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CONCLUSION ON PESTICIDES PEER REVIEW

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

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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 EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Ireland, and co-rapporteur Member State, France, for the pesticide active substance maltodextrin and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 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 2020/103. The conclusions were reached on the basis of the evaluation of the representative uses of maltodextrin as an insecticide and acaricide on all edible and non-edible crops. 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 reported where identified.

KEYWORDS

acaricide, insecticide, maltodextrin, peer review, pesticide, risk assessment

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SUMMARY

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2020/103, 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, as amended by Commission Implementing Regulation (EU) No 2018/155. Maltodextrin is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Ireland, and co-rapporteur Member State (co-RMS), France, received an application from Certis Belchim B.V. for the renewal of approval of the active substance maltodextrin.

An initial evaluation of the dossier on maltodextrin 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 2020/103.

The following overall conclusions were derived by the peer review.

The uses of maltodextrin according to the representative uses as an insecticide and acaricide via foliar spray application on edible and non-edible crops in the field and in greenhouses (permanent and non-permanent structures, including walk-in tunnels), as proposed at EU level, result in a sufficient insecticidal and acaricidal efficacy against the target pests.

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

Considering that maltodextrin is rapidly metabolised with metabolites being a standard energy source (e.g. glucose), and considering its uses as a food ingredient, in cosmetics and in medicinal products, maltodextrin is of low toxicological concern and no risks to human health are expected from its use as an active substance in a plant protection product. Therefore, data waivers for toxicological studies with maltodextrin are supported, toxicological reference values are not allocated and no quantitative risk assessment for operators, workers and bystanders, and residents are considered necessary.

In the area of **residues**, issues that could not be finalised or critical areas of concern were not identified for the active substance. Considering the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion of maltodextrin in Annex IV of Regulation (EC) No 396/2005, criteria III and IV (toxicological reference values unnecessary, exposure linked to the use as plant protection product is negligible compared to natural exposure) are met.

In the area of **fate and behaviour into the environment**, no issues that could not be finalised or critical areas of concern were identified for the active substance. The parametric legal drinking water limit of 0.1 µg/L may be exceeded in the majority of scenarios when the most critical GAP is considered. However, exceedance is obtained only for a minority or none of the scenarios for crops representing less critical GAPs.

In the area of **ecotoxicology**, several data gaps leading to an assessment not finalised were identified:

- for aquatic organisms for uses represented by the scenario winter cereals (4/9 FOCUS scenarios for autumn applications) in non-permanent greenhouses (for uses at 20 × 44.9 kg a.s./ha);
- for honey bees for all representative uses (other than those in permanent greenhouses) with single applications above 7.5 kg a.s./ha;
- for non-target arthropods for all representative uses of 20 × 44.9 kg a.s./ha (other than those in permanent greenhouses);
- for soil macroorganisms, other than earthworms, for all representative uses, other than those in permanent greenhouses.

According to 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, it can be concluded that maltodextrin is unlikely to be an endocrine disruptor.

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012,[1] as amended by Commission Implementing Regulation (EU) No 2020/103[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).

In accordance with Article 1 of the Regulation, the RMS, Ireland, and co-RMS, France, received an application from Certis Belchim B.V. for the renewal of approval of the active substance maltodextrin. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (France), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on maltodextrin in the RAR, which was received by EFSA on 11 November 2022 (Ireland, 2022).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Certis Belchim B.V., for consultation and comments on 8 June 2023. 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 7 August 2023. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. In addition, the applicant was invited to respond to the comments received. The comments and the applicant's response were evaluated by the RMS in column 3 of the reporting table.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a teleconference between EFSA and the RMS on 5 October 2023. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

The outcome of the teleconference, 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 from December 2024 to February 2025.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation for representative uses, evaluated in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal on the basis of the representative uses of maltodextrin as an insecticide and acaricide on all edible and non-edible crops, as proposed by the applicant. 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 for representative uses is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for maltodextrin 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, 2025), 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 table (12 October 2023);

[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, pp. 26–32.

[2]Commission Implementing Regulation (EU) No 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances. OJ L 19, 24.1.2020, pp. 1–4.

[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, pp. 1–50.

