CONCLUSION ON PESTICIDES PEER REVIEW

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

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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, Hungary, and co-rapporteur Member State, Ireland, for the pesticide active substance dimoxystrobin as well as the assessment of maximum residue levels (MRLs) and confirmatory data following the review of the existing MRLs of dimoxystrobin according to Article 12 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. In June 2023, the European Commission sent a mandate confirming the need to adopt and publish a conclusion on the peer review of the pesticide risk assessment of the active substance dimoxystrobin excluding the full assessment of endocrine-disrupting properties, containing all the results of the peer review process related to the renewal of approval as well as the assessment of the application for MRL for oilseed rapeseed, poppy seed, mustard seed and gold of pleasure seed, and the MRL application addressing the confirmatory data identified during the MRL review under Article 12 of Regulation (EC) No 396/2005. The conclusions were reached on the basis of the evaluation of the representative uses of dimoxystrobin as a fungicide on oilseed rape and sunflower. MRLs were assessed in rapeseeds, poppy seed, mustard seed and Gold of pleasure seed. The reliable end points, appropriate for use in regulatory risk assessment and the proposed MRLs, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are presented where identified.

Keywords: dimoxystrobin, peer review, risk assessment, pesticide, fungicide, MRL application, Art 12 confirmatory data

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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 as amended by Commission Implementing Regulation (EU) No 2016/183. Dimoxystrobin 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), Hungary, and co-rapporteur Member State (co-RMS), Ireland, received an application from BASF SE for the renewal of approval of the active substance dimoxystrobin. In addition, BASF SE submitted applications for maximum residue levels (MRLs), as referred to in Article 7 of Regulation (EC) No 396/2005 and confirmatory data following the review of the existing MRLs of dimoxystrobin according to Article 12 of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on dimoxystrobin 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.

Prior to completion of the peer review process, at the meeting of the Standing Committee on Plants, Animals, Food and Feed, Section Phytopharmaceuticals – Legislation (SCoPAFF) that took place on 24–25 May 2023, risk managers supported the non-renewal of approval of the active substance dimoxystrobin. The decision for non-renewal was based on the high potential for groundwater contamination by groundwater relevant metabolites 505M08 and 505M09 in geoclimatic conditions represented by all the relevant FOCUS groundwater scenarios for all the representative uses assessed, as concluded in the EFSA statement issued by EFSA on 5 October 2022 (EFSA, 2022) following a specific mandate from the Commission. To facilitate the future work on this active substance, particularly in the context of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, in June 2023, by way of a further specific mandate, the European Commission confirmed the need to adopt and publish a conclusion on the peer review of the pesticide risk assessment of the active substance dimoxystrobin, containing all the results of the peer review process available so far: (i) on the application for renewal of approval in the framework of Commission Implementing Regulation (EU) No 844/2012, including the assessment of the application for MRL for oilseed rapeseed, poppy seed, mustard seed and gold of pleasure seed; and (ii) for the MRL application addressing the confirmatory data identified during the MRL review under Art.12 of Regulation (EC) No 396/2005.

Although the risk assessment has not yet been completed with respect to the endocrine-disrupting properties of dimoxystrobin for non-target organisms other than mammals, the Commission confirmed that it is not necessary to request the applicant to provide additional information in this regard under Article 13(3a) of Regulation (EU) No 844/2012 as this issue is not relevant for the upcoming work under Regulation (EC) No 396/2005.

The following conclusions were derived by the peer review.

The representative uses of dimoxystrobin as a fungicide on oilseed rape and sunflower, by foliar field spraying, as proposed at EU level result in a sufficient **fungicidal** efficacy against the target pathogens.

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 and chemical properties and analytical methods.**

In the **mammalian toxicology** section, no critical area of concern or issues not finalised were identified. For the representative use on sunflower, the exposure estimates for residents and bystanders are exceeding the (acute) acceptable operator exposure level ((A)AOEL).

In the area of **residues,** the following assessments could not be finalised: The residue definition for risk assessment in rotational crops is provisionally proposed as dimoxystrobin because of a data gap to conclude on the genotoxic potential of metabolites observed in high proportions in several crop parts of the rotational crops; the risk assessment residue definition for products of animal origin (ruminants) due to the outstanding data to address the genotoxic potential and the general toxicity of 505M76. An assessment of residues in livestock commodities was not triggered by the representative uses in the framework of the renewal peer review but was necessary for the assessment of MRLs. For the representative uses, the provisional chronic dietary intake according to the EFSA PRIMo rev. 3.1 accounted for 0.3% of the acceptable daily intake (ADI) (NL toddler) and the highest acute intake

accounted for 0.2% of the acute reference dose (ARfD) (rapeseeds/canola seeds). The consumer exposure and risk assessment through drinking water with regard to metabolites 505M08 and 505M09 was not carried out as these compounds were considered toxicologically relevant groundwater metabolites.

The **MRL applications for rapeseeds, mustard seeds, poppy seeds and gold of pleasure seeds** were fully supported by the available Northern EU (NEU) and Southern EU (SEU) residue trials on rapeseeds according to the current extrapolation rules. However, these intended uses are impacted by the outstanding data on aneugenicity/clastogenicity to conclude on the genotoxic potential for several metabolites in order to finalise the risk assessment residue definition for rotational crops and livestock. A provisional consumer dietary risk assessment was conducted including all uses related to the MRL application and the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005. The calculated chronic dietary intake according to the EFSA PRIMo rev. 3.1 model accounted for 11% of the ADI (NL toddler) and the highest acute intake accounted for 0.2% of the ARfD (rapeseeds/canola seeds).

An **MRL application** has been submitted to address the **confirmatory data** identified during the MRL review (Art.12). All the data gaps were addressed except the data gap for four additional residue trials compliant with the SEU outdoor use on sunflower.

The data available on **environmental fate and behaviour** were sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. A critical area of concern was identified for the potential for groundwater contamination by the relevant metabolites (point 3.10 of Annex II to Regulation (EC) No 1107/2009).

In the area of **ecotoxicology**, a high risk was identified for aquatic organisms leading to a critical area of concern. In addition, the risk assessment for honey bee larvae could not be finalised.

Dimoxystrobin does not meet the **endocrine disruption** (ED) criteria for the oestrogen, androgen, steroidogenesis and thyroid (EATS) modalities in humans according to point 3.6.5 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605. The same conclusion also applies for wild mammals as non-target organisms. Based on the available data, this was also confirmed for non-mammalian species for the T-modality. However, the assessment for the oestrogen, androgen and steroidogenesis (EAS)-modalities for non-target organisms other than mammals could not be finalised and further data would be needed. Therefore, a conclusion on whether the ED criteria according to point 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605, are met could not be drawn.

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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 Hungary and co-RMS Italy received an application from BASF SE for the renewal of approval of the active substance dimoxystrobin. In addition, BASF SE submitted an application for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005[4] and confirmatory data following the review of the existing MRLs of dimoxystrobin according to Article 12 of Regulation (EC) No 396/2005. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Ireland), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on dimoxystrobin in the RAR, which was received by EFSA on 1 September 2017 (Hungary, 2017). The RAR included a proposal to set MRLs, submitted under Article 7 of Regulation (EC) No 396/2005 and an assessment of confirmatory data following the review of the existing MRLs of dimoxystrobin according to Article 12 of Regulation (EC) No 396/2005.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, BASF SE, for consultation and comments on 21 February 2019. 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 26 April 2019. 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 telephone conference between EFSA and the RMS on 17 July 2019. 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.

[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 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, pp. 1–50.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, pp. 1–16.

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.

Prior to completion of the peer review process, at the meeting of the Standing Committee on Plants, Animals, Food and Feed, Section Phytopharmaceuticals – Legislation (SCoPAFF) that took place on 24–25 May 2023, risk managers supported the non-renewal of approval of the active substance dimoxystrobin. The decision for non-renewal was based on the high potential for groundwater contamination by groundwater relevant metabolites 505M08 and 505M09 in geoclimatic conditions represented by all the relevant FOCUS groundwater scenarios for all the representative uses assessed, as concluded in the EFSA statement issued by EFSA on 5 October 2022 (EFSA, 2022). This statement was produced following a specific mandate from the European Commission received in August 2022, in which EFSA was requested to provide a statement containing the available outcomes of the assessment related to environmental fate and behaviour and ecotoxicology.

