cm^3 and a 12 hour day)* * Atmopheric Oxidation Programme V.3.1 (1994) is used.
Volatilization ‡	From plant surfaces: No data
	from soil: The sum of evaporated radio-labelled clomazone was 6.9%, and therefore below the 20% limit recommended by the guideline to require an estimation of a photochemical-oxidative degradation in air

PEC (air)

Method of calculation	Not possible to calculate from the presented data

$PEC_{(a)}$

Maximum concentration	Not calculated

Residues requiring further assessment

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil:	Clomazone
	Surface water:	Clomazone; N-(2-chlorobenzyl)-3-hydroxy-2,2-dimethylpropanamide (FMC 65317) and N-(2-chlorobenzyl)-2-methylpropanamide (FMC 55657)
	Sediment:	None
	Groundwater:	Clomazone
	Air:	Clomazone

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

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

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Active substance	Candidate for R53 May cause long-term adverse effects to the environment

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

Appendix 1.6: Effects on non-target Species

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

Acute toxicity to mammals ‡	LD_{50} = 1369 mg/kg bw (female rats)
Chronic toxicity to mammals ‡	NOAEL = 100 mg a.s./kg bw/day
Acute toxicity to birds ‡	LD_{50} > 2510 mg/kg bw (*Colinus virginianus, Anas platyrhynchos*)
Dietary toxicity to birds ‡	LC_{50} >5620 ppm (*Colinus virginianus*, *Anas platyrhynchos*) (toxic dose: 1671 mg a.s./kg bw/day)
Reproductive toxicity to birds ‡	NOEC = 1000 ppm (*Colinus virginianus*) (toxic dose: 94 mg a.s./kg bw/day)

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
0.120	Oilseed rape	Herbivorous bird	acute	316	10
0.120	Oilseed rape	Insectivorous bird	acute	387	10
0.120	Oilseed rape	Herbivorous bird	short term	458	10
0.120	Oilseed rape	Insectivorous bird	short term	462	10
0.120	Oilseed rape	Herbivorous bird	long term	49	5
0.120	Oilseed rape	Insectivorous bird	long term	26	5
0.120	Oilseed rape	Medium herbivorous mammal	acute	468	10
0.120	Oilseed rape	Medium herbivorous mammal	long term	141	5

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				
Oncorhynchus mykiss	Clomazone	96 hours (static)	LC_{50}	15.5 mg a.s./L
Oncorhynchus mykiss	Clomazone	96 hours (static)	NOEC (sub-lethal)	1.0 mg a.s./L
Oncorhynchus mykiss	Clomazone	21 days (flow-through)	NOEC (sub-lethal)	2.30 mg a.s./L
Oncorhynchus mykiss	FMC 65317	96 hours (static)	NOEC (mortality)	20.0 mg a.s./L

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Oncorhynchus mykiss	FMC 55657	96 hours (static)	NOEC (mortality)	20.0 mg a.s./L
Oncorhynchus mykiss	Command 360 G/L CS	96 hours (semi-static)	LC_{50}	187.9 mg a.s./L
Oncorhynchus mykiss	Command 360 G/L CS	96 hours (semi-static)	NOEC (mortality/sub-lethal)	142.8 mg a.s./L
Crassostrea virginica	Clomazone	96 hours (flow-through)	EC_{50} (reduction in shell deposition)	5.3 mg a.s./L
Crassostrea virginica	Clomazone	96 hours (flow-through)	NOEC (reduction in shell deposition)	2.75 mg a.s./L
Daphnia magna	Clomazone	48 hours (static)	EC_{50} (immobility)	12.7 mg a.s./L
Mysidopsis bahia	Clomazone	96 hours (flow-through)	EC_{50} (immobility)	0.57 mg a.s./L
Daphnia magna	Clomazone	21 days (flow-through)	NOEC (immobility)	4.38 mg a.s./L
Daphnia magna	Clomazone	21 days (flow-through)	NOEC (reproduction)	2.2 mg a.s./L
Daphnia magna	FMC 65317	48 hours (static)	NOEC (immobility)	5 mg a.s./L
Daphnia magna	FMC 55657	48 hours (static)	NOEC (immobility)	5 mg a.s./L
Daphnia magna	Command 360 G/L CS	48 hours (static)	EC_{50} (immobility)	155.7 mg a.s./L
Daphnia magna	Command 360 G/L CS	48 hours (static)	NOEC (immobility)	79.3 mg a.s./L
Navicula pelliculosa	Clomazone	120 hours (static)	E_bC50	0.136 mg a.s./L
Navicula pelliculosa	Clomazone	120 hours (static)	E_rC50	>0.185 mg a.s./L
Navicula pelliculosa	Clomazone	120 hours (static)	NOEC	0.05 mg a.s./L
Selenastrum capricornutum	Clomazone	72 hours (static)	E_bC50	2.0 mg a.s./L
Selenastrum capricornutum	Clomazone	72 hours (static)	E_rC50	4.1 mg a.s./L