- the evaluation table (7 February 2025);
- 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 (Ireland, 2025), and the peer review report, both documents are considered 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

The active substance is considered by the International Organization for Standardization (ISO) not to require a common name. Maltodextrin is used in the literature. Maltodextrin is glucose polymer with different chain lengths in which monomeric units are connected with α-1,4 glycosidic bonds.

The representative formulated product for the evaluation was 'Eradicoat', a soluble concentrate (SL) containing 598 g/L maltodextrin.

The representative uses evaluated were foliar spray applications in the field and in permanent greenhouses and non-permanent structures, such as walk-in tunnels, on edible and non-edible crops for the control of spider mite, whitefly and aphid. Full details of the GAPs can be found in the list of end points in Appendix B.

The information on the active substance and the formulation for representative uses, including the co-formulants in this formulation, was considered in the overall assessment during the peer review. None of the co-formulants are unacceptable co-formulants listed in Annex III of Regulation (EC) No 1107/2009; however,[4] one co-formulant is a currently approved active substance under Regulation (EC) 1107/2009.[5]

Details on the composition of the formulations cannot be reported in conclusions because of the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009; however, this information was fully available and evaluated during the peer review. A proposal for the classification of the formulation according to Regulation (EC) 1272/2008 was provided by the applicant and assessed by the RMS (please see Volumes 3 CP of the RAR).

Data were submitted to conclude that the use of maltodextrin according to the representative uses proposed at EU level results in a sufficient insecticidal and acaricidal efficacy against the target organisms, following the guidance document SANCO/2012/11251-rev. 5 (European Commission, 2019).

CONCLUSIONS OF THE EVALUATION

General aspects

With regard to the mammalian toxicity information available for the formulation for representative uses 'Eradicoat', studies on acute toxicity endpoints were not performed. Instead, according to Commission Regulation (EU) No. 284/2013,[6] classification for acute toxicity is based on the calculation of the individual constituents, following the additivity approach outlined in CLP Regulation (EC) No. 1272/2008.[7] With regard to the co-formulants contained in the formulation for representative uses 'Eradicoat', toxicological data were not available for all the components and were not assessed.[8] Therefore, genotoxicity and repeated-dose toxicity information over the short and long term might be considered to reach a final conclusion on the safety assessment of 'Eradicoat' (see Section 10).

The availability of ecotoxicity data with the formulation for representative uses was discussed at the experts' meeting, and a data gap was identified (refer to Section 5).[9] Furthermore, the experts also discussed the data retrieval search and the available data for the individual components. No concerns were identified.

[4]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, pp. 7–26.

[5]Please see Regulation (EC) No 1107/2009 for acceptability criteria for co-formulants and Section 2.13.6 of the Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods (EFSA, 2019).

[6]Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, pp. 85–152.

[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, pp. 1–1355.

[8]Refer to experts' consultation points 2.3 in the report of the Pesticide Peer Review TC 141 and TC 142 (EFSA, 2025).

[9]Refer to experts' consultation points 1.1 and 5.2 in the report of the Pesticide Peer Review TC 146 (EFSA, 2025).

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).

The proposed specification for maltodextrin is based on batch data from industrial production. The proposed minimum purity of the technical material is 853 g/kg maltodextrin with chain lengths of 3–20 monomer units and dextrose equivalent (DE) value 18–20. Based on data submitted for the renewal procedure, it is proposed that the reference specification is updated to better reflect the definition of maltodextrin. The proposed reference specification is considered acceptable from a toxicological point of view (see Section 2) and supported by the batches used in the ecotoxicity study (See Section 5). There is no FAO specification available for maltodextrin.

The main data regarding the identity of maltodextrin and its physical and chemical properties are given in Appendix B. Information on the purity of the starting materials used for the manufacturing of the active substance is missing (**data gap**, see Section 10).

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and representative formulation.

Analytical methods for the determination of residues in food and feed of plant and animal origin, body fluids and tissues, and in environmental compartments are not required since residue definitions for monitoring are not proposed.

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance maltodextrin was discussed at the Pesticide Peer Review Teleconference (TC) 142 (25 June to 3 July 2024).

Regarding the proposed reference specification, considered acceptable from a toxicological point of view, no toxicologically relevant impurities are identified.

Considering that maltodextrin is rapidly metabolised with metabolites being a standard energy source (e.g. glucose), and considering its uses as a food ingredient, in cosmetics and in medicinal products, maltodextrin is of low toxicological concern, and no risks to human health are expected from its use as an active substance in a plant protection product. In addition, no evidence for acute toxicity was observed in studies with a 50% w/w aqueous maltodextrin solution.

