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CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance clomazone

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Denmark, and co-rapporteur Member State, Germany, for the pesticide active substance clomazone are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of clomazone as a herbicide on potato and spring/winter oilseed rape. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEYWORDS

clomazone, herbicide, peer review, pesticide, risk assessment

CONTENTS

SUMMARY

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Clomazone is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Denmark, and co-rapporteur Member State (co-RMS), Germany, received an application for the renewal of the approval of the active substance clomazone. The application was submitted by the two task forces, the Clomazone AIR Task Force (CATF), consisting of FMC Agricultural Solutions and ADAMA Agan Ltd. and the second clomazone task force (OAS), consisting of Oxon Italia SpA, Albaugh Europe Sàrl and Sapec Agro S.A.

An initial evaluation of the dossier on clomazone was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of clomazone according to the representative uses as a herbicide applied by broadcast direct soil spraying or overall spraying on potato and spring/winter oilseed rape in field, as proposed at EU level, result in a sufficient herbicidal efficacy against the target weeds.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to **identity, physical–chemical and technical properties** of the active substance and the representative formulations and analytical methods.

As regards the area of **mammalian toxicology and non-dietary exposure**, issues could not be finalised in relation to the representativity of test materials used in toxicity studies in respect to the current and newly proposed reference specifications for the active substance and associated impurities, and on lack of fit-for-purpose analytical methods used in relevant toxicological studies.

In the area of **residues**, some data gaps were identified, specifically regarding the field trials on oilseed rape and rotational crops. The consumer risk assessment is considered provisional, due to these data gaps on the residue trials and the missing genotoxicity data for 2-chlorobenzyl alcohol.

In the area of **environmental fate and behaviour**, a data gap was identified for information on the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for the production of drinking water. This has led to the consumer risk assessment from the consumption of drinking water not being finalised for all the representative uses.

In the area of **ecotoxicology**, the risk assessment for non-target terrestrial plants could not be finalised due to lack of data on sensitive species.

Regarding the assessment of the **endocrine disruption** (ED) properties, based on the available information, it could be concluded that clomazone does not meet the ED criteria as laid down in the points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, for human and wild mammals. The assessment of the endocrine disruption potential of clomazone on non-target organisms other than mammals through the EATS-modalities according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, could not be finalised.

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012,[1] as amended by Commission Implementing Regulation (EU) No 2018/1659,[2] (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009.[3] This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS, Denmark, and co-RMS, Germany, received an application received an application for the renewal of the approval of the active substance clomazone. The application was submitted by the two task forces, the Clomazone AIR Task Force (CATF), consisting of FMC Agricultural Solutions and ADAMA Agan Ltd. and the second clomazone task force (OAS), consisting of Oxon Italia SpA, Albaugh Europe Sàrl and Sapec Agro S.A. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Germany), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on clomazone in the RAR, which was received by EFSA on 12 February 2018 (Denmark, 2018).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, for consultation and comments on 22 November 2018. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 23 January 2019. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicants were invited to respond to the comments in column 3 of the reporting table. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS and the European Chemical Agency (ECHA) on 11 April 2019. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

In addition, following a consultation with Member States in the Pesticides Peer Review Experts' meetings PREV 13 and PREV 14 (September 2019), it was considered necessary to apply an additional clock stop of 30 months in accordance with Commission Implementing Regulation (EU) No 2018/1659, to be able to conclude whether the approval criteria for endocrine disruption in line with the scientific criteria for the determination of endocrine-disrupting properties, as laid down in Commission Regulation (EU) 2018/605,[4] are met.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November–December 2024.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation(s) for representative uses, evaluated on the basis of the representative uses of clomazone as a herbicide on

[1]Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

[2]Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3]Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4]Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine-disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

potato and oilseed rape, as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for clomazone according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2024), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting tables (11 April 2019 and 16 January 2024[5]);
- the evaluation table (16 December 2024);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Denmark, 2024) and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATION(S) FOR REPRESENTATIVE USES

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

The formulations for representative uses for the evaluation were 'FMC-Clomazone 360 CS' and 'ALB 36 CL' both capsule suspensions (CS) containing 360 g/L pure clomazone.

The information on the active substance and the formulations for representative uses, including the co-formulants in these formulations, was considered in the overall assessment during the peer review.

Specifically for FMC-Clomazone 360 CS and ALB 36 CL, the following were identified. For FMC-Clomazone 360 CS, one co-formulant component is listed as unacceptable co-formulant in Annex III of Regulation (EC) No 1107/2009,[6] present below the level set in Regulation (EU) 2021/383 paragraph (14) for acceptable unintentional impurity. Additionally, one co-formulant is an approved active substance, while one co-formulant and three co-formulant components are not approved active substances under Regulation (EC) 1107/2009. For ALB 36 CL, one co-formulant component is listed as unacceptable co-formulant in Annex III of Regulation (EC) No 1107/2009, present below the level set in Regulation (EU) 2021/383[6] paragraph (14) for acceptable unintentional impurity. Furthermore, one co-formulant is an approved active substance, while one co-formulant and two co-formulant components are not approved active substances under Regulation (EC) 1107/2009. Due to the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009, the detailed composition of the formulations cannot be reported in the conclusions. However, this information was fully available and evaluated during the peer review. A proposal for classification of the formulations according to Regulation (EC) 1272/2008[7] was provided by the applicant and assessed by the RMS (see Volumes 3 CP of the RAR).

The representative uses evaluated were broadcast direct soil spray or overall spray on potato and oilseed rape in field to control weeds (dicotyledonous and monocotyledonous) and annual grasses. Full details of the GAPs can be found in the list of end points in Appendix B.

Data were submitted to conclude that the uses of clomazone according to the representative uses proposed at EU level result in a sufficient herbicidal efficacy, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

[5]Reporting tables following consultation on the revised RAR on the assessment of the endocrine-disrupting properties made available after the clock stop applied in accordance with Commission Regulation (EU) No 2018/1659.

[6]Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and Council listing co-formulants which are not accepted for inclusion in plant protection products. OJ L 74, 4.3.2021, p. 7–26.

[7]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

CONCLUSIONS OF THE EVALUATION

General aspects

With regard to the toxicological information available for the formulations for representative uses FMC-Clomazone 360 CS (Centium 36 CS) and ALB 36 CL (Clomate), studies were conducted on acute toxicity endpoints. For the majority of **co-formulants** present in these formulations, sufficient toxicological data were available. However, for two co-formulants in FMC-Clomazone 360 CS (present in amounts well below 10%) and two co-formulants in ALB 36 CL (present in limited amount or below 10%), the peer review experts considered that the available toxicological information did not sufficiently address the genotoxicity, general toxicity, reproductive toxicity and developmental toxicity. As a result, the lack of data for these co-formulants may require further assessment. The collected information (not covering all endpoints), including the existing uses other than plant protection products, under regulated EU frameworks, did not reveal any concerns (see Section 10).[8]

The available ecotoxicity data with the formulations for representative uses were discussed at the experts' meeting[9] (see Section 5). It was noted that, based on the available acute data (see Section 5), the formulations for representative uses are not more acutely toxic than expected from the active substance.

The peer review experts also discussed the data retrieval search and the available data for the individual components. However, due to the lack of any ecotoxicological information on some components present in amounts below 10% in the two formulations, a conclusion on the safety of the formulations for representative uses could not be reached (**data gap**, see Section 10).