To facilitate the future work on this active substance, particularly in the context of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, on 26 June 2023, by way of a further specific mandate, the European Commission confirmed the need to adopt and publish a conclusion on the peer review of the pesticide risk assessment of the active substance dimoxystrobin, containing all the results of the peer review process available so far:

i) on the application for renewal of approval in the framework of Commission Implementing Regulation (EU) No 844/2012, including the assessment of the application for MRL for oilseed rapeseed, poppy seed, mustard seed and gold of pleasure seed;
ii) for the MRL application addressing the confirmatory data identified during the MRL review under Art.12 of Regulation (EC) No 396/2005.

While the risk assessment has been finalised for all areas with the exception of the endocrine-disrupting properties of dimoxystrobin for non-target organisms other than mammals, the European Commission confirmed that it is not necessary to request the applicant to provide additional information with respect to the endocrine disruption potential under Article 13(3a) of Regulation (EU) No 844/2012 as this issue is not relevant for the upcoming work under Regulation (EC) No 396/2005. Consequently, an additional clock stop has not been applied.

Based on the mandate, EFSA proceeded to complete drafting the conclusion in June 2023 summarising the outcome of the peer review of the risk assessment of the active substance and the formulation for representative uses, evaluated on the basis of the representative uses of dimoxystrobin as a fungicide on oilseed rape and sunflower, 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. MRLs were assessed in rapeseeds, poppy seed, mustard seed and gold of pleasure seed.

A final consultation on the conclusions arising from the peer review of the risk assessment as well as on the proposed MRLs and on the confirmatory data assessment following the MRL review under Article 12 of Regulation (EC) No 396/2005 took place with Member States via a written procedure in August 2023.

A list of the relevant end points for the active substance and the formulation for representative uses as well as the proposed MRLs and the assessment of confirmatory data following the Article 12 MRL review is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for dimoxystrobin 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, 2023), 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 (22 July 2019);
- the evaluation table (September 2023);
- the reports 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 latest revisions (Hungary, 2022), 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 formulated product

Dimoxystrobin is an ISO common name for (2*E*)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-*N*-methylacetamide (IUPAC).

The formulated product for the representative uses in the context of the evaluation was 'BAS 540 01 F', a suspension concentrate (SC) containing 200 g/L dimoxystrobin and 200 g/L boscalid.

The representative uses evaluated were hydraulic foliar spray application on oilseed rape and sunflower as a fungicide against a broad range of pathogens. Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix B.

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

Conclusions of the evaluation

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,b, 2010).

The new proposed reference specification for dimoxystrobin is based on batch data from industrial plant production. Based on the submitted renewal batch data, a higher minimum purity of 994 g/kg (980 g/kg in the current reference specification) and lower levels of some impurities are proposed. The batches used in the toxicological assessment support both the original and the newly proposed reference specification (see Section 2). No information is available to confirm whether the batches used in the ecotoxicology studies are compliant with the specification (see Section 5). There is no FAO specification available for dimoxystrobin.

The main data regarding the identity of dimoxystrobin and its physical and chemical properties are given in Appendix B.

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 in the formulation for representative uses and for the determination of the respective impurities in the technical material.

Dimoxystrobin residues can be monitored in food and feed of plant origin by the quick, easy, cheap, effective and safe method (QuEChERS) using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS), with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. For high water content commodities, acceptable efficiency of the extraction procedure used was demonstrated whereas for high oil content commodities, extractability was low. As a consequence, a **data gap** for a new validated monitoring method including sufficient extractability for high oil content commodities was identified (see Section 10). Efficiency of the extraction procedure used was not verified for high acid content and dry commodities because of a lack of metabolism study in these commodities (not required considering the representative uses). Residues of metabolite 505M09 in food of animal origin can be determined by DFG S19 method with LC–MS/MS with a LOQ of 0.01 mg/kg in all animal matrices. Efficiency of the extraction procedure used was demonstrated for

liver and kidney; for other animal matrices, residues above the LOQ, as a result of the representative uses and the intended uses related to the MRL application, are not expected.

Dimoxystrobin residues in soil can be monitored by HPLC–MS/MS with a LOQ of 0.002 mg/kg. Dimoxystrobin and metabolites 505M01, 505M08 and 505M09 can be analysed in water by HPLC–MS/MS with a LOQ of 0.025 μg/kg. Appropriate LC–MS/MS method exists for monitoring of dimoxystrobin residues in air with a LOQ of 0.167 $\mu g/m^3$.

A QuEChERS method using LC–MS/MS can be used for monitoring of dimoxystrobin and its metabolite 505M09 in body fluids (urine and blood) with a LOQ of 0.010 mg/kg. Dimoxystrobin residues (and metabolite 505M09) in body tissues can be determined by using the monitoring methods for residues in food of animal origin.

2. Mammalian toxicity

The toxicological profile of the active substance dimoxystrobin and its metabolites was discussed at the Pesticides Peer Review Experts' Teleconference 70 in January 2022 and at the Pesticides Peer Review Experts' Teleconference 78 in June 2022. The assessment was based on the following guidance documents: European Commission (2003, 2012), EFSA (2014c, 2017) and ECHA (2017).

With regard to the original/newly proposed reference **specification**, no toxicologically relevant impurities are identified. The original and newly proposed reference specifications are considered covered by the batches used in the toxicological studies.

Oral **absorption** of dimoxystrobin is 46% based on biliary excretion in the rat metabolism study. Dimoxystrobin is extensively distributed and rapidly excreted mainly via faeces. There is no evidence for accumulation. It is extensively metabolised with a pronounced first pass metabolism (more than 45 identified metabolites in rat and with metabolite 505M81 identified as major metabolite), with a major route being hydroxylation, oxidation and cleavage of the ether bond. Based on the comparative *in vitro* metabolism study and metabolism studies in rats, no unique human metabolites are identified for dimoxystrobin.

Dimoxystrobin and metabolite 505M09 are proposed for monitoring purposes in body fluids and tissues.

Dimoxystrobin is of low **acute** oral and dermal **toxicity**. However, it has harmonised classification[5] for toxicity by inhalation (acute toxicity category 4 – H332 ('Harmful if inhaled')). It is not irritant to the skin or to the eye and it has no sensitising potential. Dimoxystrobin was not phototoxic in the OECD 3T3 NRU-PT test.

The overall **short-term** oral **toxicity** no observed adverse effect level (NOAEL) is 3 mg/kg bw per day, based on clinical chemistry changes and increased thickness of duodenal mucosa in the 90-day study in rat.

Dimoxystrobin was negative for gene mutations in bacterial and mammalian cells, *in vitro* chromosome aberrations in mammalian cells and *in vivo* micronucleus in mice bone marrow, with proof of exposure. Based on this, dimoxystrobin is unlikely to be **genotoxic**.[6]

In rat, the **long-term toxicity,** NOAEL is 2 mg/kg bw per day based on the effects in testes (increased weight and incidence in Leydig cell cystic degeneration) and duodenum (single incidence of increased mucosal thickening together with changes in ALP levels); the NOAEL for carcinogenicity is 7 mg/kg bw per day based on thyroid C-cell adenomas. In mice, the long-term toxicity NOAEL is 4 mg/kg bw per day, based on reduced body weight gain and increased ovary weight; the NOAEL for carcinogenicity is 20 mg/kg bw per day based on increased incidences of duodenal focal hyperplasia, adenomas and adenocarcinomas. Hypothesised mode of action responsible for duodenal tumours in mice and for thickening of the duodenal mucosa in mice and rats involves the interaction of dimoxystrobin with iron uptake at the duodenal receptor level. Human relevance cannot be excluded. Also, two mechanistic 7-day studies in rats showed a NOAEL of 4 mg/kg bw per day for the decrease in serum iron levels and no difference in sensitivity in young animals. Dimoxystrobin has harmonised classification according to Regulation (EC) No 1272/2008[7] as Carc. Cat. 2, H351 ('Suspected of causing cancer').