Therefore, data waivers for toxicological studies with maltodextrin are supported; toxicological reference values are not allocated; and no quantitative risk assessment for operators, workers and bystanders, and residents are considered necessary.[10]

3 | RESIDUES

Experimental data on the residue behaviour of maltodextrin and residue levels upon application as a pesticide on crops were not provided. Waiving such data is acceptable in view of the nature of maltodextrin and the low toxicological concern of this substance (see Section 2). Moreover, the applicant provided estimates for different scenarios on the expected residue levels of maltodextrin on crops when used according to the critical GAP, and the corresponding estimates of consumer dietary intakes. These conservative estimates indicate that the dietary exposure of consumers from the use of maltodextrin in crop protection is very likely to be much lower than the dietary exposure from other sources, in particular from industrially processed foods to which maltodextrin is added for its functional properties and from foods for special nutritional needs such as infant formula and sports nutrition products.

The five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for inclusion in Annex IV of Regulation (EC) No 396/2005, i.e.: approval as a basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), exposure linked to the use as a plant protection product is negligible compared to natural exposure (criterion IV) and consumer exposure is not expected considering the mode of application for the intended uses (criterion V) was assessed. Three criteria (I, II, V) are not met, while two criteria (III and IV) are met.

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Aspects of the fate and behaviour into the environments were discussed at the Pesticide Peer Review Teleconference (TC) 144 (24–26 June 2024).

[10]Refer to experts' consultation point 2.2 in the report of the Pesticides Peer Review TC 142 (EFSA, 2025).

Publicly available scientific literature shows that microbial degradation is the major route of transformation of polysaccharides such as maltodextrin in the environment. Maltodextrin is cleaved by glycoside hydrolase enzymes into simple sugars (glucose), which are natural energy sources for living organisms and considered of no toxicological concern. Guideline studies on the route and rate of degradation of maltodextrin in the environment have not been submitted. Instead, a study investigating the mineralisation in soil was provided. The study is not considered fully reliable, but sufficiently informative for the purpose of this assessment, and no further data is needed.

Considering the high application rate, some effects on the environment cannot be excluded, and a risk assessment has been performed based on realistic worst-case assumptions. The use of BIOWIN3 quantitative structure–activity relationship (QSAR), proposed by the applicant to derive worst-case modelling input parameters, was deemed not acceptable. Taking into account the results of the soil mineralisation study, as supportive information, it was agreed to assume a conservative DT_{50} of 5 days for the environmental risk assessment.[11]

QSAR K_{oc}Win (v2.00), within EPIWEB/EPI Suite 4.1, was used to estimate the mobility of maltodextrin in soil. The K_{oc} value proposed by the RMS (K_{oc} of 93.6 mL/g, with 1/n of 1) was considered adequate by the peer review for groundwater and surface water modelling in this case.

There is no data regarding the degradation of maltodextrin in the surface water compartment. However, maltodextrin is anticipated to be readily biodegradable based on the fact that starch is classified as readily biodegradable. The default value of 15 days for DT_{50} water as reported in the ECHA guidance for readily biodegradable substances with the associated reference temperature of 12°C was selected for the surface water exposure assessment (ECHA, 2016). The majority of experts agreed to normalise this value to 20°C and to use a DT_{50} of 7.1 days at 20°C in surface water modelling.[11] As ecotoxicology data for the sediment compartment were not required, PEC sediment calculations were considered unnecessary. However, to run the surface water models (e.g. FOCUS STEP 3), a sediment DT_{50} needs to be assumed. Therefore, the FOCUS default DT_{50} value of 1000 days for the sediment compartment was used to run the models. However, the resulting sediment PECs are not to be used in the risk assessment and so have not been reported in Appendix B.

PEC (predicted environmental concentration) values in soil for maltodextrin were provided considering the most critical GAP (5 × 22.4 kg a.s/ha/season for field uses and 20 × 44.9 kg a.s./ha/season for non-permanent protected crops) and the less critical one (1 × 3 kg a.s./ha) with 0% crop interception. As maltodextrin is rapidly degraded (DT_{90} < 1 year in soil) PEC in soil values do not need to be calculated for uses under permanent protected structures.