1 | IDENTITY, PHYSICAL/CHEMICAL/TECHNICAL PROPERTIES AND METHODS OF ANALYSIS

The following guidance documents were followed in the production of this conclusion: European Commission (2000a, 2000b, 2010).

An update of the reference specification is proposed based on batch data from industrial plant production. The proposed minimum purity of the technical material is 960 g/kg. No relevant impurities were proposed; however, toxicological assessment of some of the impurities is open (see Section 2), and as a consequence, new data such as spectral data, content of the impurities before and after the storage of the formulation and methods for analysis of the relevant impurities in the formulation might be required. The batches used in the toxicological assessment did not support the current and newly proposed updated reference specification (see Section 2). Insufficient information was available to support the compliance of the batches used in ecotoxicological studies with the proposed updated reference specification (see Section 5). FAO specification was not available for clomazone.

The main data regarding the identity of clomazone and its physical and chemical properties are given in Appendix B. A **data gap** related with encapsulation step of the formulation process of ALB 36 CL was identified (see Section 10). It is noted that during the accelerated storage stability and shelf-life studies of FMC-Clomazone 360 CS and accelerated storage stability study of ALB 36 CL the content of the total clomazone remained in the acceptable limits; however, the content of the free clomazone decreased significantly in both formulations, and an explanation on these results is missing (**data gaps**, see Section 10). Additional justification on the explosive properties of FMC-Clomazone 360 CS and ALB 36 CL and on the oxidising properties of ALB 36 CL is required (**data gaps**, see Section 10).

Adequate methods are available for the generation of data required for the risk assessment except for 1-year study in dog, 2-year study in rats and 90-day studies in rats and mice (see Section 2). Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulations. Methods for analysis of the significant impurities in the technical material are available. However, information demonstrating that the methods are sufficiently precise to analyse significant impurities at levels appropriate to the proposed specification, although provided by the Applicant, was not assessed by the RMS and not included in the RAR, therefore not considered during the peer review (**data gap**, see Section 10).

Clomazone residues in food/feed of plant origin can be monitored by DFG S19 method using LC–MS/MS with LOQs of 0.005 mg/kg in high water and high oil content matrices and with LOQs of 0.01 mg/kg in dry and high acid content matrices. QuEChERS method using LC–MS/MS can also be used for monitor of clomazone residues in all plant matrix groups with LOQs of 0.01 mg/kg. The efficiency of the extraction procedures used in both methods was not verified for all plant commodities. A **data gap** for verification of the extraction efficiency in high oil and high water content plant matrices was identified (see Section 10).[10] For the other plant matrices, a data gap for addressing extraction efficiency was not set because uses in dry and high acid matrices were not intended. Residue definition for monitoring in animal products is not proposed (see Section 3); therefore, monitoring method is not required.

[8]See expert's consultation point 2.14 in the Report of the Pesticides Peer Review Experts' Teleconference 136 (EFSA, 2024).

[9]See expert's consultation point 5.7 in the Report of the Pesticide Peer Review Experts' TC 124–139 (EFSA, 2024).

[10]Refer to data requirement 1.13 in the Evaluation Table section 1 (EFSA, 2024).

Clomazone residues in soil can be monitored with LC–MS/MS methods with the lowest LOQ of 0.5 µg/kg. Two LC–MS/MS methods were provided for analysis of clomazone in drinking and surface water with LOQs of 0.1 µg/L and 0.05 µg/L in drinking water and 0.1 µg/L and 5 µg/L in surface water. Appropriate LC-MS/MS methods exist for monitoring of clomazone residues in air with LOQs of 0.025 µg/m^3 and 0.002 µg/m^3, respectively. LC–MS/MS can be used for monitoring of clomazone residues in body fluids and tissues with LOQs of 0.01 mg/L and 0.01 mg/kg, respectively. Analytical method for biomonitoring of clomazone in body fluids and tissues was not provided by the task force OAS (**data gap**, see Section 10).

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance clomazone and its metabolites was discussed at the Pesticides Peer Review Experts' Meeting 13 (20 September 2019) and TC 136 (22 May 2024). The assessment is based on the following guidance documents: European Commission (2003, 2012), EFSA (2014b, 2017), and ECHA (2017).

Regarding the proposed updated reference specification, the assessment of the toxicological relevance of some impurities could not be finalised (**data gap**, see Section 9.1). Additionally, the analytical methods used in feed, body fluids and tissues, air and any additional matrices in support of the toxicity studies were considered fit-for-purpose for most of the relevant studies, with the exception of the 1-year study in dog, the 2-year study in rats and the 90-day studies in rats and mice; therefore, no conclusion could be drawn on the full reliability of these studies (**data gap**, see Section 9.1). Overall, the test materials used in toxicity studies are not fully representative of the current and newly proposed reference specifications for the active substance and associated impurities (**issue that could not be finalised**, see Section 9.1).

The oral **absorption** of clomazone is estimated to account for > 87% based on urinary excretion levels after oral and intravenous administration in rats. A rapid and almost complete excretion mainly via urine was observed. Clomazone is widely distributed throughout the body, with no evidence of bioaccumulation. Extensive metabolisation was observed in rat with hydroxylation and cleavage reactions identified as the main **metabolic** pathway.

In a comparative in vitro metabolism study, similar metabolic profiles were reported in the three species (human, dog and rat) and no unique human metabolites were identified.

The **residue definition** for body fluids and tissues includes clomazone.

Clomazone has moderate **acute** toxicity by the oral and inhalation routes and is not acutely toxic via dermal administration. It is neither a skin or eye irritant, nor a skin sensitiser. In reason of its UV/Vis spectrum, no phototoxicity and photomutagenicity testing is warranted for clomazone.

Short-term oral toxicity studies were provided for rats, mice and dogs. Liver was identified as the main target organ in all the tested species, showing adverse effects including increased liver weight, changes in clinical chemistry parameters (elevated cholesterol levels) and histopathological changes. The relevant short-term toxicity NOAEL of 13.3 mg/kg body weight (bw) per day was identified from the 1-year study in dog, based on increased cholesterol levels and liver weight at ≥ 67 mg/kg bw per day.

Based on the available **genotoxicity** studies, clomazone is unlikely to be genotoxic.

After **long-term exposure** in the rat and the mouse, liver was confirmed as the target organ for clomazone. The relevant NOAEL in the 2-year study in rats is 27 mg/kg bw per day, based on effects observed at 55 mg/kg bw per day including increased liver weight and hepatocytomegaly. A relevant NOAEL of 89 mg/kg bw per day is identified from the 2-year study in mouse, based on increased liver weight and larger portion of persistent thymic glands in females at 182 mg/kg bw per day.

The substance showed no treatment-related tumours in rats and mice. ECHA RAC concluded that classification for carcinogenicity is not warranted (ATP 17, delegated Regulation 2021/849[11]; ECHA, 2019).

With regard to **reproductive toxicity**, no adverse effects were observed on fertility and overall reproductive performance. Two multigenerational studies in rats are available for clomazone. In the relevant two-generation study, a parental NOAEL of 43 mg/kg bw per day is identified, based on changes in the urinary tract and liver at 154 mg/kg bw per day. No adverse effects were observed in the offspring and the reproductive in the two studies up to the highest tested doses. The relevant offspring and reproductive NOAELs are 354 mg/kg bw per day.