[5] 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; as amended.

[6] See experts' consultation point 2.3 in the Report from the Pesticides Peer Review Experts' Teleconference 70 in January 2022.

[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.

In the two-generation **reproductive toxicity** study in rat, the parental NOAEL is 17 mg/kg bw per day based on reduced food consumption, body weight (gain) and increased testes weight in F0 males; the reproductive NOAEL is 55 mg/kg bw per day based on increased incidence of stillborn pups, decreased viability and decreased number of implantation sites per dam. The offspring NOAEL is 1.5 mg/kg bw per day based on increased incidence of dilated renal pelvis observed in the enhanced one generation study in rat.

With regard to teratogenicity studies, the maternal and **developmental** NOAEL in rat is 60 mg/kg bw per day based on reduced food consumption and body weight gain and on increased incidence of dilated renal pelvis, respectively. In rabbit, the overall maternal NOAEL is 5 mg/kg bw per day based on mortality, clinical signs, reduced food consumption and body weight gain; the overall developmental NOAEL is 20 mg/kg bw per day based on reduced gravid uterus weight, increased resorption rate, increased post-implantation loss and increased number of fetuses with fused sternebrae. The RMS disagreed on the overall developmental NOAEL in rabbit, supporting instead a NOAEL of 50 mg/kg bw per day.[8] Dimoxystrobin has harmonised classification according to Regulation (EC) No 1272/2008 as Repr. Cat. 2, H361d ('Suspected of damaging the unborn child').

Dimoxystrobin did not show evidence of **immunotoxicity** in the standard toxicity studies. For **neurotoxicity**, no specific effects were observed in acute and repeated dose studies.

The **acceptable daily intake** (ADI) is established at 0.015 mg/kg bw per day based on the offspring NOAEL from the enhanced one-generation study, supported by the NOAEL for systemic toxicity from the long-term rat study, and applying a standard uncertainty factor (UF) of 100. Previous ADI was 0.004 mg/kg bw per day based on the chronic toxicity study in mice, using an UF of 1,000 (an additional UF of 10 was applied because in young animals a 10-fold higher utilisation of iron was supposed, compared to the adults) (European Commission, 2006). The **acute reference dose** (ARfD) is established at 0.04 mg/kg bw based on the overall NOAEL of 4 mg/kg bw per day (from the 7-day mechanistic study in rats and the new 7-day mechanistic study in 3 weeks old rats) and applying a standard UF of 100. Previous ARfD was 0.004 mg/kg bw, based on the 7-day mechanistic study in rats, using an UF of 1,000 (an additional UF of 10 was applied because in young animals a 10-fold higher utilisation of iron was supposed, compared to the adults, European Commission, 2006). The **acceptable operator exposure level** (AOEL) is established at 0.007 mg/kg bw per day, considering the same basis as the ADI, applying a standard UF of 100 and a correction for oral absorption value of 46%. The **acute AOEL** (AAOEL) is established at 0.018 mg/kg bw, on the same basis as the ARfD, applying an UF of 100 and a correction for oral absorption value of 46%. Previous AOEL was 0.02 mg/kg bw per day, based on the chronic toxicity study in mice, using an UF of 200 (European Commission, 2006).

Dimoxystrobin **metabolites**[9] **505M02**, **505M03** (might be equal to **505M63**) and its conjugate **505M79**, are considered unlikely to be genotoxic; reference values of the parent are applicable to 505M03 and 505M79 but not to 505M02. The metabolites **505M33**, **505M76** and **505M88** showed negative reliable QSAR predictions for mutations in bacterial cells and unreliable predictions for other genotoxicity endpoints; aneugenicity and clastogenicity are not addressed; therefore, the genotoxic potential cannot be concluded (**data gap,** see Section 9.1.1). No reference values can be established for metabolites 505M33, 505M76 and 505M88 (**data gap,** see Section 9.1.1). Metabolites **505M08** and **505M09** are unlikely to be genotoxic. Available data demonstrate that metabolites 505M08 and 505M09 do not share the carcinogenic properties of the parent compound; however, this is not the case for the reproductive toxicity properties of the parent. Consequently, they are considered as toxicologically relevant groundwater metabolites (see also Section 4). As **505M09** is the unconjugated form of the major rat metabolite 505M81, the parent reference values would be applicable for consumer risk assessment (see also Section 3). Metabolite **505M01** is considered unlikely to be mutagenic and clastogenic; however, aneugenicity has not been investigated (**data gap,**[10] see Sections 3 and 9.1). Data are missing to demonstrate that metabolite 505M01 does not share the carcinogenicity and reproductive toxicity properties of the parent. Consequently, metabolite 505M01 has to be considered as toxicologically relevant groundwater metabolite (see also Section 4).

[8] See experts' consultation point 2.5 in the Report from the Pesticides Peer Review Experts' Teleconference 70 in January 2022.

[9] See experts' consultation point 2.9 in the Report from the Pesticides Peer Review Experts' Teleconference 70 in January 2022 and experts' consultation point 2.1 in the Report from the Pesticides Peer Review Experts' Teleconference 78 in June 2022.

[10] Since 505 M01 is a groundwater but also a residue metabolite, the outstanding data gap identified applying the SANCO Guidance rev. 10 (2003) and reported in the Statement (EFSA, 2022) is revised in this context as a data gap related to consumer risk assessment, whilst considerations on consumer risk assessment were not subject of the EFSA Statement (2022).

The **dermal absorption** values for the formulation for representative uses 'BAS 540 01 F' containing dimoxystrobin and boscalid were determined on the basis of *in vitro* studies with human skin. The values for dimoxystrobin are 0.1% and 13% for the concentrate and in-use dilution, respectively. The values for boscalid are 7% and 5.6% for the concentrate and in-use dilution, respectively.

With regard to **non-dietary exposure** for the representative use on **oilseed rape** (low crop), estimates, using EFSA model (2014c), are below the (A)AOEL for operators wearing gloves during mixing/loading, for workers during inspection/irrigation and for bystanders and residents with a default buffer strip of 2–3 m. For the representative use on **sunflower** (high crop), the estimates, using EFSA model (2014c), are below the (A)AOEL for operators wearing gloves during mixing/loading and application and using a closed cabin in case of tractor-mounted application, and for workers during inspection/irrigation; while for bystanders and residents, they are above the (A)AOEL. Similarly, the results for the combined exposure to boscalid are only exceeding the (A)AOEL in the case of residents for the representative use on sunflower. It is noted that the conclusion for bystanders and residents is taking into account that the calculations should have been done for a buffer strip of minimum 5 m in case of upwards spraying (see also results in Appendix B).

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).

3.1. Representative use residues

The metabolism of dimoxystrobin was investigated in oilseed rapeseeds (pulses and oilseeds) and in wheat (cereal/grass crops) following foliar treatment, using either phenyl or benzyl ^{14}C-labelled dimoxystrobin. For both labellings, dimoxystrobin was found to be the predominant compound of the total residues in rapeseeds (57.5% TRR), wheat forage (93% TRR), wheat grain (58.4% TRR) and in wheat straw (93% TRR). The possible isomerisation of dimoxystrobin (*E*-isomer) to its *Z*-isomer (**505M098**) was investigated and any change in the isomeric ratio was not observed. The residue definition for **enforcement** and **risk assessment** is proposed as dimoxystrobin and it is applicable to pulses/oilseeds and cereal/grass crops following foliar treatment.