Since the application is not for specified individual crops but is intended to cover uses on all edible and non-edible crops, a limited number of crops were selected for modelling to cover representative situations for all possible crops.

Predicted environmental concentration (PEC) in surface water were calculated with the peer review agreed input parameters for the most critical and less critical GAPs, both for field and greenhouse (permanent) uses.[11] Calculations were performed up to FOCUS Step 4 for the most critical situation (highest application rate, winter cereals, autumn application) in order to consider the effect of a 20-m drift buffer which was combined with a 20-m vegetative buffer strip to reduce inputs to surface water in the FOCUS run-off scenarios.

Results of FOCUS groundwater modelling showed that the parametric legal drinking water limit of 0.1 µg/L may be exceeded (even largely exceeded) in the majority of scenarios when the most critical GAP is used on crops represented by the simulations performed for winter cereals. However, exceedance is obtained only for a minority or none of the scenarios for crops represented by the simulations performed for apples, cabbage, tomatoes and strawberries. It is acknowledged that maltodextrin used as a plant protection product has no pesticidal activity once in the soil and water column; however, the regulatory legal limits established by Directive (EU) 2020/2184[12] are applicable since maltodextrin is an organic compound and the renewal of its approval as an insecticide or acaricide at EU level has been requested.

The PECs in soil, surface water and groundwater covering the representative uses assessed are available in Appendix B of this conclusion.

5 | ECOTOXICOLOGY

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

Aspects of the ecotoxicological risk assessment were discussed at the Pesticide Peer Review Teleconference (TC) 146 (4–12 July 2024). The batch used in the ecotoxicity study performed with maltodextrin was demonstrated to be sufficiently comparable to the existing and updated reference specifications.

The representative uses of maltodextrin include uses in permanent greenhouses and non-permanent structures (e.g. walk-in tunnels). The use in permanent greenhouses poses a low risk to non-target organisms, other than those in surface water, based on limited exposure (see paragraph on aquatic organisms).

No toxicity data were available for **birds**, and only acute toxicity data with maltodextrin were available for wild **mammals**. Nevertheless, considering the nature of maltodextrin and that it, or closely related substances, will be in the diet of

[11]Refer to expert's consultation point 4.1 in the report of Pesticides Peer Review TC 144 (EFSA, 2025).

[12]Directive (EU) 2020/2184 of the Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. OJ L 435, 23.12.2020, pp. 1–62.

birds and wild mammals, a low acute and long-term risk was concluded. This conclusion is in line to the considerations for waiving the assessment of endocrine properties (Section 6) and the toxicology assessment (Section 2).

An acute toxicity study with maltodextrin and **aquatic invertebrates** was available. However, no chronic toxicity data were available. No data for fish (acute and chronic) nor algae were available. Furthermore, no toxicity data with the formulation for representative uses was available. The aquatic risk assessment was discussed at the experts' meeting where it was agreed that, considering the nature and composition of the substance, no toxicity data for fish and algae were needed.[13] The experts agreed that acute toxicity data with the formulation for representative uses for aquatic invertebrates was needed (**data gap**, see Section 10) and, once such data were available, the need for a chronic toxicity study with aquatic invertebrates and sediment-dwelling organisms should be further considered. The experts agreed that toxicity data with the formulation for representative uses were not required for fish and algae.[13] A quantitative acute risk assessment for aquatic invertebrates was performed and the outcome is summarised in Table 1. Since the assessment was based on an unbounded toxicity value and a conservative exposure assessment, where a low risk was not demonstrated, a **data gap** leading to an issue not finalised was identified (see Section 9.1).

Since the representative uses assessed was for all edible and non-edible crops in the field (1–5 applications of between 3.0 and 22.4 kg a.s./ha) and greenhouses (non-permanent structures (e.g. walk in tunnels) and permanent) (1–20 applications of between 3.0 and 44.9 kg a.s./ha), the exposure assessment followed a risk envelope approach with selected scenarios (Table 1).

TABLE 1 Outcome of the acute risk assessment for aquatic invertebrates for maltodextrin.