With regard to **developmental toxicity**, three studies in rats and two in rabbits are available. Decreased fetal body weight, increased early resorptions and increased incidence of skeletal malformations were observed in a developmental study in rats at ≥ 300 mg/kg bw per day. In the second study in rats, in which clomazone with a higher purity profile was tested, fetal toxicity and malformations (mainly consisting in increased incidence of arthrogryposis) were observed at ≥ 500 mg/kg bw per day. The developmental NOAELs for the two studies are identified at 100 and 250 mg/kg bw per day, respectively. No developmental effects were observed in the third study in a different rat strain up to the highest tested dose of 750 mg/kg bw per day. The relevant NOAEL for maternal toxicity throughout the three rat studies is 250 mg/kg bw per day, based on decreased body weight, weight gain and food intake at ≥ 500 mg/kg bw per day. In the rabbit teratogenicity studies, maternal toxicity, including decreased body weight and body weight gain, increased abortion rate and mortality,

[11]Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 188, 28.5.2021, p. 27–43.

was observed at 700 mg/kg bw per day. Developmental toxicity, including fetal mortality in the first study and malformations related to arthrogryposis in the second study, was observed at 700 mg/kg bw per day. The relevant maternal and fetal NOAELs were identified at 350 mg/kg bw per day. ECHA RAC concluded that no classification is warranted for reproductive or developmental effects (ATP 17, delegated Regulation 2021/849; ECHA, 2019).

With respect to **immunotoxicity**, all experts agreed that clomazone does not show a potential for immunotoxic effects in the standard regulatory toxicity studies.[12]

Clomazone does not show signs of **neurotoxicity** in the available in vivo data set. In addition, it does not have a neurotoxic mode of action. Overall, clomazone shows no potential for neurotoxicity and no additional neurotoxicity studies are deemed as necessary.

The **acceptable daily intake** (**ADI**) is 0.13 mg/kg bw per day, based on the NOAEL identified in the 1-year study in dog, applying a standard uncertainty factor (UF) of 100. The **acceptable operator exposure level** (**AOEL**) is 0.13 mg/kg bw per day, based on the same NOAEL and UF used for the ADI derivation and without correction for oral absorption. Due to a different rounding, these values differ from the previous peer review (European Commission, 2007), where the ADI and AOEL of 0.133 mg/kg bw per day were derived on the same basis.

The **acute reference dose** (**ARfD**) and **acute AOEL** (**AAOEL**) were established at 2.5 mg/kg bw, based on the developmental NOAEL from the most recent developmental study in rat and applying a standard UF of 100. The derivation of an ARfD and AAOEL were not considered necessary in the previous peer review (European Commission, 2007).

No studies were available to assess for the **dermal absorption** of clomazone in the formulations for representative uses ALB 36 CL and FMC-Clomazone 360 CS. Based on the EFSA guidance (EFSA, 2017), the default dermal absorption values to be used for risk assessment are 25% for the concentrate and 70% for the spray dilutions.

The **non-dietary exposure** estimates for operators using FMC-Clomazone 360 CS or ALB 36 CL are below the (A)AOEL with the use of standard workwear during mixing/loading and application (EFSA, 2014b). For the workers, the use of workwear is also sufficiently protective during the inspection/irrigation activities (EFSA, 2014b). For the residents and bystanders, the experts agreed to use the moderately volatile option for the vapour pressure in the EFSA calculator,[13] and the resulting exposure estimates were below the (A)AOEL, without specific risk reduction measures.

Toxicological studies and information have been provided for **metabolites** FMC 61569, CLZ-M01 and CLZ-M03. Genotoxic potential could be excluded for FMC 113728 and CLZ-M05 (see Table 1). The assessment of metabolites FMC 61659, CLZ-M01 and CLZ-M03 could not be finalised due to the data gaps identified in the characterisation of their genotoxic and repeated toxicity potential (**data gap** leading to **an issue that could not be finalised**, see Section 9.1).

TABLE 1 Overview table of the toxicological profile of metabolites found as residues in livestock and/or crops.

Compound (name and/or code)	Genotoxicity	General toxicity reference values (RV)	Additional source of human exposure[a]
2-chlorobenzyl alcohol (FMC 61569)	Negative in Ames test. Data gap for clastogenicity and aneugenicity	Oral LD50 > 5000 mg/kg bw Data gap for repeated exposure toxicity studies	None.
Clomazone-3-OH-propanamide (CLZ-M01, FMC 65317)	Negative in Ames test. Data gap for clastogenicity and aneugenicity	Oral LD50 > 5000 mg/kg bw; Data gap for repeated exposure toxicity studies	Groundwater
2-chlorobenzoic acid (CLZ-M03, FMC 14791)	Minor rat metabolite. No experimental data in the dossier (In silico analysis considered not sufficient – data gap)	No experimental data available in the dossier (in silico analysis considered not sufficient for general toxicity – Data gap)	None.
3′-OH clomazone (FMC 113728)	Covered by parent compound	Covered by parent compound	None.
5-OH clomazone (CLZ-M05, FMC 60217)	Covered by parent compound	Covered by parent compound	None.

[a]As groundwater metabolite, please refer to the assessment summarised under Table 3.

3 | RESIDUES

The assessment in the residue section is based on the following guidance documents: OECD (2009, 2011), European Commission (2011) and JMPR (2004, 2007).

Clomazone was discussed at the Pesticide Peer Review Meeting TC 10 (8 October 2019).

The metabolism of primary crops was investigated in root crops (potatoes, sweet potatoes), leafy crops (tobacco), pulses and oilseeds (oilseed rape (OSR), soya beans and cotton) using both benzyl and isoxazolidine labels of clomazone. The studies on potatoes and OSR were conducted at the application rates comparable to the representative good agricultural practices (GAP), while the remaining studies were overdosed (18-37N). In the potato and oilseed rape studies, the levels of the recovered radioactivity in the edible parts were very low (< 0.02 mg/kg); therefore, no further identification of residues

[12]See experts' consultation point 2.8 in the Report of the Pesticides Peer Review Experts' Meeting 13 (EFSA, 2024).

[13]See experts' consultation point 2.11 in the Report of the Pesticides Peer Review Experts' Meeting 13 (EFSA, 2024).

was possible. Clomazone was extensively metabolised, resulting in the formation of 2-chlorobenzyl alcohol in almost all the investigated crops, i.e. 15% and 48% of TRRs in sweet potatoes tuber and soya bean forage, respectively. Despite the metabolite 4, 4 dimethyl isoxazolidinone (FMC57091) was found at 55% of TRRs in OSR forage, its absolute amount was only 0.025 mg/kg and not further recovered in other parts of the crop, this is why is considered relevant. (3′, 4′ and 5′)-hydroxy clomazone was found in soya beans at 19% of TRR. 2-chlorobenzoic acid was found mainly in green part of the investigated crops in small proportions, i.e. less than 8%of TRR.

A confined rotational metabolism study in leafy (spinach), root crops (turnip) and cereals (wheat) covering all plant back intervals (PBIs) was submitted. It is noted however that, considering the PEC accumulation of residues in the soil, the submitted metabolism study in rotational crops was underdosed (approximately 0.6 N). The overall metabolic pattern is similar to the primary crops; with clomazone found at 17% of the TRRs (spinach) and the metabolite 2 chlorobenzoic acid found at 65% of the TRRs (in turnip root). Additionally, 2-chlorobenzyl alcohol and 3′-OH-clomazone were found also relevant, either in relative amounts greater than 10% of the TRRs or in absolute amounts greater than 0.01 mg/kg mainly in root crops.