In the rotational crops (lettuce, wheat and radish) following bare soil treatment with ^{14}C-labelled dimoxystrobin, unchanged dimoxystrobin was present in significant proportions in lettuce (38% TRR), wheat forage (21.6% TRR), wheat grain (19% TRR) and radish roots and tops/leaves (54% and 26.5% TRR, respectively). Furthermore, glucoside and malonylglucoside conjugates of 505M01, 505M02, 505M63, 505M88 and the aglycone 505M33 were identified in significant proportions (> 10% TRR) in several crop parts. Both under their free and conjugated forms, **505M01** was found in wheat grain and straw (15.7% TRR and 12.3% TRR, respectively), **505M02** in lettuce, wheat forage and wheat straw (26.6%, 30% and 15.6% TRR, respectively), **505M63** in lettuce and wheat straw (29.1% TRR and 19.7% TRR, respectively) and **505M88** in wheat straw (9.5% TRR). In radish root, **505M33** was found at a level of 26.7% TRR. Significant fractions of the radioactive residues in wheat straw and grain (27% TRR and 53% TRR, respectively) were incorporated into lignin, cellulose/ haemicellulose and starch.

Considering the high persistence of dimoxystrobin and the moderate to high persistence of metabolites 505M08 and 505M09 in soil (see Section 4), the total radioactive residues in soil after ageing and ploughing covered the maximum soil PECaccu calculated for these compounds according to the representative uses. The confined metabolism studies were therefore sufficiently dosed (up to 3.5 N rate) to fully elucidate the metabolic pathway of dimoxystrobin in rotational crops. Although the actual residue concentrations of dimoxystrobin and all the identified metabolites are expected to be below 0.01 mg/kg or 0.05 mg/kg, respectively, in food and feed items at the 1 N rate, a data gap is set to address the genotoxic potential of metabolites **505M01, 505M88** (free and conjugated) and of the aglycone **505M33** (**data gaps,** see Sections 2 and 9.1.1) in view of their high proportions observed in several rotational crops parts (> 10% TRR) and in the absence of rotational crop field trials to determine the accurate residue levels of these compounds in the relevant edible crop parts. For the time being, these compounds were not included in the risk assessment residue definition for rotational crops pending the outcome of the data gap, and the residue definitions for **enforcement** and **risk assessment** for rotational crops are proposed as dimoxystrobin on a **provisional** basis.

As regards the representative uses on oilseed rape and sunflower, sufficient and acceptable NEU and SEU GAP-compliant residue trials have been submitted. These trials are supported by acceptable storage stability data (see Appendix B) and validated analytical methods.

Dimoxystrobin was hydrolytically stable under the standard hydrolysis conditions representative of food processing. The *E:Z* isomeric ratio remained unchanged under all tested conditions. Studies investigating the magnitude of residues of dimoxystrobin in processed commodities of oilseed rapeseed and sunflower seed were also provided and processing factors were derived accordingly (see Appendix B).

Metabolism studies were conducted in poultry and ruminants with [^{14}C]-benzyl- and [^{14}C]-phenyl-labelled dimoxystrobin, respectively. In milk, eggs and tissues, dimoxystrobin was extensively metabolised and it was recovered at a level of 15% TRR in poultry fat only. In poultry, the predominant residues were **505M02** under its free form in fat (33.2% TRR) and both free and as glucuronide conjugate (**505M78**) in liver (up to 31.2% TRR). Metabolite **505M09** was present < 10% TRR in fat and liver. A significant fraction of the residues in liver was associated with proteins (up to 28% TRR). Identification of residues was not carried out in muscle because of the very low total residues (< 0.01 mg/kg). In lactating goats, **505M09** under its free form was present in significant proportions in milk, liver and kidney (14.4% TRR, 21.8% TRR and 17% TRR, respectively) and as glucuronide conjugate (**505M81**) in liver and kidney (11.5% TRR and 19.5% TRR, respectively). Furthermore, **505M76** was identified in significant proportions in milk and liver (10.3% TRR and 19.2% TRR, respectively) and **505M79** (glucuronide conjugate of 505M03) in liver and kidney (10.1% TRR and 22.8% TRR, respectively). Also, a significant proportion of the radioactive residues in liver and kidney was associated with proteins (24% TRR). Identification of residues was not carried out in muscle and fat because of the very low total residues (< 0.01 mg/kg). The ratio of the *E*/*Z* isomers of dimoxystrobin remained unchanged in the liver extract while the other matrices were not investigated. The poultry and ruminant metabolism studies were conducted at highly exaggerated dose rates compared to the actual exposure levels assessed for the representative uses (< 0.004 mg/kg bw). Therefore, the total residue concentrations in milk, eggs and tissues are expected to be at a trace level (far below 0.01 mg/kg). MRLs for products of animal origin are not required in respect of the representative uses (see also Section 3.2).

However, since the European authorised uses according to the Art.12 MRL review (EFSA, 2013a) trigger an exposure assessment for ruminants, a guideline compliant ruminant metabolism study has been submitted in the framework of the process for the renewal of approval of dimoxystrobin and residue definitions for enforcement and for risk assessment were assessed for ruminant commodities. The residue definition for **enforcement** is proposed as **505M09** only, which confirms the residue definition used in the Art. 12 MRL review. The residue definition for the **risk assessment** is set as **505M09,** its glucuronide conjugate **505M81**, **505M76 and 505M79** (glucuronide conjugate of 505M03) for milk and tissues, which now includes additional compounds compared to the Art. 12 MRL review as risk assessment considerations have changed since then. Because the aneugenicity/ clastogenicity of **505M76** was inconclusive, its genotoxic potential could not be concluded and reference values could not be established for 505M76 (**data gap,** see Sections 2 and 9.1.1). Whether all these compounds need to be considered together or separately to perform the consumer dietary risk assessment with regard to products of animal origin is pending a complete toxicological assessment of 505M76 and the residue definition for ruminant commodities is therefore provisional.

In a feeding study on lactating cows with dimoxystrobin, the parent and its metabolites, 505M09 and 505M76, were analysed in milk and tissues with an analytical method that does not include a hydrolysis step in order to release the conjugates of 505M09. This shortcoming may underestimate the actual residue levels of 505M81 (glucuronide conjugate of 505M09) that is found to be predominant in liver and kidney. The residue levels of 505M79 were also not analysed. Storage stability data for animal matrices were not required since the residue samples from the feeding studies were analysed within 30 days. As the representative uses do not trigger a feeding study, the need for a new ruminant feeding study should be reconsidered in the case of additional uses that would trigger the investigation of residues of 505M09/505M81 and 505M79 in animal matrices. A feeding study for poultry was not provided and it is not required considering the representative and the intended uses (see Section 3.2).

Although the log P*ow* of dimoxystrobin is above 3, its potential for accumulation in fatty tissues is not expected based on the outcome of the poultry metabolism study and the ruminant feeding study. Furthermore, considering the relevant feed items for fish as rapeseed meal, sunflower seed meal and oilseeds vegetable oils and the respective residue levels of dimoxystrobin, the calculated dietary intake did not trigger a fish metabolism study.

Oilseed rapeseeds and sunflower seeds are representative uses that have a melliferous capacity. Although the NEU residue trials provided on oilseed rapeseeds were conducted with one application instead of two applications at 100 g a.s./ha, the treatment occurred at the full flowering stage (BBCH growth stage 65). Under these conditions, the residue levels of dimoxystrobin were below the LOQ of 0.01 mg/kg in honey and a second application before or after this stage is not expected to contribute significantly to the final residue levels of dimoxystrobin in honey. However, sufficient residue trials on oilseed rapeseeds conducted in the southern zone of Europe are required to definitively conclude on the residue levels of dimoxystrobin in honey and other bee products (see **data gap in Section 10**). Pending also upon the finalisation of the risk assessment residue definition in rotational crops, **residues in pollen and bee products** might need to be addressed with regard to the metabolites of relevance in rotational crops.