Representative use		FOCUS step 2	FOCUS step 3	FOCUS step 4
Pome fruits, early applications	5 × 22.4 kg a.s./ha	Low risk	–	–
Pome fruits, late applications	5 × 22.4 kg a.s./ha	Low risk	–	–
Winter cereals/leafy vegetables, protected crops in non-permanent structures, summer applications	20 × 44.9 kg a.s./ha	Low risk	–	–
Winter cereals, protected crops in non-permanent structures, autumn application	20 × 44.9 kg a.s./ha	High risk not excluded	High risk could not be excluded in 5/9 scenarios (D1, D2, D6, R1 and R3) Low risk was indicated in 4/9 scenarios (D3, D4, D5 and R4)	High risk could not be excluded in 4/9 scenarios (D1, D2, D6 and R3) Low risk was indicated in 1 scenario (R1) with a 20-m no spray buffer zone and 20-m vegetative filter strips as mitigation measure
Leafy vegetables, protected crops in non-permanent structures	20 × 44.9 kg a.s./ha	High risk not excluded	High risk could not be excluded in 2/7 scenarios (R3 and R4) Low risk was indicated in 5/7 scenarios (D3, D4, D6, R1, R2)	Low risk was indicated in 2 scenario (R3 and R4) with a 20-m no spray buffer zone and 20-m vegetative filter strips as mitigation measure
All crops, protected crops in permanent structures	20 × 44.9 kg a.s./ha	Low risk	–	–

Acute contact and oral toxicity studies with the formulation for representative uses were available for **honey bees**. Chronic toxicity data with honey bee larvae were available for formulation other than the one for representative uses. The study was discussed at the experts meeting where it was agreed that, with the information available, it was not demonstrated that the formulation was sufficiently comparable.[14] Moreover, a semi-field study with honey bees was available where the formulation for representative uses applied to flowering *Phacelia tanacetifolia*. The risk assessment for honey bees was discussed at the experts meeting.[14] An acute risk assessment for honey bees was presented in accordance with the EFSA guidance document (EFSA, 2013b). A risk assessment in accordance with European Commission (2002) was not presented, but a similar outcome to the acute assessment according to EFSA (2013b) would be expected. However, owing to the relatively high application rate in the representative uses, the risk assessment was not sufficient to exclude a high acute oral and contact toxicity to honey bees. Moreover, a concern was raised regarding whether the standard assessment was sufficiently protective since maltodextrin has a physical mode of action. Therefore, the experts discussed a weight-of-evidence assessment for honey bees using the information from the available semi-field study together with considerations of the nature and persistence of the substance.[10] Overall, the experts agreed that a low risk to honey bees could be concluded for the representative uses of 20 applications of 7.5 kg a.s./ha to attractive and non-attractive crops. For higher application rates to attractive crops, there was insufficient data available to demonstrate a low risk to honey bees (**data**

[13]Refer to experts' consultation point 5.2 in the report of the Pesticide Peer Review TC 146 (EFSA, 2025).

[14]Refer to experts' consultation point 5.3 in the report of the Pesticide Peer Review TC 146 (EFSA, 2025).

gap leading to an assessment not finalised, see Section 9.1). For higher applications to crops which are not attractive to honey bees, the experts noted that exposure would still occur through residues on weeds, plants in the field margin and adjacent crops. The experts agreed that a quantitative risk assessment could be performed to check which of the representative uses led to less exposure than 7.5 kg a.s./ha (i.e. the application rate applied in the available semi-field study). However, as this was not available, the experts agreed that a low risk to honey bees could not be concluded for application rates above 7.5 kg a.s./ha even for crops which are not attractive to honey bees[10] (**data gap** leading to an assessment not finalised, see Section 9.1).

Toxicity data were available with the two standard **non-target arthropod** test species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*). The risk assessment for non-target arthropods was discussed at the experts meeting where the experts noted that there was an effect on reproduction in the available study with *T. pyri*.[15] Furthermore, the experts agreed that there is some uncertainty whether the standard risk assessment methodology is suitable considering the physical mode of action of maltodextrin. Nevertheless, based on the available tier 1 risk assessment, a low risk to in-field and off-field non-target arthropods was concluded for representative uses of up to five applications of 22.4 kg a.s./ha. However, for the representative use of 20 applications of 44.9 kg a.s./ha, a low in-field risk was not demonstrated (**data gap** and assessment not finalised, see Section 9.1).