Two rotational field trials in radish, leaf lettuce and barley were provided. They were analysed for clomazone residues only, all found < 0.01 mg/kg at all plant back intervals. As already observed in the metabolism study, also the rotational field study did not cover the PEC accumulation of residues in the soil. Since from the underdosed rotational crops metabolism study, the metabolites 2-chlorobenzoic acid (CLZ-M03), 2-chlorobenzyl alcohol (FMC 61569) and 3′-OH-clomazone (FMC 113728) were found in levels > 0.01 mg/kg in edible crop parts and they were not analysed in the rotational field trials, additional rotational crops trials covering the PEC accumulation in the soil are needed (**data gap** in Section 9.1), (see the PEC accumulation in Section 4). It is highlighted that the genotoxic potential of 2-chlorobenzyl alcohol and 2-chlorobenzoic acid has not been investigated (see Table 1 in Section 2). Considering the overall findings in primary and rotational crops, the residue definitions applicable to all crops are proposed **as clomazone for both risk assessment and enforcement**. This proposal is provisional pending the tox assessment of 2-chlorobenzyl alcohol and 2-chlorobenzoic acid (see Section 2) and the results on the additional required rotational field trials.

Stability of clomazone residues under frozen condition was demonstrated in several crop categories for 6 up to 40 months (see details in Appendix A). In oilseed rape, however, the available studies provided contradicting results, and therefore, the stability could be proven to be for 1 month only.

In all submitted field trials on potato and OSR, residues levels were all below 0.01 mg/kg. However, in the studies found in open literature that investigated the magnitude of residues in QSR at comparable GAP, residues were found at 0.011 and 0.017 mg/kg. Since the storage intervals in most of the OSR trials exceeded the proven storage stability period of 1 month, it is unclear whether the residue levels below 0.01 mg/kg are due to extended storage times. EFSA disagrees with the RMS' conclusion that sufficient trials in OSR were available even though these trials were stored at longer period of time and considers that additional trials covered by storage stability need to be provided (**data gap**, see Section 10). For potatoes, sufficient field trials covered by storage stability data were available.

Residue evaluation in processed commodities is not deemed necessary as all residues found in field trials were below 0.01 mg/kg. However, pending the additional trials from the primary and rotational crops, processing studies might be necessary as well.

The assessment of livestock and fish is not triggered based on the dietary burden calculation using the LOQ from the field trials. It should be noted, however, that the need of such studies may be reconsidered in the view of the data gaps identified for the field trials on OSR and rotational crops. From the draft assessment report (DAR) and its addenda prepared for the first approval (Denmark, 2005, 2007), two studies in poultry and goat were available. These studies were considered not sufficient to depict the metabolic pattern of clomazone as they were labelled only in the phenyl ring, and further identification of residues was not made.

As regards the level of residues in pollen and bee products, they were waived based on the fact that no residues following pre-emergence applications are expected to be > 0.01 mg/kg. However, pending the results from the primary and rotational crop field trials, residue trials in bees' products might also be needed.

An indicative consumer risk assessment using the EFSA Pesticide Residues Intake model (PRIMo) rev.3.1 was conducted, using the LOQs for potatoes and OSR, the ADI of 0.13 mg/kg bw per day and the ARfD of 2.5 mg/kg bw per day as inputs. The highest chronic exposure is for NL toddler and amounts to 1% of the ADI. The estimated acute exposure is below 0.06% of the ARfD for all commodities. The consumer risk assessment is considered provisional pending the toxicological assessment of 2-chlorobenzyl alcohol 2-chlorobenzoic acid and the magnitude of metabolites 2-chlorobenzoic acid, 2-chlorobenzyl alcohol and 3′-OH-clomazone in rotational crops.

The consumer risk assessment from the consumption of drinking water is not finalised considering the lack of appropriate information to address the effect of water treatment processes on the nature of residues, potentially present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water (see Sections 4 and 9.1). Regarding the confirmatory data requested for several commodities to address the data gaps identified under the Article 12 MRL review application, no data was submitted under the renewal process.

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Clomazone was discussed at the Pesticide Peer Review Meeting TC 15 (20 September 2019).

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS kinetics guidance (FOCUS, 2006). In soil laboratory incubations under aerobic conditions in the dark, clomazone exhibited low to high persistence, forming no major (> 10% applied radioactivity (AR)) metabolites. Mineralisation of the ^{14}C isoxazolidinone radiolabel to carbon dioxide accounted for 23%–58% AR after 120 days, of the ^{14}C phenyl radiolabel to carbon dioxide accounted for 23%–52% AR after 120 days, and of the ^{14}C methylene radiolabel to carbon dioxide accounted for 23%–57% AR after 67 days. The formation of unextractable residues (not extracted by acetone, acetone/water and acetonitrile/water and methanol/water) for these ^{14}C radiolabels accounted for 12%–35% AR after 120 days, 20%–43% AR after 120 days, 23%–28% AR after 67 days, respectively. In anaerobic soil incubations, clomazone degraded more slowly than under aerobic conditions forming the major metabolite CLZ-M01 (max. 25% AR), which exhibited low persistence and triggered further exposure assessment for the representative use on winter cereals only. In soil photolysis conditions, clomazone degradation was slower than in the dark control, but no metabolites were formed. Clomazone exhibited very high to medium mobility in soil. Metabolite CLZ-M01 exhibited very high soil mobility. It was concluded that the adsorption of clomazone and the metabolite CLZ-M01 was not pH dependent. In satisfactory field dissipation, studies carried out at 27 sites from Belgium, the Netherlands, Germany, United Kingdom, Spain and France (direct application to the soil), clomazone exhibited moderate to high persistence. Sample analyses were carried out for the parent clomazone. Field study DegT50 values were derived following normalisation to FOCUS reference conditions (20°C and pF2 soil moisture) following the EFSA (2014a) DegT50 guidance. The field data endpoints were combined with lab values to derive modelling endpoints for clomazone.

In laboratory incubations in dark aerobic natural sediment water systems, clomazone exhibited moderate to medium persistence, forming the major metabolites CLZ-M01 (max. 28.1% AR in water and max. 16.4% AR in sediment), CLZ-M02 (max. 11.8% AR in water), CLZ-M03 (max. 25.1% AR in water), CLZ-M04 (max. 31.7% AR in water) and CLZ-M05 (max. 14.7% AR in water). The unextractable sediment fraction (not extracted by methanol/water, acetonitrile/water) was the major sink for the phenyl and isoxazolidine radiolabels, accounting for 3.4%–44.8% AR and 10%–14.7% AR at study end (150 days), respectively. Mineralisation of these radiolabels accounted for 3.6%–47.1% AR and 51.3%–69.2% AR at the end of the study. The rate of decline of clomazone in a laboratory sterile aqueous photolysis experiment was slow relative to that occurred in the aerobic sediment water incubations. No chromatographically resolved components were formed.

The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for clomazone and its metabolites CLZ-M01, CLZ-M02, CLZ-M03, CLZ-M04, CLZ-M05 using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator) for all representative uses (ALB 36 CL and FMC-Clomazone 360 SC). For the metabolites CLZ-M01, CLZ-M02, CLZ-M03, CLZ-M04, appropriate step 3 (FOCUS, 2001) were available.