A provisional consumer dietary risk assessment was conducted considering the representative uses only. The calculated chronic dietary intake of dimoxystrobin according to the EFSA PRIMo rev. 3.1 accounted for 0.3% of the ADI (NL toddler) and the highest acute intake accounted for 0.2% of the ARfD (rapeseeds/canola seeds). According to the EFSA PRIMo rev. 2, the TMDI accounted for 1% of the ADI (WHO Cluster Diet E) while the IESTI is 0.1% of the ARfD (rapeseeds). As the representative formulation contains the active substance boscalid besides dimoxystrobin, an evaluation was also performed with regard to residues of boscalid in terms of the representative uses. Boscalid and dimoxystrobin do not have common metabolites. Residues from other sources than uses in plant protection are unlikely. For boscalid, EFSA has already assessed comparable GAPs in oilseed rape and sunflower under the remit of the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.[11] In this respect, a dietary intake concern for the uses in oilseed rape and sunflower was not identified, and therefore, a concern is also not expected with regard to residues of boscalid arising from the representative uses assessed in the present peer review for dimoxystrobin.

The PECgw values calculated for the metabolites **505M08** and **505M09** exceeded 0.75 μg/L (2.733 and 1.844 μg/L, respectively, see Section 4). However, as these compounds were considered toxicologically relevant groundwater metabolites (see Section 2), a consumer exposure and risk assessment for drinking water was not carried out.

3.2. Maximum residue levels and confirmatory data MRL review

The **MRL applications for rapeseeds, mustard seeds, poppy seeds and gold of pleasure seeds** were fully supported by the available NEU and SEU residue trials on rapeseeds according to the current extrapolation rules. However, these intended uses being also impacted by the outstanding data on aneugenicity for several metabolites in order to finalise the risk assessment residue definition for rotational crops and for ruminant commodities (see Section 3.1), the consumer dietary risk assessment conducted for all the uses related to the MRL application is provisional. The derived STMR and HR values (see Appendix B) were used as input values for the commodities subject to the MRL application. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005, considering the amendment by Regulation (EU) 2015/1040[12], were used as input values.

The calculated chronic dietary intake according to the EFSA PRIMo rev. 3.1 accounted for 11% of the ADI (NL toddler) and the highest acute intake accounted for 0.2% of the ARfD (rapeseeds/canola seeds). According to EFSA PRIMo rev. 2, the TMDI accounted for 9.3% of the ADI (WHO Cluster Diet E) while the IESTI is 0.1% of ARfD (for each rapeseeds, poppy seeds, sunflower seeds, mustard seeds).

A **MRL application to address the confirmatory data identified during the MRL review (Art.12)** (EFSA, 2013a) for an inter-laboratory validation (ILV) and a confirmatory method for enforcement of 505M09 in ruminant milk, fat, liver, kidney and muscle has been addressed in the draft renewal assessment report. Four additional residue trials compliant with the SEU outdoor GAP on sunflower (2 × 100 g a.s./ha, BBCH 20–65, PHI: 28 days) were not provided and they are required since the GAP is authorised in SEU (see **data gap** in Section 10). Finally, the data gap for four residue

[11] European Food Safety Authority (EFSA), 2014b. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014; 12(7):3799, 127 pp. https://doi.org/10.2903/j.efsa.2014.3799

[12] Commission Regulation (EU) 2015/1040 of 30 June 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products, OJ L 167, 1.7.2015, pp. 10–56.

trials compliant with the NEU outdoor GAP on grass is considered as obsolete as the use on grass in Northern Europe is no longer supported.

A screening assessment for all MRLs in force is not necessary as it has *de facto* already been carried out as part of the assessment of the MRL application for oilseed rape, mustard seeds, poppy seeds and gold of pleasure seeds. Moreover, as the toxicological reference values for dimoxystrobin have been increased compared to the toxicological reference values established during the previous peer review and used in the MRL review (Art.12), an issue with the MRLs in place was not expected. The identified data gap to fully address the genotoxicity for several metabolites as outcome of the peer review is noted.

4. Environmental fate and behaviour

Dimoxystrobin was discussed at the Pesticides Peer Review Experts' Teleconference 71 in January 2022.

Dimoxystrobin test substance used in fate and behaviour studies included low amounts of *Z*-isomer; however, the *Z*-isomer remained at low levels in all environmental compartments. The sum of both isomers was considered for the environmental exposure assessment.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, dimoxystrobin exhibited high to very high persistence, forming the major (> 10% applied radioactivity (AR)) metabolite **505M09** (max. 13% AR, moderate to high persistence in soil) and metabolite **505M08** (> 10% of the initially measured dimoxystrobin in 0–10 cm soil layer in field studies, moderate to high persistence in soil). Mineralisation to carbon dioxide accounted for 15% AR after 119 days for the benzyl ring ^{14}C radiolabel and for 25% AR after 122 days for the phenyl ^{14}C radiolabel. The formation of unextractable residues accounted for 24% AR and 25% AR after 119 and 122 days for the benzyl and the phenyl ^{14}C radiolabels, respectively. In anaerobic soil incubations, dimoxystrobin was essentially stable. In laboratory soil photolysis studies, dimoxystrobin degraded more rapidly than in the dark control forming the major metabolite **505M01** (max. 11% AR), which exhibited low to moderate persistence under aerobic dark conditions. Dimoxystrobin exhibited medium to low mobility in soil. Metabolites 505M08 and 505M09 exhibited very high to high mobility, and 505M01 exhibited very high soil mobility. It was concluded that the adsorption of dimoxystrobin and metabolite 505M01 was not pH dependent, while the adsorption of metabolites 505M08 and 505M09 was pH dependent, with adsorption decreasing in alkaline soils. In satisfactory field dissipation studies carried out at four sites in Germany, three in Spain, one in Sweden, one in Italy, one in France and one in the UK, dimoxystrobin exhibited medium to high persistence in soil. Sample analyses were carried out for dimoxystrobin, 505M01, 505M08 and 505M09. These three metabolites were only determined sporadically above the limit of quantification precluding the derivation of formation and decline kinetic endpoints. Field study DegT50 values for parent dimoxystrobin 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 not combined with laboratory values to derive modelling endpoints as following the DegT50 guidance the laboratory and field values were considered to represent different populations.

In a lysimeter study of 2-year duration, the mean annual concentration of dimoxystrobin was < 0.1 μg/L. Metabolites **505M08** and **505M09** were found to reach a maximum annual average concentration of 2.35 and 2.0 μg/L, respectively. No other known metabolites were detected in any leachate sample.

In laboratory incubations in dark aerobic natural sediment water systems, dimoxystrobin exhibited high to very high persistence, forming the major metabolite **505M96** (max. 10% AR in water exhibiting moderate persistence). The unextractable sediment fraction (not extracted by acetonitrile/water) accounted for 6–11% AR at study end (100 days) for the phenyl and benzyl ring ^{14}C radiolabel. Mineralisation of these radiolabels accounted for only 0.8–2.1% AR at the end of the study. The rate of decline of dimoxystrobin in a laboratory sterile aqueous photolysis experiment was faster (low persistence) relative to that which occurred in the aerobic sediment water incubations. No chromatographically resolved component (excluding dimoxystrobin) accounted for > 8% AR.

The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for the metabolites 505M08, 505M09, 505M01 and 505M96, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). For the active substance dimoxystrobin, appropriate step 3 (FOCUS, 2001) and

step 4 calculations were available. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 57–92.5% spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 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 5.0.1) 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} < 2,000 mL/g (i.e. dimoxystrobin), 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, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4[13] for dimoxystrobin and its metabolites. The potential for groundwater exposure from the representative uses by dimoxystrobin above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all six FOCUS groundwater scenarios.

For the representative use on oilseed rape (early and late triennial applications), the 80th percentile annual average recharge concentrations leaving the 1 m soil layer were estimated to be > 0.1 μg/L at all of the six scenarios for metabolites **505M08** and **505M09** in both acidic and alkaline soils, and in one out of six scenarios for metabolite 505M01.

For the representative use on sunflowers (triennial application), the 80th percentile annual average recharge concentrations leaving the 1 m soil layer were estimated to be > 0.1 μg/L at both of the FOCUS sunflower scenarios for metabolite **505M08** in both acidic and alkaline soils and for metabolite **505M09** in alkaline soils, and in one out of these two scenarios for metabolite 505M09 in acidic soils, while concentrations leaving the 1 m soil layer were estimated to be < 0.1 μg/L at both of the scenarios for metabolite 505M01.