No toxicity data were available for **earthworms, other soil macroorganisms** or **soil microorganisms**. Instead, the risk assessment was based on qualitative arguments which were discussed at the experts' meeting.[16] For earthworms and soil microorganisms, the experts agreed that a low risk could be concluded given the nature of the substance and the relatively low persistence in soil. However, the experts considered that a quantitative risk assessment for soil macroorganisms is needed considering that maltodextrin is an insecticide with a physical mode of action (**data gap** and assessment not finalised, see Section 9.1).

No toxicity data were available for **non-target terrestrial plants**. Considering the nature and composition of maltodextrin, a low risk to non-target plants was concluded for all representative uses. A low risk to biological methods for sewage treatment was also concluded.

6 | ENDOCRINE DISRUPTION PROPERTIES

The endocrine disruption properties of maltodextrin were discussed at the Pesticides Peer Review Joint Mammalian Toxicology-Ecotoxicology Experts' Teleconference (TC) 141 (24–25 June 2024).

With regard to the assessment of the endocrine disruption potential of maltodextrin **for humans and non-target organisms**, although no studies were available to sufficiently investigate the endocrine activity/adversity of maltodextrin in line with the ECHA/EFSA ED Guidance (2018), this was not considered scientifically necessary, and a waiver for a full ED assessment was proposed and discussed among the experts.[17] Overall, although some uncertainties were identified based on the paucity of available information, a waiver was accepted when considering the following:

- The nature and composition of the active substance, i.e. carbohydrates,
- The physical mode of action (MoA) of the active substance, i.e. contact (adhesion and blocking of insect spiracles),
- The available information on the (eco)toxicological profile of the active substance.

According to 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, it can be concluded that maltodextrin is unlikely to be an endocrine disruptor.

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
Maltodextrin	**Data gap** for soil macroorganisms, other than earthworms[a]

[a]Relevant for all uses other than those in permanent greenhouses.

[15]Refer to experts' consultation point 5.4 in the report of the Pesticide Peer Review TC 146 (EFSA, 2025).

[16]Refer to experts' consultation points 5.5 and 5.6 in the report of the Pesticide Peer Review TC 146 (EFSA, 2025).

[17]Refer to experts' consultation points 2.1 and 5.1 in the report of the Pesticide Peer Review TC 141 (EFSA, 2025).

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
Maltodextrin	Yes (majority of scenarios with highest application rate in the uses on crops represented by winter cereals) Max 16.95 μg/L (winter cereals, protected crops,[c] Porto, PELMO 5.5.3)	Yes	–	–	Yes

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).

[b]FOCUS scenarios or relevant lysimeter. Ranges indicated for FOCUS scenarios include the results from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014) guidance.

[c]Winter cereals are unlikely to be a protected crop. This crop was selected by the applicant as a worst-case surrogate for modelling purposes.

TABLE 4 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Maltodextrin	Low risk to aquatic organisms for the majority of scenarios[a]

[a]High risk could not be excluded for 4/9 scenarios (D1, D2, D6 and R3) for uses represented by the exposure assessment performed for winter cereals (autumn application), protected crops in non-permanent structures (20×44.9 kg a.s./ha).

TABLE 5 Air.

Compound (name and/or code)	Toxicology
Maltodextrin (default)	–

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 (Table 6). These measures are 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 and 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 Risk mitigation measures proposed for the representative uses assessed.

	Winter cereals, protected crops in non-permanent structures, autumn application	Leafy vegetables, protected crops in non-permanent structures
Representative use	**Foliar spray 20×44.9 kg a.s./ha**	**Foliar spray 20×44.9 kg a.s./ha**
Risk to aquatic organisms	RMM equivalent to 20-m no-spray buffer zone, for run-off situations combined with a 20 m vegetated buffer for 1/9 scenario[a]	RMM equivalent to 20-m no-spray buffer zone, for run-off situations combined with a 20-m vegetated buffer for 2/7 scenarios[b]

[a]R1 scenario.

[b]R3 and R4 scenarios.

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[18] and if the issue is of such

[18]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, pp. 127–175.

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. For the representative uses represented by the scenario winter cereals (autumn applications) in non-permanent protected structures (20×44.9 kg a.s./ha), the aquatic risk assessment for 4/9 FOCUS scenarios could not be finalised.

    a. Further information is needed to perform an acute risk assessment for aquatic organisms in 4/9 FOCUS scenarios for autumn applications in winter cereals in non-permanent protected structures (D1, D2, D6 and R3).