For the active substance clomazone, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available.[14] Vapour drift and deposition to adjacent untreated areas had been accounted for due to the high potential of clomazone for volatilisation indicated by its vapour pressure value (see Section 5). For FMC Clomazone 360 SC calculations using the worst-case vapour pressure for clomazone were available for all scenarios at step 3 considering dry depositions and at step 4 including dry deposition based on wind tunnel measurements and mitigation measures. However, for ALB 36 CL calculations using the worst-case vapour pressure for clomazone were available only for the worst-case R3 scenario for the use on potato at step 3 considering dry depositions and at step 4 including dry depositions and mitigation measures, (**data gaps**, see Section 10). The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 10 m being implemented for the drainage scenarios (representing a 77%–86% spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 10 m (reducing solute flux in run-off by 80% and erosion run-off of mass adsorbed to soil by 95%) being implemented for the run-off scenarios. The SWAN tool (version 4.0.1) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that while run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2000 mL/g (i.e. clomazone), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.[15] The potential for groundwater exposure from the representative uses by clomazone and metabolite CLZ-M01 above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS scenarios for potato, and six FOCUS scenarios for winter oilseed rape and three scenarios for spring oilseed rape.

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for the production of drinking water. This has led to the identification of a **data gap** and results in the **consumer risk assessment not being finalised** (see Section 9.1).

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix B of this conclusion. A key to the wording used to describe the persistence and mobility of the compounds assessed can be found in Appendix C of this conclusion.

[14]Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

[15]Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

5 | ECOTOXICOLOGY

The risk assessment was based on the following documents: European Commission (2002a), SETAC (2001), EFSA (2009, 2013) and EFSA PPR Panel (2013).

Clomazone was discussed at the Pesticides Peer Review Meeting 14 (19 September 2019), TC 136 (13–17 and 22 May 2024) and TC 139 (30–31 May and 6 June 2024).

Information to support the compliance of the batches used in ecotoxicological studies with the proposed specification was considered insufficient (**data gap**, see Section 10).

Acute and reproductive toxicity studies with **birds** and **mammals** with the active substance (a.s.) were available. A low acute and long-term risk due to dietary exposure to the active substance was concluded at the screening tier for all representative uses of clomazone. The risk assessment for plant metabolites was not addressed (**data gap**, see Section 10). A low risk was concluded for both birds and wild mammals when exposed via consumption of water contaminated with clomazone or with the soil metabolite CLZ-M01. An assessment of the risk to birds and wild mammals from secondary poisoning was not required in consideration of the relatively low lipophilicity of clomazone.

Suitable **aquatic** acute and chronic toxicity data (fish, aquatic and sediment-dwelling invertebrates, algae and macrophytes) were available with the active substance. Toxicity data for fish (acute only), invertebrates (acute only) and algae were also available for metabolites CLZ-M01, CLZ-M02, CLZ-M03, CLZ-M04, CLZ-M05, i.e. all metabolites to be considered in the aquatic risk assessment. Additional metabolite studies were available with macrophytes (for CLZ-M01 and CLZ-M02) and with sediment-dwelling invertebrates (CLZ-M01). Acute toxicity data for fish and aquatic invertebrates as well as toxicity data for algae were available with the two formulations for representative uses (ALB 36 CL and FMC Clomazone 360 SC).

A low risk to fish (acute and chronic), algae and macrophytes could be concluded for all representative uses of clomazone for the active substance and its metabolites, based on PEC calculated at the FOCUS Step 1–2. All experimental data for metabolites suggest a significantly lower toxicity compared to clomazone. Thus, for those situations where no experimental endpoint was available, the risk assessment was performed by assuming that the toxicity of the metabolite is equal to the one of clomazone. Nonetheless, the same conclusion of low risk to fish, algae and macrophytes could be achieved even when a 10-time higher toxicity was assumed.

However, the aquatic risk assessment for clomazone was driven by the effects observed in the aquatic invertebrate *Americamysis bahia*. The acute and chronic regulatory acceptable concentrations (RACs) derived from tests with this species were extremely close to one another (within a factor of 2).

Based on these RACs and on the FOCUS step 3 PECs (modified to account for dry deposition), a low risk for all scenarios was identified for the uses on spring oilseed rape. A low risk was also concluded for all but one scenario (D2, both stream and ditch) concerning the uses of clomazone on winter oilseed rape. Since drainage is the main entry route for scenario D2, the exposure could not be mitigated. A low risk for all but one scenario (R3, stream) was concluded for the uses on potato. However, a low risk could be concluded also for scenario R3 when using PEC step 4 accounting for run-off reduction by 10 m vegetative filter strip and drift reduction by 10 m no-spray buffer zone.

In light of the much higher sensitivity shown by *Americamysis bahia* compared to other tested invertebrates, the endpoints from clomazone were also used for the risk assessment of metabolites, even if acute experiment with daphnids were available for all of them. The only exception was the metabolite CLZ-M05, for which an acute study with *Americamysis bahia* was available and was thus used in the risk assessment.

The assessment based on PEC calculated at FOCUS step 1–2 allowed concluding a low risk for metabolite CLZ-M05 for all representative uses of clomazone. The same conclusion of low risk could be achieved for metabolites CLZ-M02 and CLZ-M03 when using FOCUS step 3 PECs. For metabolites CLZ-M01 and CLZ-M04, a low risk could be concluded in all cases except for the winter oilseed rape use of ALB 36 CL, for which a high risk could not be excluded for scenario D2 (stream only).

Suitable acute (contact and oral) toxicity data with honey**bees** and bumblebees were available for clomazone and also for both representative formulations (for honeybees only). Furthermore, chronic oral and 22-day larvae toxicity studies were available for clomazone. Specific assessments for accumulative effects or sublethal effects for honeybees were not available (**data gap** for sublethal effects, see Section 10). No data were available for solitary bees. The risk assessments according to European Commission (2002b) indicated a low acute risk for all representative uses of clomazone. A risk assessment based on EFSA (2013) also indicated a low risk to honey bees either at the screening step (acute oral, acute contact, larvae) or at the tier 1 (chronic oral) for all representative uses. Also, a low acute risk for bumblebees was indicated at the screening step for all representative uses. The risk to plant metabolites was not addressed (**data gap**, see Section 10).

For **non-target arthropods other than bees**, tier 1 (glass plate) with the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were available for both formulations for the representative uses. For formulation FMC-Clomazone 360 CS additional tier-1 studies (on *Poecilus cupreus* and *Aleochara bilineata*) as well as additional extended laboratory tests on four species were available. A low in-field and off-field risk was concluded for all representative uses of clomazone.

Concerning **soil macro-organisms**, valid chronic toxicity tests on earthworms were available with the active substance and with formulation ALB 36 CL, but no reliable studies were available with formulation FMC-Clomazone 360 CS (**data gap**, see Section 10). Studies on *Folsomia candida* and *Hypoaspis aculeifer* were available for the active substance and formulation FMC-Clomazone 360 CS. In addition, studies with earthworms and *Folsomia candida* were available for metabolite CLZ-M01. All data consistently indicated a low chronic risk to soil macro-organisms for all representative uses of clomazone. Low risk to **soil micro-organisms** was also concluded for clomazone and CLZ-M01 for all representative uses.