It should be noted that though concentrations in groundwater were > 0.75 μg/L for metabolites 505M08 and 505M09 as they are concluded as relevant at Step 3 of the applicable guidance (see Sections 2 and 7), the only concentration that needed to be assessed against was 0.1 μg/L.

A **critical area of concern** is identified (see Section 9.1.2) as relevant groundwater metabolites (see Sections 2 and 7) have been indicated to be above the parametric drinking water limit of 0.1 μg/L in annual average recharge concentrations leaving the top 1 m soil layers in geoclimatic conditions represented by all the pertinent FOCUS groundwater scenarios and in a relevant lysimeter, in the context of all the representative uses assessed and the whole range of soil pH conditions.

The applicant provided appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water, though it should be noted that for groundwater metabolites 505M01, 505M08 and 505M09 concentrations will legally need to be below 0.1 μg/L in groundwater.

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.

5. Ecotoxicology

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

No information was available to confirm whether the batches used in the ecotoxicology studies are compliant with the reference specification of the active substance (**data gap**, see Section 10).

The formulation for representative uses, i.e. 'BAS 540 01 F', contains another active substance (i.e. boscalid) in the same proportion. In some cases, different formulations than the representative one were used in the ecotoxicity tests. Based on all the available information, bridging between the formulations 'BAS 540 01 F' and 'BAS 540 00 F' is supported and both formulations can be considered comparable. In addition, ecotoxicity studies conducted with the solo-formulation ('BAS 505 01 F') and with the old representative formulation ('BAS 507 00 F'), which contains epoxiconazole as second active substance in lower proportion, were also available for the aquatic section.

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

Several aspects pertaining to the risk assessment of dimoxystrobin were discussed at the Pesticide Peer Review Experts' Teleconference 72 (January 2022) and at the Pesticides Peer Review Experts' Teleconference 79 in June 2022.

Suitable acute and long-term ecotoxicity studies were available with dimoxystrobin with **birds**[14] and **mammals**.[15] Acute studies with the formulation for representative uses were also available for both groups. A low acute and long-term risk to birds and mammals was identified for all representative uses.

An assessment of the major plant metabolites of dimoxystrobin (i.e. 505M01, 505M08, 505M09, 505M93, 505M95, 505M96), to which birds and wild mammals can be exposed to, was available in the RAR and the risk was considered as low. In addition, the risk to birds and mammals resulting from the exposure to contaminated water and the risk due to secondary poisoning were also concluded as low for all representative uses.

Acute toxicity data with the active substance were available for **fish** (three species) and aquatic invertebrates (on the standard species *Daphnia magna*, on *Asellus aquaticus* and with the marine species *Americamysis bahia* and *Crassostrea virginica*). The aquatic invertebrate endpoints for *A. aquaticus* and on *A. bahia* were discussed at the experts' meeting.[16]

Chronic toxicity data with the active substance were available for fish, aquatic invertebrates and algae. No reliable data were available for macrophytes.

Acute toxicity data with fish and aquatic invertebrates as well as chronic data for algae were available with the formulation for representative uses.

In addition, acute toxicity data with other formulations ('BAS 505 01 F' and 'BAS 507 00 F') were also available with additional fish species. The reliability of several acute fish studies was discussed during the experts' meeting.[17]

The potential use of the fish acute toxicity data with formulations including a second active substance in a refinement at Tier 2 was also discussed at the experts' meeting.[18] It was agreed that data from formulation with another active substance should not be used in Tier 2 assessment since the presence of another active substance would add uncertainty to the calculation. Therefore, only data on the active substance and the solo formulation were considered at Tier 2, using the geomean approach; the species-sensitivity distribution (SSD) approach was not considered acceptable for the refined risk assessment since it includes data from formulation with two active substances.

Endpoints for the two chronic early-life stage (ELS) fish studies and the two chronic fish modified exposure studies were discussed at the experts' meeting.[19] It was agreed that the endpoint of 8 μg/L from a standard ELS study on fathead minnow (revised to cover potential effect on growth) should be used in the risk assessment. Toxicokinetic–Toxicodynamic (TKTD) modelling, using the **general unified threshold model of survival** (GUTS), was submitted for refining the chronic risk assessment for fish, and was discussed in the follow-up experts' meeting.[20] The TKTD model was comprehensively reported and relied on a large experimental data set. However, the calibration and the interpretation of the validation of the model presented some deficiencies which decrease the overall reliability of the model application. In addition, GUTS model addresses lethal effects whereas the Tier 1 risk assessment was driven by sublethal effects; the calibration/validation of the model was carried out for rainbow trout whereas the sublethal effects were observed on the fathead minnow, and interspecies extrapolation is not recommended in the EFSA PPR Panel (2018). Therefore, the experts concluded that this modelling could not be used for refining the chronic fish risk assessment for dimoxystrobin.

For further refinement for **aquatic invertebrates**, a mesocosm study was also available with the solo formulation. The proposed endpoint from the mesocosm study was also discussed during the experts' meetings.[21] The experts agreed that an overall endpoint could not be derived for aquatic organisms due to several shortcomings (e.g. few species, especially vulnerable ones, with sufficient abundance, lack of pre-exposure sampling for some taxa; an effect class 3A was observed at the

[14] See experts' consultation 5.1 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023).
[15] See experts' consultation 5.2 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023).
[16] See experts' consultation 5.6 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023).
[17] See experts' consultation 5.4 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023).
[18] See experts' consultation 5.8 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023).
[19] See experts' consultation 5.5 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023).
[20] See expert consultation in the Report of Pesticide Peer Review Expert's Teleconference 79 (EFSA, 2023).
[21] See experts' consultation 5.7 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023) and expert consultation in the Report of Pesticide Peer Review Expert's Teleconference 79 (EFSA, 2023).

lowest concentration). Only a specific provisional ecological recovery option (ERO) – regulatory acceptable concentration (RAC) could be derived for *Daphnia*, and the experts agreed not to use this endpoint in the risk assessment since it has not been demonstrated that the exposure in the mesocosm covers the predicted exposure profiles of the representative uses and that this endpoint might not be protective enough for molluscs (driving the Tier 1 risk assessment), crustaceans with long reproductive cycle and the most sensitive phytoplankton taxa.

Regarding **sediment-dwelling organisms**, toxicity data were available with the active substance.

Based on the available Tier 1 data, a high acute risk for fish and aquatic invertebrates was identified at FOCUS Step 3 for all scenarios for the two representative uses.

Considering Tier 2 refinement (geomean), a **high acute risk to fish** was identified for all scenarios and representative uses, using FOCUS Step 3 PECsw, except for scenario D5 on sunflower. At FOCUSsw Step 4, a high acute risk to fish remained for 2/6 scenarios (D2 and D4) for the use on oilseed rape. Low acute risk was concluded for the remaining scenarios for the use on oilseed rape when considering risk mitigation measures (RMMs) up to 20 m no-spray buffer zone in combination with 20 m vegetated filter strip. For the use on sunflower, low acute risk to fish was concluded when considering RMM up to 20 m no-spray buffer zone in combination with a 20-m vegetated filter strip.

An overview of the outcome of the risk assessment for aquatic organisms is presented in Table 1 below.