2. For all representative uses with single applications above 7.5 kg a.s./ha other than those in permanent protected structures (greenhouses), the risk assessment for honey bees could not be finalised with the available information.

    a. Further information is needed to demonstrate a low risk to honey bees for single applications above 7.5 kg a.s./ha.

3. For all representative uses of 20×44.9 kg a.s./ha other than those in permanent protected structures (greenhouses), the risk assessment for non-target arthropods could not be finalised with the available information.

    a. Further data are needed to demonstrate a low risk to non-target arthropods for the representative use of 20×44.9 kg a.s./ha.

4. For all representative uses, other than those in permanent protected structures (greenhouses), the risk to soil macroorganisms other than earthworms could not be finalised with the available information.

    a. Further data are needed to perform a risk assessment for soil macroorganisms other than earthworms (relevant for all representative uses other than those in permanent greenhouses).

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 a 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 regarding the hazard cut-off criteria outlined in Appendix A.

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 concern 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		All edible crops, all non-edible crops Field uses	All edible crops, all non-edible crops Protected structures other than permanent greenhouses	All edible crops, all non-edible crops Permanent greenhouses
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			
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[2,4,a,b]	X[2,3,4,a,b,c]	
Risk to aquatic organisms	Risk identified			
	Assessment not finalised		4/9 FOCUS scenarios[1,d]	
Groundwater exposure to active substance	Legal parametric value breached	X[e] 4/9 FOCUS scenarios for crops represented by winter cereals 1/4 FOCUS scenarios for crops represented by strawberries	X[f] 8/9 scenarios for crops represented by winter cereals 3/9 scenarios for crops represented by apples 3/7 scenarios for crops represented by cabbage 1/4 scenarios for crops represented by strawberries	X[f] 8/9 scenarios for crops represented by winter cereals 3/9 scenarios for crops represented by apples 3/7 scenarios for crops represented by cabbage 1/4 scenarios for crops represented by strawberries
	Assessment not finalised			
Groundwater exposure to metabolites	Legal parametric value breached			
	Parametric value of 10 µg/L breached			
	Assessment not finalised			

Note: The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–7 for further information.

[a]For soil macroorganisms other than earthworms for all representative uses.

[b]For honey bees for single applications above 7.5 kg a.s./ha.

[c]For non-target arthropods for applications of 20 × 44.9 kg a.s./ha.

[d]For uses represented by the exposure assessment performed for winter cereals (autumn application), protected crops in non-permanent structures (20 × 44.9 kg a.s./ha).

[e]For representative uses with an application rate of 5 × 22.4 kg a.s./ha.

[f]For representative uses with an application rate of 20 × 44.9 kg a.s./ha.

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:

- Not for all the components of the formulation for representative uses 'Eradicoat', genotoxicity and repeated-dose toxicity information over the short and long term was available; therefore, in order to allow a final conclusion on the safety assessment of 'Eradicoat', genotoxicity and repeated-dose toxicity data for the components (short and long term) might

be considered for further assessment to be confirmed by Member States when assessing applications for PPP authorisation (relevant for the representative uses evaluated; see Section 'General aspects').
- Information on the purity of the starting materials used for manufacturing the active substance is missing.
- Acute toxicity data for aquatic invertebrates with the formulation for representative uses, 'Eradicot', are needed. Pending on the results of the study, chronic toxicity data with aquatic invertebrates and sediment-dwelling organisms may be needed.

ABBREVIATIONS

1/*n*	slope of Freundlich isotherm
a.s.	active substance
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MOA	mode of action
QSAR	quantitative structure–activity relationship
RAR	Renewal Assessment Report

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REFERENCES

ECHA (European Chemicals Agency). (2016). *Guidance on information requirements and Chemical Safety Assessment*. Chapter R.16: Environmental exposure assessment. Version 3.0. February 2016. Reference: ECHA-16-G-03-EN; ISBN: 978–92–9247-775-2. https://echa.europa.eu/documents/10162/17224/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af?t=1455553705739

ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson, N., Arena, M., Auteri, D., Barmaz, S., Grignard, E., Kienzler, A., Lepper, P., Lostia, A. M., Munn, S., Parra Morte, J. M., Pellizzato, F., Tarazona, J., Terron, A., & Van der Linden, S. (2018). Guidance for the identification of endocrine disruptors in the context of regulations (EU) No 528/2012 and (EC) No 1107/2009. *EFSA Journal*, *16*(6), 5311. https://doi.org/10.2903/j.efsa.2018.5311.ECHA-18-G-01-EN

EFSA (European Food Safety Authority). (2009). Guidance on risk assessment for birds and mammals on request from EFSA. *EFSA Journal*, *7*(12), 1438. https://doi.org/10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority). (2013a). Conclusion on the peer review of the pesticide risk assessment of the active substance maltodextrin. *EFSA Journal*, *11*(1), 3007. https://doi.org/10.2903/j.efsa.2013.3007

EFSA (European Food Safety Authority). (2013b). EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). *EFSA Journal*, *11*(7), 3295. https://doi.org/10.2903/j.efsa.2013.3295

EFSA (European Food Safety Authority). (2019). Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. EFSA supporting publication 2019:EN-1623. 32 pp https://doi.org/10.2903/sp.efsa.2019.EN-1623

EFSA (European Food Safety Authority). (2025). *Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance maltodextrin*. https://open.efsa.europa.eu/question/EFSA-Q-2021-00018

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues). (2013). Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. *EFSA Journal*, *11*(7), 3290. https://doi.org/10.2903/j.efsa.2013.3290

European Commission. (2015). Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No. 396/2005. SANCO/11188/2013-rev. 2, 14 September 2015.

European Commission. (2019). Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No. 844/2012 (the Renewal Regulation). SANCO/2012/11251-rev. 5, 22 March 2019.

European Commission. (2000a). *Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for annex II (part A, section 4) and annex III (part A, section 5) of directive 91/414*. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission. (2000b). *Technical material and preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for annex II (part A, section 4) and annex III (part A, section 5) of directive 91/414*. SANCO/3030/99-rev. 4, 11 July 2000.

European Commission. (2002). *Guidance document on terrestrial ecotoxicology under council directive 91/414/EEC*. SANCO/10329/2002-rev. 2 final. 17 October 2002.

European Commission. (2014). *Assessing potential for movement of active substances and their metabolites to ground water in the EU*. Report of the FOCUS Workgroup. EC document reference SANCO/13144/2010-v. 3, 613 pp., as outlined in generic guidance for tier 1 FOCUS groundwater assessment, v. 2.2, May 2014.

Ireland. (2022). *Renewal Assessment Report (RAR) on the active substance maltodextrin prepared by the rapporteur Member State Ireland, in the framework of Commission Implementing Regulation (EU) No 844/2012, November 2022*. www.efsa.europa.eu

Ireland. (2025). *Revised Renewal Assessment Report (RAR) on maltodextrin prepared by the rapporteur Member State Ireland in the framework of Commission Implementing Regulation (EU) No 844/2012, January 2025*. https://open.efsa.europa.eu/question/EFSA-Q-2021-00018

McCall, P. J., Laskowski, D. A., Swann, R. L., & Dishburger, H. J. (1980). Measurements of sorption coefficients of organic chemicals and their use in environmental fate analysis. In: *Test protocols for environmental fate and movement of toxicants*. In: *Proceedings of the 94th annual meeting of the American Association of Official Analytical Chemists (AOAC)*. October 21–22, Washington, DC. pp. 89–109.

SETAC (Society of Environmental Toxicology and Chemistry), Candolfi, M. P., Barrett, K. L., Campbell, P. J., Forster, R., Grandy, N., Huet, M. C., Lewis, G., Oomen, P. A., Schmuck, R., & Vogt, H. (2001). *Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods*. ESCORT 2 workshop.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

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

Properties		Conclusion[a]
CMR	**Carcinogenicity (C)** **Mutagenicity (M)** **Toxic for Reproduction (R)**	Maltodextrin is not considered to be mutagenic, carcinogenic or toxic for reproduction according to points 3.6.2, 3.6.3 and 3.6.4 of Annex II of Regulation (EC) No 1107/2009
Endocrine disrupting properties		Maltodextrin is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Maltodextrin 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**	Maltodextrin 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**	Maltodextrin 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 uses

Appendix B can be found in the online version of this output ('Supporting Information' section): https://doi.org/10.2903/j.efsa.2025.9294

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[19] 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

Note: 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).

[19] 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.