Available data and risk assessment related to **non-target terrestrial plants** were discussed at the expert's meeting.[16] The available data package included studies on vegetative vigour and seedling emergence with both formulations for the representative uses of clomazone. Additional higher tier tests were available, including field monitoring studies and a tunnel study. Especially the latter was considered in detail both from the exposure (i.e. spatiotemporal aspects of volatilisation and re-deposition) and the effect (bleaching) side, but the results were not quantitatively considered in the risk assessment, due to some uncertainties identified with the short duration of the observation. The data package based on standard OECD tests was nonetheless considered appropriate also for addressing phytotoxic effects, including bleaching. Non-crop plants (i.e. weeds) were only present in one vegetative vigour study with formulation FMC-Clomazone 360 CS. From this assay, it was clear that these species were considerably more sensitive to clomazone than any other tested plant.

The lack of data on these sensitive species for seedling emergence (applicable to both formulations for representative uses) and for vegetative vigour (applicable to formulation ALB 36 CL) was considered a **data gap** leading to an issue not finalised (see Section 9.1). The only risk assessment which could be completed was thus for the formulation FMC-Clomazone 360 CS in relation to vegetative vigour. Species sensitivity distributions were fitted to both biomass and phytotoxicity endpoints, with the former providing the lowest HC_5. The assessment based on this HC_5 and on exposure estimates that added the contribution of spray drift and solid re-deposition, allowed concluding a low risk for both uses of formulation FMC-Clomazone 360 CS. For formulation ALB 36 CL, suitable exposure estimates considering the joint contribution of drift and deposition were not available (**data gap**, see Section 9.1).

Based on the available data, a low risk was concluded for organisms involved in **biological methods** for **sewage treatment**.

6 | ENDOCRINE DISRUPTION PROPERTIES

With regard to the assessment of the endocrine disruption (ED) potential of clomazone for **humans** according to the ECHA/EFSA guidance (EFSA/ECHA, (2018), in determining whether clomazone interacts with the oestrogen, androgen and steroidogenesis (EAS) and thyroid (T)-mediated pathways, the number and type of effects induced; and the magnitude and pattern of responses observed across studies were considered. Additionally, the conditions under which effects occur were considered, in particular, whether or not endocrine-related responses occurred at dose(s) that also resulted in overt toxicity. The assessment is therefore providing a weight-of-evidence analysis of the potential interaction of clomazone with the EAS and T signalling pathways using the available evidence in the data set.

With regard to T modality, the data set was considered complete, and a pattern of T-mediated adversity was not identified.

With regard to EAS modality, the data set was considered complete, and a pattern of EAS-mediated adversity was not observed.

Therefore, based on the available and sufficient data set, it was concluded that the ED criteria are not met for the EATS modalities (Scenario 1a of the EFSA/ECHA (2018) ED Guidance).

The outcome of the assessment reported above for humans also applies to **wild mammals as non-target organisms (NTOs)**.

For non-target organisms other than mammals, an amphibian metamorphosis assay (AMA, OECD TG 231) and a fish short-term reproduction assay (FSTRA, OECD TG 229) were available to sufficiently investigate the endocrine activity through the T- and EAS-modalities, respectively.

For the T-modality, the available AMA showed major deficiencies (i.e. low performance in half of the control replicates was identified for most of the endpoints assessed), and it was judged as not reliable at the Peer-review meeting TC 136 & TC 139.[17]

Similarly, for the EAS-modalities, no effects were observed in the FSTRA; however, shortcomings were identified:

- The concentrations tested were considered inadequate for the purpose of the ED assessment (i.e. tested concentrations were too low) as these concentrations were set based on dose-related effects observed on fecundity (sensitive to but not diagnostic parameter) in the range-finding test in the absence of sign of overt toxicity.
- In addition, there is in vitro evidence suggesting a potential anti-androgenic (AA) mode of action (MoA) of clomazone and the FSTRA is not the most suitable assay to detect such potential MoA.

Therefore, when considering the weight of evidence, the uncertainties identified were considered too high to conclude on the potential ED properties of clomazone in NTOs.[18] Further testing would be needed (e.g. Rapid Androgen Disruption Activity Reporter (RADAR) assay, or another test in line with OECD GD 148) to clear off any potential concerns on the AA MoA.

Based on the available information, it could be concluded that clomazone does not meet the ED criteria as laid down in the points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU)

[16]See expert's consultation point 5.2 in the Report of the Pesticide Peer Review Experts' Meeting 14 (EFSA, 2019).

[17]See experts' consultation point 5.4 in the Report of the Peer Review Experts' meeting TC 136 and TC 139 Clomazone- Ecotoxicology (EFSA, 2024).

[18]See experts' consultation point 5.5 in the Report of the Peer Review Experts' meeting TC 136 and TC 139 Clomazone- Ecotoxicology (EFSA, 2024).

2018/605, for human and wild mammals, whereas the ED assessment cannot be finalised for NTOs other than mammals (**data gap** leading to **an issue not finalised**, see Section 9.1).

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 2–5)

TABLE 2 Soil.

Compound (name and/or code)	Ecotoxicology
Clomazone	Low risk to soil organisms
CLZ-M01	Low risk to soil organisms

TABLE 3 Groundwater.[a]

Compound (name and/or code)	>0.1 μg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
Clomazone	No	Yes	–	–	Yes
CLZ-M01	No	Not triggered	Not triggered (Assessed as a residue, see Table 1)	–	–

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
[b]FOCUS scenarios or relevant lysimeter.

TABLE 4 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Clomazone	Low risk to aquatic organisms for the majority of the representative FOCUS surface water scenarios, but high risk for scenario D2 (uses on winter oilseed rape)
CLZ-M01	Low risk to aquatic organisms for the majority of the representative FOCUS surface water scenarios, but high risk could not be excluded for scenario D2 (uses on winter oilseed rape of ALB 36 CL)
CLZ-M02	Low risk to aquatic organisms
CLZ-M03	Low risk to aquatic organisms
CLZ-M04	Low risk to aquatic organisms for the majority of the representative FOCUS surface water scenarios, but high risk could not be excluded for scenario D2 (uses on winter oilseed rape of ALB 36 CL)
CLZ-M05	Low risk to aquatic organisms

TABLE 5 Air.

Compound (name and/or code)	Toxicology
Clomazone	Rat inhalation LC50 = 4.53 mg/L (4h exposure, whole body), classified as Acute tox 4, H332 harmful if inhaled

8 | PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT BY RISK MANAGERS

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level (Table 6).

TABLE 6 Risk mitigation measures proposed for the representative uses assessed.

Representative use	FMC-clomazone 360 CS Potato 90 g/ha	FMC-clomazone 360 CS Winter oilseed rape 120 g/ha	FMC-clomazone 360 CS Spring oilseed rape 120 g/ha	ALB 36 CL Potato 108 g/ha	ALB 36 CL Winter oilseed rape 119 g/ha	ALB 36 CL Spring oilseed rape 119 g/ha
Risk to aquatic organisms	RMM equivalent to 10-m no-spray buffer zone combined with a 10-m vegetated run-off buffer for 1/6 scenarios[a]			RMM equivalent to 10-m no-spray buffer zone combined with a 10-m vegetated run-off buffer for 1/6 scenarios		

[a]R3 stream.

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[19] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

1. The lack of full representativity of the test materials used in toxicity studies in respect to the current and newly proposed reference specifications for the active substance and associated impurities, owing to:

   a. The assessment of the toxicological relevance of some impurities in the proposed updated reference specification could not be finalised.
   b. The lack of fit-for-purpose analytical methods for some relevant studies, including 1-year study in dog, the 2-year study in rats and the 90-day studies in rats and mice.