Table 1: Overview of the outcome of the risk assessment for aquatic organisms

FOCUSsw scenario	Acute fish (geomean)	Chronic fish	Invert. acute (*C. virginica*)	Invert. chronic	Chironomus riparius	Algae
Oilseed rape – 1 or 2 applications						
D2	**HR**	**HR**	**HR**	**HR**	**HR**	**HR**
D3	LR step 4 10 m + 10 m	LR	LR step 4 20 m + 20 m	LR	LR step 4 10 m + 10 m	LR
D4	**HR**	**HR**	**HR**	LR	**HR**	**HR**
D5	LR step 4 10 m + 10 m	LR	**HR**	LR	**HR**	LR
R1	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m	**HR**	LR step 4 10 m + 10 m	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m
R3	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m	**HR**	LR step 4 10 m + 10 m	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m
Sunflower						
D5	LR	LR	**HR**	LR	LR step 4 10 m + 10 m	LR
R1	LR step 4 10 m + 10 m	LR step 4 10 m + 10 m	**HR**	LR	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m
R3	LR step 4 10 m + 10 m	LR step 4 10 m + 10 m	**HR**	LR	LR step 4 10 m + 10 m	LR step 4 10 m + 10 m
R4	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m	**HR**	LR step 4 10 m + 10 m	LR step 4 20 m + 20 m	LR step 4 10 m + 10 m

HR: High risk remaining with the RMM; LR: Low risk concluded (FOCUS step 3).
LR step 4 10 m + 10 m: Low risk concluded at FOCUS step 4 with RMM of 10 m no-spray buffer zone in combination with a 10-m vegetated filter strip.
LR step 4 20 m + 20 m: Low risk concluded at FOCUS step 4 with RMM of 20 m no-spray buffer zone in combination with a 20-m vegetated filter strip.

By using Tier 1 data, high **chronic risk for fish** was identified at FOCUS Step 3 for 4/6 scenarios for the representative use on oilseed rape and 3/4 scenario for the use on sunflower. At FOCUSsw Step 4, for the use in oilseed rape, a high chronic risk to fish remains with a 20-m buffer zone combined with a 20-m vegetated filter strip for 2/6 scenarios; low chronic risk to fish was concluded when considering a 10-m no-spray buffer zone in combination with a 10-m vegetated filter strip for the 2 remaining scenarios. For the representative use on sunflower, low chronic risk was concluded when considering a 10-m no-spray buffer zone in combination with a 10-m vegetated filter strip for all remaining scenarios.

As regards **acute risk to aquatic invertebrates**, based on the most sensitive species *(C. virginica*, acute endpoint based on shell deposition), high risk was concluded for all relevant scenarios and uses (except for one scenario (D3) for the use on oilseed rape) at FOCUSsw Step 4 when considering a 20 m no-spray buffer zone in combination with a 20-m vegetated filter strip (**critical area of concern**, see Section 9.1.2).

High **chronic risk to aquatic invertebrates** was identified at FOCUS Step 3 for 3/6 scenarios for the use on oilseed rape. By using FOCUSsw Step 4 exposure estimations, a high chronic risk remains for one scenario; low chronic risk to aquatic invertebrates was concluded when considering a 10-m no-spray buffer zone in combination with a 10-m vegetated filter strip for two scenarios. For the use on sunflower, the chronic risk was high at FOCUS step 3 for 1/4 scenarios, for which a low risk was identified at FOCUSsw Step 4, with a 10 m no-spray buffer zone in combination with a 10-m vegetated filter strip.

In addition, high **chronic risk to sediment-dwelling organisms** was concluded at FOCUSsw Step 3 for all scenarios for both representative uses. Using the FOCUSsw Step 4 calculations that considered a 20-m no-spray buffer zone in combination with a 20-m vegetated filter strip, high chronic risk to sediment-dwelling organisms was identified for 3/6 scenarios for the use on oilseed rape. For the use on sunflower, low risk was concluded at FOCUSsw Step 4 for all scenarios when considering RMM up to 20 m no-spray buffer zone combined with 20 m vegetated filter strip.

By using FOCUSsw Step 3 calculations, 4/6 and 3/4 scenarios showed a high risk to **algae** for the uses in oilseed rape and sunflower, respectively. At FOCUSsw Step 4, for the use on oilseed rape, the high risk remained for 2 scenarios (D2 and D4) even after considering a 20-m no-spray buffer zone in combination with a 20-m vegetated filter strip, whereas a low risk was identified for the remaining scenarios when considering a 10-m no-spray buffer zone in combination with a 10 m vegetated filter strip. For the use on sunflower, a low risk to algae could be concluded when considering a 10 m no-spray buffer zone in combination with a 10-m vegetated filter strip.

To conclude on aquatic organisms, **1/6 scenarios shows a low risk** applying RMM of 20 m no-spray buffer zone in combination with 20 m vegetated filter strip for the use on **oilseed rape**, whereas a **high risk is identified for the remaining 5 scenarios**; for the use on **sunflower**, a high risk is identified **for all scenarios** even considering RMM.

Several pertinent **metabolites** of dimoxystrobin have been identified in surface water (**501M01, 505M08, 505M09, 505M096**). These pertinent aquatic metabolites were tested acutely for fish, invertebrates and algae. Low acute risk was concluded for all the pertinent aquatic metabolites by using FOCUS Step 1 PECsw for fish, aquatic invertebrates and algae for all uses. The metabolites 505M08, 505M09, 505M01, 505M96 were also identified as relevant in the sediment phase. However, no risk assessment for sediment dwellers was submitted (**data gap,** see Section 10).

Oral acute toxicity data on **honey bees** were available for dimoxystrobin and two formulated products (i.e. 'BAS 540 01 F' and 'BAS 540 00 F').[22] Acute contact toxicity data were available for the same formulations but not for the active substance (**data gap**, see Section 10). Furthermore, chronic studies for larvae and adults were available. The chronic toxicity study was conducted with the active substance; however, since the formulation for representative uses contains more than one active substance,[23] chronic toxicity data with the formulation are considered necessary. This data requirement applies to honey bee adults and larvae (**data gap,** see Section 10). An 8-day larval toxicity study was available and conducted with the formulation for representative uses. However, since brood effects were observed in the available study and it does not cover the main developmental stages of honey bee larvae in line with the current recommendations, a data gap for a proper 22-day study with honey bee larvae was identified (i.e. a test with repeated dosing and longer test duration according to OECD Guidance No 239 is preferable)[24] (**issue not finalised**, see Section 9.1.1). To address the potential risk to honey bee larvae, higher tier data were submitted (see below paragraph on higher tier data for further information). No information was available on bumblebees and solitary bees.

An acute risk assessment following the SANCO Guidance on Terrestrial ecotoxicology (European Commission, 2002) was available for dimoxystrobin. Low acute risk to honey bees from oral and

[22] Ecotoxicity endpoints for bees obtained from both formulations are similar and in the same range. The formulations are comparable based on existing information.

[23] In line with the EU data requirements in Regulation (No) 284/2013, when a formulation for representative uses contains more than 1 active substance, further data to address the risk to bees need to be available. Data gap identified by EFSA in Section 10 following the Statement issued in 2022 (EFSA, 2022).

[24] A further consideration to the risk to honey bee larvae is given below taking into account the available tunnel study.

contact exposure was concluded for both representative uses. Following the Tier 1 risk assessment according to the EFSA bee guidance (EFSA, 2013b), the same conclusion could be reached for the acute scenario as assessed with the SANCO Guidance. Likewise, low chronic risk to adult honey bees could also be concluded for dimoxystrobin for all representative uses and the acute and chronic risk to adult bees from exposure to contaminated water was considered low as well.

A suitable assessment for sub-lethal effects was not available (**data gap**, see Section 10). An assessment to address the potential effects of plant metabolites occurring in pollen and nectar as a result of the representative uses was not available (**data gap**, see Section 10). An assessment of accumulative effects on bees was not available.

In addition to the Tier 1 ecotoxicity data for honey bees, a number of higher tier studies were also available. The available tunnel study considered ecotoxicological parameters related to the honey bee risk assessment (i.e. brood developmental observations), whilst the other two studies, residue studies under semi-field and field conditions,[25] aimed at characterising the residue situation in pollen and nectar for oilseed rape and sunflowers. Those studies were discussed at the experts' meeting.[26]

The information from the residue studies showed several deficiencies (i.e. the sampling method was not in line with the recommendations of the EFSA bee guidance (EFSA, 2013b), the residue trials were not independent from each other, there were adverse environmental conditions that could have affected the residue decline etc.); therefore, it was concluded that the information provided could not be used to refine exposure parameters in the risk assessment equations.