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Selenastrum capricornutum	Clomazone	72 hours (static)	NOEC	0.50 mg a.s./L
Selenastrum capricornutum	FMC 65317	72 hours (static)	NOEC	3.0 mg a.s./L
Selenastrum capricornutum	FMC 55657	72 hours (static)	NOEC	3.0 mg a.s./L
Pseudokirchneriella subcapitata	Command 360 G/L CS	72 hours (static)	E_bC50	53.3 mg a.s./L
Pseudokirchneriella subcapitata	Command 360 G/L CS	72 hours (static)	E_rC50	116.1 mg a.s./L
Pseudokirchneriella subcapitata	Command 360 G/L CS	72 hours (static)	NOEC	29.8 mg a.s./L
Lemna gibba	Clomazone	7 days (static)	EC50, growth rate	34 mg a.s./L
Lemna minor	Command 360 G/L CS	7 days (static)	EC50, biomass EC50, growth rate EC50, fronds	435 mg a.s./L 1127 mg a.s./L 333 mg a.s./L
Lemna gibba	Command 360 G/L CS	7 days (static)	$E_r C50$	357 mg a.s./L
Lemna gibba	Command 360 G/L CS	7 days (static)	$E_b C50$	138 mg a.s./L
Lemna gibba	Command 360 G/L CS	7 days (static)	NOEC, frond number	106 mg a.s./L

Microcosm or mesocosm tests
No data submitted. Not required.

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

FOCUS Step1

Clomazone in winter oilseed rape (120 g/ha)

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PECi mg/L	PECtwa	TER	Annex VI Trigger
a.s.	*O. mykiss*	15.5	Acute	0.03	-	517	100
a.s.	*O. mykiss*	2.30	Chronic	0.03	-	77	10

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

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PECi mg/L	PECtwa	TER	Annex VI Trigger
a.s.	*Daphnia magna*	12.7	Acute	0.03	-	423	100
a.s.	*Daphnia magna*	2.2	Chronic	0.03	-	73	10
a.s.	*Mysidopsis bahia*	0.57	Acute	0.03	-	18.9	100
a.s.	*C. virginica*	5.3	Acute	0.03	-	177	100
a.s.	*S. capricornutum*	2.0 (b)	Acute	0.03	-	67	10
a.s.	*S. capricornutum*	>4.1(r)	Acute	0.03	-	>137	10
a.s.	*N. pelliculosa*	0.136 (b)	Acute	0.03	-	4.5	10
a.s.	*N. pelliculosa*	>0.185 (r)	Acute	0.03	-	>6.2	10
a.s.	*Lemna gibba*	34	Short-term	0.03	-	1133	10
Command 36 CS	*O. mykiss*	187.9	Acute	0.03	-	6220	100
Command 36 CS	*D. magna*	155.7	Acute	0,03	-	5150	100
Command 36 CS	*P. subcapitata*	53.3 (b)	Acute	0.03	-	1760	10
Command 36 CS	*P. subcapitata*	116.1 (r)	Acute	0.03	-	3840	10
Command 360 G/L CS	*Lemna minor*	435 (b) 1127 (r) 333 (# frond)	Short-term	0.03	-	4597 11910 3520	10

FOCUS Step 2

Winter oilseed rape 120 g/ha, June-September, South Europe

Test substance	N/S	Organism	Toxicity endpoint (mg/L)	Time scale	PEC[1] (mg/L)	TER	Annex VI Trigger
a.s.	S	*Mysidopsis bahia*	0.57	Acute	0.009	62	100
a.s.	S	*N. pelliculosa*	0.136 (b)	Acute	0.009	15.1	10
a.s.	S	*N. pelliculosa*	>0.185 (r)	Acute	0.009	>20.6	10

[1] maximum PEC

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

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Initial PEC (PECglobal, max, FOCUSsw step 3) of Clomazone in surface water and TER for *Mysidopsis bahia* (LC_{50} = 566 µg a.s./L) following application to winter oilseed rape, 120 g a.s./ha

FOCUS Surface water scenario (meteorological station)	Tier 1 PECsw values (considering DT^{50} = 167.6 days for degradation in soil)	
	PECglobal, max [µg as./L]	TER for M. bahia
D2 ditch (Brimstone)	4.560	124
D2 stream (Brimstone)	2.853	198
D3 ditch (Vredepeel)	0.766	739
D4 pond (Skousbo)	1.011	560
D4 stream (Skousbo)	1.451	390
D5 pond (La Jailliere)	0.771	734
D5 stream (La Jailliere)	0.792	715
R1 pond scenario (Weiherbach)	0.026	21769
R1 stream scenario (Weiherbach)	0.503	1125
R3 stream scenario (Bologna)	2.265	250