2. The risk assessment to non-target terrestrial plants could not be finalised owing to:

   a. The lack of a reliable seedling emergence study addressing the toxicity to the most sensitive weed species (relevant for all representative uses evaluated, see Section 5).
   b. The lack of a reliable vegetative vigour study addressing the toxicity to the most sensitive weed species (relevant for all representative uses of formulation ALB 36 CL, see Section 5).
   c. The lack of exposure estimates integrating the contribution of spray drift and solid re-deposition (relevant for all representative uses of formulation ALB 36 CL, see Section 5).

3. The ED assessment for non-target organisms other than mammals could not be finalised for the EATS modalities (see Section 6).
4. The consumer dietary risk assessment could not be concluded since the risk assessment residue definition for plants, primary and rotational crops is provisional only (see Section 3).

   a. Field trials in rotational crops analysed for the metabolites 2-chlorobenzoic acid, 2-chlorobenzyl alcohol and 3'-OH-clomazone covering the PEC accumulation of residues persistent in the soil (relevant for the uses in oilseed rape and potatoes, see Section 3).
   b. Data are missing to clarify the genotoxicity and repeated toxicity potential of potential of 2-chlorobenzoic alcohol (FMC 61659), clomazone-3-OH-propanamide (CLZ-M01) and 2-chlorobenzoic acid (CLZ-M03) (see Section 2).

[19]Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

5. The consumer risk assessment from the consumption of drinking water could not be finalised since satisfactory information to address the effect of water treatment processes on the nature of residues in surface water, when surface is abstracted for drinking water was not available. Probably in the first instance, a consideration of the processes of ozonation and chlorination would appear appropriate. If an argumentation is made that concentrations at the point of abstraction for drinking water purposes will be low, this argumentation should cover metabolites predicted to be in surface water, as well as the active substance. Should this consideration indicate that novel compounds might be expected to be formed from water treatment, the risk to human or animal health through the consumption of drinking water containing them should be addressed (see Sections 3 and 4).

9.2 | Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

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

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

No critical areas of concerns were identified.

9.3 | Overview of the concerns identified for each representative use considered (Table 7)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 7.)

TABLE 7 Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios.

Representative use		FMC-clomazone 360 CS Potato 90 g/ha	FMC-clomazone 360 CS Winter oilseed rape 120 g/ha	FMC-clomazone 360 CS Spring oilseed rape 120 g/ha	ALB 36 CL Potato 108 g/ha	ALB 36 CL Winter oilseed rape 119 g/ha	ALB 36 CL Spring oilseed rape 119 g/ha
Operator risk	Risk identified						
	Assessment not finalised						
Worker risk	Risk identified						
	Assessment not finalised						
Resident/ bystander risk	Risk identified						
	Assessment not finalised						
Consumer risk	Risk identified						
	Assessment not finalised	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]
Risk to wild non-target terrestrial vertebrates	Risk identified						
	Assessment not finalised						
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified						
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]

(Continues)

TABLE 7 (Continued)

Representative use		FMC-clomazone 360 CS Potato 90 g/ha	FMC-clomazone 360 CS Winter oilseed rape 120 g/ha	FMC-clomazone 360 CS Spring oilseed rape 120 g/ha	ALB 36 CL Potato 108 g/ha	ALB 36 CL Winter oilseed rape 119 g/ha	ALB 36 CL Spring oilseed rape 119 g/ha
Risk to aquatic organisms	Risk identified		X (1/6 FOCUS scenarios)			X (1/6 FOCUS scenarios)	
	Assessment not finalised						
Groundwater exposure to active substance	Legal parametric value breached						
	Assessment not finalised						
Groundwater exposure to metabolites	Legal parametric value breached[a]						
	Parametric value of 10 µg/L[b] breached						
	Assessment not finalised						

Note: The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2.

[a]When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

[b]Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

10 | LIST OF OTHER OUTSTANDING ISSUES

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- For two of the components of the formulations for representative uses FMC-Clomazone 360 CS and ALB 36 CL, the available toxicological information did not sufficiently address the genotoxicity, general toxicity, reproductive toxicity and developmental toxicity in order to allow a final conclusion on the safety assessment of these formulations; therefore, this lack of information might be considered for further assessment (to be confirmed by Member States when assessing applications for PPP authorisation; relevant for all representative uses evaluated; see Section 'General aspects').
- Insufficient information was available to conclude on the ecotoxicological safety of the formulation for representative uses (to be confirmed by Member States when assessing applications for PPP authorisation; relevant for all representative uses evaluated; see Section 'Conclusions of the evaluation' under 'General aspects').
- Additional information on the encapsulation step of the formulation process of ALB 36 CL (relevant for representative uses of formulation ALB 36 CL, see Section 1).
- Explanation on the decrease of the free clomazone during the accelerated storage stability and shelf-life studies of the FMC-Clomazone 360 CS (relevant for representative uses of formulation FMC-Clomazone 360 CS, see Section 1).
- Explanation on the decrease of the free clomazone during the accelerated storage stability study of ALB 36 CL (relevant for representative uses of formulation ALB 36 CL, see Section 1).
- Information demonstrating that the methods for the analysis of the significant impurities in the technical material are sufficiently precise to analyse significant impurities at levels appropriate to the proposed specification. Study has been provided by the applicant but a transparent assessment of the provided information by the RMS is missing in the RAR and is not peer-reviewed (relevant for all representative uses, see Section 1).
- Verification of the extraction efficiency of the monitoring methods in high oil and high water content plant matrices (relevant for all representative uses, see Section 1).
- Analytical method for biomonitoring of clomazone in body fluids and tissues provided by the task force OAS (relevant for task force OAS, see Section 1).
- Additional justification on the explosive properties of FMC-Clomazone 360 CS (relevant for representative uses of formulation FMC-Clomazone 360 CS, see Section 1).
- Additional justification on the explosive and oxidising properties of ALB 36 CL (relevant for representative uses of formulation ALB 36 CL, see Section 1).
- Additional residue trials in oilseed rape covered by storage stability data (relevant for the oilseed rape representative uses, see Section 3).

- PECsw, sed calculations using the worst-case vapour pressure for clomazone at step 3 considering dry depositions (relevant for representative uses of formulation ALB 36 CL, see Section 4).
- PECsw, sed calculations using the worst-case vapour pressure for clomazone at step 4 including dry depositions and mitigation measures (relevant for representative uses of formulation ALB 36 CL, see Section 4).
- Further information to support the compliance of the batches used in ecotoxicological studies with the proposed specification was missing (relevant for all representative uses, see Section 5).
- The dietary risk to birds, wild mammals and bees due to exposure to plant metabolites was not addressed (relevant for all representative uses, see Section 5).
- Data to address the risk to honey bees from sublethal effects were not available (relevant for all representative uses, see Section 5).
- Data addressing the chronic toxicity to earthworms for the representative formulation FMC-Clomazone 360 CS where not available (relevant for representative uses of formulation FMC-Clomazone 360 CS, see Section 5).

ABBREVIATIONS

1/*n*	slope of Freundlich isotherm
a.s.	active substance
AAOEL	acute acceptable operator exposure level
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AhR	aryl hydrocarbon receptor
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AOP	adverse outcome pathway
AP	alkaline phosphatase
AR	androgen receptor
AR	applied radioactivity
ARfD	acute reference dose
ARSTTA	Stably Transfected Human Androgen Receptor Activation Assay
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
C&L	classification and labelling
CAS	Chemical Abstracts Service
CFU	colony-forming units
ChE	cholinesterase
CHO	Chinese hamster ovary cells
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
C_{max}	concentration achieved at peak blood level
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EAS	oestrogen, androgen and steroidogenesis modalities
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median

ErC_{50}	effective concentration (growth rate)
ERO	ecological recovery option
ERSTTA	Stably Transfected Human Oestrogen Receptor-alpha Transcriptional Activation Assay
ETO	ecological threshold option
ETR	exposure toxicity ratio
ETR_{HPG}	exposure toxicity ratio for effects on honeybee hypopharygeal glands
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the United Nations
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSTRA	Fish Short-Term Reproduction Assay
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
HGPRT	hypoxanthine-guanine phosphoribosyl transferase
HPG	hypopharygeal glands
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC–MS	high-pressure liquid chromatography–mass spectrometry
HQ	hazard quotient
HR	hazard rate
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LAGDA	Larval Amphibian Growth and Development Test
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC–MS	liquid chromatography–mass spectrometry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LDD_{50}	lethal dietary dose; median
LDH	lactate dehydrogenase
LH	luteinizing hormone
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M&K	Maximisation test of Magnusson & Kligman
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mm	millimetre (also used for mean measured concentrations)
MOA	mode of action
MRL	maximum residue level
MS	mass spectrometry
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content

Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PHED	pesticide handler's exposure data
PHI	preharvest interval
PIE	potential inhalation exposure
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization

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APPENDIX A

Consideration of cut-off criteria for clomazone according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[a]
CMR	Carcinogenicity (C)	Clomazone is not classified as a carcinogen (category 1A or 1B) according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009, based on: Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process (ATP 17, delegated Regulation 2021/849), and according to ECHA RAC opinion (ECHA, 2019)
	Mutagenicity (M)	Clomazone is not classified to be a mutagen according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009, based on: Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process (ATP 17, delegated Regulation 2021/849), and according to ECHA RAC opinion (ECHA, 2019)
	Toxic for Reproduction (R)	Clomazone is not classified as toxic for reproduction (category 1A or 1B) according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009, based on: Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process (ATP 17, delegated Regulation 2021/849), and according to ECHA RAC opinion (ECHA, 2019)
Endocrine disrupting properties		Clomazone is not considered to meet the criteria for endocrine disruption for human health and wild mammals as non-target organisms according to points 3.6.5 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605. The assessment of the endocrine disruption potential of clomazone on NTOs other than mammals through the EATS-modalities according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, could not be finalised
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Clomazone is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Clomazone is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
vPvB	**Persistence** **Bioaccumulation**	Clomazone is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.

[a]Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

APPENDIX B

List of end points for the active substance and the formulation(s) for representative formulation

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2025.9206.

APPENDIX C

Wording EFSA used in section 4 of this conclusion, in relation to DT and Koc 'classes' exhibited by each compound assessed

Wording	DT_{50} normalised to 20°C for laboratory incubations[20] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT50 when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1 to < 10 days
Moderate persistence	10 to < 60 days
Medium persistence	60 to < 100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

Notes: These classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

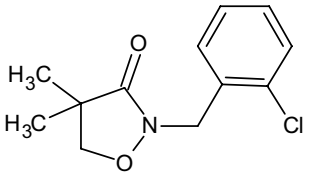
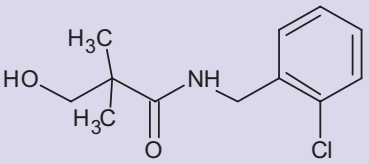
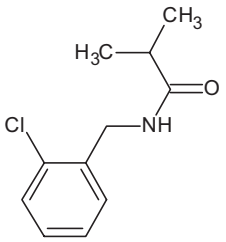
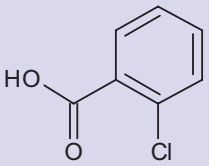
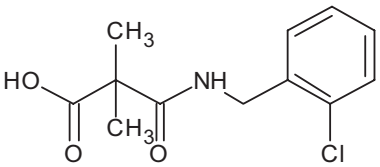
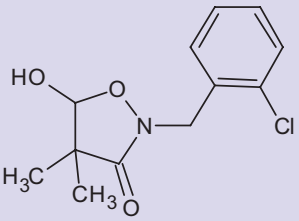
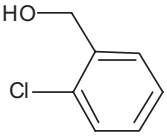
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2000
Slight mobility	2001–5000
Immobile	> 5000

Note: Based on McCall et al. (1980).

[20] For laboratory soil incubations normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

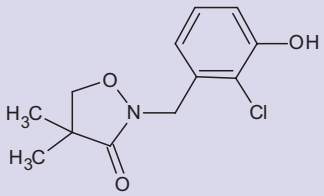
APPENDIX D

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Clomazone	2-(2-chlorobenzyl)-4,4-dimethylisoxazolidin-3-one CC1(C)CON(Cc2ccccc2Cl)C1 = O KIEDNEWSYUYDSN-UHFFFAOYSA-N	
CLZ-M01 (FMC 65317)	*N*-[(2-chlorophenyl) methyl]-3-hydroxy-2,2-dimethylpropanamide CC(C)(CO)C(=O)NCc1ccccc1Cl TWJXCDFCKPEPHD-UHFFFAOYSA-N	
CLZ-M02 (FMC 55657)	*N*-[(2-chlorophenyl)methyl]-2-methylpropanamide CC(C)C(=O)NCc1ccccc1Cl SQHPDMWKOSRTGY-UHFFFAOYSA-N	
CLZ-M03 (FMC 14791)	2-chlorobenzoic acid O=C(O)c1ccccc1Cl IKCLCGXPQILATA-UHFFFAOYSA-N	
CLZ-M04 (CADO)	3-{[(2-chlorophenyl)methyl]amino}-2,2-dimethyl-3-oxopropanoic acid CC(C)(C(O) = O)C(=O)NCc1ccccc1Cl UEGTYMQOQWMYEK-UHFFFAOYSA-N	
CLZ-M05 (FMC 60217)	2-[(2-chlorophenyl) methyl]-5-hydroxy-4,4-dimethyl-1,2-oxazolidin-3-one CC1(C)C(O)ON(Cc2ccccc2Cl)C1 = O MDZOMCCXUBFSBT-UHFFFAOYSA-N	
2-chlorobenzyl alcohol OCB-alcohol (FMC 61569)	(2-chlorophenyl)methanol OCc1ccccc1Cl MBYQPPXEXWRMQC-UHFFFAOYSA-N	

(Continues)

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
3'-OH-Clomazone (FMC 113728)	2-[(2-chloro-3-hydroxyphenyl) methyl]-4,4-dimethyl-1,2-oxazolidin-3-one CC1(C)CON(Cc2cccc(O)c2Cl)C1 = O XMGWYYDBYIQXLC-UHFFFAOYSA-N	

[a]The name in bold is the name used in the conclusion.

[b]ACD/Name 2023.2.4 ACD/Labs 2023.2.4 (File Version N25E41, Build 137185, 31 January 2024).

[c]ACD/ChemSketch 2023.2.4 ACD/Labs 2023.2.4 (File Version C45H41, Build 137010, 18 January 2024).