Bioconcentration

Bioconcentration factor (BCF) ‡	40 (28 days, whole fish)
Annex VI trigger for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	Within 24 hours
Level of residues (%) in organisms after the 14 day depuration phase	1 (whole fish)

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	LD_{50} > 85.29 µg a.s./bee	LD_{50} > 100.0 µg a.s./bee
Preparation	-	-
Metabolite	-	-
Field or semi-field tests No data		

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

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s. (LD_{50} > 100 µg a.s./bee)	Contact	< 1.4	50
a.s. (LD_{50} > 85.29 µg a.s./bee)	oral	< 1.2	50
Preparation	Contact	-	50
Preparation	oral	-	50

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

Species	Stage	Test Substance	Dose (kg a.s./ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
‡*Aphidiyus rhopalosiphi*	<24 hours	Command 36 CS, 31.7% w/w Clomazone	0.32	Mortality Fecundity	5% 0%	30% - not exceeded
‡*Typhlo-dromus pyri*	≤ 3 days	Command 36 CS, 31.7% w/w Clomazone	0.32	Mortality Fecundity	4.3% 29.1%	30% - not exceeded
‡*Poecilius cupreus*	8 weeks	Centium 36CS, 32.3% w/w Clomazone	0.32	Mortality Feeding	0% 8 %	30% - not exceeded
‡*Aleochara bilineate*	1-7 days	Centium 36CS, 32.3% w/w Clomazone	0.32	Fecundity	-8.6%*	NA

* Negative number shows increase in fecundity relative to control.

Field or semi-field tests
No data submitted

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

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Acute toxicity ‡	Clomazone technical, 89.9% as $LC_{50\ corr}$ = 78 mg/kg soil dw* $NOEC_{corr}$ = 41 mg/kg soil dw* * corrected due to logPow above 2
Reproductive toxicity ‡	No statistically significant effect of Centium 36 CS at normal field rate (120 g a.s./ha = 0.16 mg a.s./kg soil) and at a rate corresponding to five times normal field rate (600 g a.s./ha) on reproduction of *Eisenia foetida Andrei.*

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

Application rate (kg a.s./ha)	Crop	Time-scale	TER	Annex VI Trigger
0.120	Oilseed rape	14 days	488	10
0.600	Oilseed rape	56 days	1875	10

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

Nitrogen mineralization ‡	No significant effect observed at exposure rates up to six times normal field rate (720 g a.s./ha = 0.96 mg a.s./kg soil) 90.5 % of control after 6 h 77.2 % of control at day 14 109.4 % of control at day 28.
Carbon mineralization ‡	No effects on soil respiration measured as CO2 evolution was observed at a rate up to six times normal field rate (720 g a.s./ha = 0.96 mg a.s./kg soil). 109.9 % of control after 6 h 97 % of control at day 14 94.8 % of control at day 28.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} biomass g a.s./ha	Exposure[1] (g a.s./ha)	Buffer zone	TER	Trigger
Comm. shickweed	Command 360 (360 g a.s./L)	4.5	120 g a.s./ha	1	1.4	5

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

Most sensitive species	Test substance	ER_{50} biomass g a.s./ha	Exposure[1] (g a.s./ha)	Buffer zone	TER	Trigger
Common chickweed	Command 360 (360 g a.s./L)	4.5 g a.s./ha	120	5	6.6	5
Lettuce	Command 360 (360 g a.s./L)	52.5	120	1	15.8	5

[1] Based on Ganzelmeier drift data

Additional studies (e.g. semi-field or field studies)

The two field studies using the formulated product showed no to minor damage on non-target plant species (application rate: 90 g a.s./ha). In one study (IIA 8.6.1/05) two cases of bleaching symptoms were found at field edges and in a distance of 1-2 m from the treated field. In the other field study (IIA 8.6.1/06) three cases of effects were recorded. These were generally in the form of minor marginal bleaching in spray overlap areas.

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	The toxicity of Clomazone to activated sludge micro-organisms has been tested with Clomazone technical (92.7% as) and the EC_{50} was determined to be 856 mg/liter corresponding to 793 mg a.s./liter. Based on this value and the intended use pattern of Clomazone, the risk of measurable adverse effects on sewage sludge treatment processes is considered negligible.
Pseudomonas sp	-

Ecotoxicologically relevant compounds

Compartment	
soil	Clomazone
water	Clomazone
sediment	None
groundwater	Clomazone

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

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance	N	Harmful to the environment
	R50/R53	Very toxic to aquatic organisms, may cause long term-adverse effects in the aquatic environment
Preparation	No classification	

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

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry

LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year