In the tunnel study, high variability on the brood termination rate was observed. In addition, due to several shortcomings in terms of experimental set-up and conditions, the study was considered unsuitable to fully address the risk to honey bee larvae. As a consequence of the data gap identified for Tier 1 data for honey bee larvae and the unsuitability of a refinement based on the available tunnel study, the risk assessment for honey bee larvae is considered as an **issue that could not be finalised** (see Section 9.1.1).

Standard and extended laboratory toxicity tests with the formulation 'BAS 540 00 F' were available for **non-target arthropods other than bees**. By using the available data, low in- and off-field risk could be concluded for all representative uses.

Based on the available laboratory data with dimoxystrobin, high chronic risk was identified for **earthworms** for all representative uses at Tier 1. Three field studies were available to refine the risk. The studies were discussed at the experts' meeting.[27] Two were considered only as supportive information due to several shortcomings identified (e.g. uncertain exposure, limited information in terms of pre-application sampling and pesticide history, poor performance of the toxic reference), whilst the study conducted in line with the GAPs under assessment was considered reliable and relevant to refine the risk assessment. Considering the information from all the studies, it was possible to conclude low risk for earthworms for both representative uses.

For other **soil macro- and meso-fauna** (i.e. *Folsomia candida* and *Hypoaspis aculeifer*), low chronic risk was concluded for all representative uses at Tier1.

Low risk to soil organisms from the exposure to the soil metabolite 505M09 was concluded for all representative uses. For the other relevant soil metabolites (i.e. 501M01, 505M08), toxicity data were not available. However, considering that metabolite 505M09 represents the worst-case metabolite in soil in terms of formed fraction and degradation time, low chronic risk to soil organisms could be concluded for all the other relevant soil metabolites for the representative uses under assessment.

Suitable ecotoxicity tests were available to conclude a low risk to **soil microorganisms** for the active substance as well as for all the relevant soil metabolites for all representative uses.

A low chronic risk to **non-target terrestrial plants** and **organisms involved in biological methods for sewage treatment** was concluded for all representative uses.

[25] One of the residue studies was conducted under semi-field conditions, while the other study was a field study.
[26] See experts' consultation 5.9 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023) for the detailed discussion on higher tier testing with honey bees.
[27] See experts' consultation 5.10 in the Report of Pesticides Peer Review Experts' Teleconference 72 (EFSA, 2023) for the detailed discussion on higher tier testing with earthworms.

6. Endocrine disruption properties

The endocrine-disrupting (ED) properties of dimoxystrobin for humans and non-target organisms were discussed at the Pesticides Peer Review Experts' Teleconference 70 and 72 (January 2022).[28]

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

The data set for the **T-modality** was considered complete. Overall, no T-mediated adverse effects were observed in a sufficient data set. The scenario 1a[29] is therefore applicable.

The data set for the **EAS-modalities** was considered complete. There was no evidence of a pattern of EAS-mediated adversity in a sufficient data set. The scenario 1a is applicable.

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

For **non-target organisms other than mammals**, a Xenopus Eleutheroembryo Thyroid Assay (XETA, OECD TG 248) was available for the **T-modality**. The study did not show any positive findings, although only the intermediate report was available (**data gap**, see Section 10). Overall, dimoxystrobin was not considered to meet the ED criteria through the T-modality for non-mammalian species. The lack of the full report of the XETA was not considered to have an impact on the overall conclusion.[30]

Specific information for the identification of the ED properties of dimoxystrobin through the **EAS-modalities** was not available; therefore, further testing would be necessary. In line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018), a fish short-term reproduction assay (FSTRA, in line with OECD TG 229) or a 21-day fish screening toxicity assay (in line with OECD TG 230) including gonad histopathology assessments should be submitted. In case of positive evidence from that study, additional testing might be necessary to further investigate adversity (i.e. level 4–5 studies).

Based on the above considerations, dimoxystrobin does not meet the ED criteria for the EATS modalities in humans according to point 3.6.5 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605. The same conclusion also applies for wild mammals as non-target organisms. Based on the available data, this conclusion was also drawn for non-mammalian species for the T-modality. However, the assessment for the EAS-modalities for non-target organisms other than mammals could not be finalised and further data would be needed (see Section 9.1.1). The European Commission confirmed in their mandate that it is not necessary to request the applicant to provide additional information with respect to the ED potential under Article 13(3a) of Regulation (EU) No 844/2012 as this issue is not relevant for the upcoming work under Regulation (EC) No 396/2005. Consequently, an additional ED clock stop has not been applied. Therefore, a conclusion on whether the ED criteria according to point 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605, are met could not be drawn.

[28] See experts' consultation 2.8 in the Report of Pesticides Peer Review Experts' Teleconference 70 for the discussion related to the ED properties of dimoxystrobin for humans and experts' consultation 5.11 in the Report of Pesticides Peer Review Experts' Teleconference 72 for the discussion related to the ED properties of dimoxystrobin for non-target organisms other than mammals (EFSA, 2023).

[29] Refer to EFSA/ECHA ED guidance (ECHA/EFSA, 2018), section 3.4.4.

[30] Refer to experts' consultation 5.11 in the Report of Pesticides Peer Review Experts' Teleconference 72 for the discussion related to ED properties of dimoxystrobin for non-target organisms other than mammals (EFSA, 2023).

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
Dimoxystrobin	Low risk to soil organisms
505M08	Low risk to soil organisms
505M09	Low risk to soil organisms
505M01	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
Dimoxystrobin	No	Yes	–	–	Yes
505M08	Yes Winter oilseed rape (early application): 1.253–2.640 µg/L 6/6 FOCUS scenarios (alkaline soils) Winter oilseed rape (late application): 1.283–2.733 µg/L 6/6 FOCUS scenarios (alkaline soils) Sunflower: 0.590–1.050 µg/L 2/2 FOCUS scenarios (alkaline soils)	No	Yes Parent dimoxystrobin is classified Repr. Cat. 2	No Toxicologically relevant groundwater metabolite (see Section 2)	Yes
505M09	Yes Winter oilseed rape (early application): 0.927–1.764 µg/L 6/6 FOCUS scenarios (alkaline soils) Winter oilseed rape (late application): 0.929–1.844 µg/L 6/6 FOCUS scenarios (alkaline soils) Sunflower: 0.270–0.684 µg/L 2/2 FOCUS scenarios (alkaline soils)	No	Yes Parent dimoxystrobin is classified Repr. Cat. 2	No Toxicologically relevant groundwater metabolite (see Section 2)	Yes
505M01	Yes Winter oilseed rape (late application): 0.111 µg/L 1/6 FOCUS scenarios	No	Yes Parent dimoxystrobin is classified Carc. Cat 2 and Repr. Cat. 2 Aneugenicity not investigated	No Toxicologically relevant groundwater metabolite (see Section 2)	Yes

(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
Dimoxystrobin	High acute risk to aquatic invertebrates for 5/6 scenarios for the uses on oilseed rape and all scenarios for the use on sunflower. High chronic risk to sediment dwelling organisms for 3/6 scenarios for the use on oilseed rape. High acute risk and chronic risk to fish for 2/6 scenarios for the use on oilseed rape. High risk to algae for 2/6 scenarios for the use on oilseed rape. High chronic risk to aquatic invertebrates for 1/6 scenarios for the use on oilseed rape
505M08	Low risk to aquatic organisms, except sediment dwellers (data gap)
505M09	Low risk to aquatic organisms, except sediment dwellers (data gap)
505M01	Low risk to aquatic organisms, except sediment dwellers (data gap)
505M96	Low risk to aquatic organisms, except sediment dwellers (data gap)

Table 5: Air

Compound (name and/or code)	Toxicology
Dimoxystrobin	Rat LC_{50} 1.3 mg/L air /4 h (head and nose) (Acute Toxicity category 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 (Table 6). 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.

8.1. Particular conditions proposed for the representative uses evaluated

Table 6: Risk mitigation measures proposed for the representative uses assessed

Representative use	Oilseed rape foliar spray	Sunflower foliar spray
Operator risk	Use of gloves is required during mixing/loading (ML)	Use of gloves is required during ML and application (A) + closed cabin in case of tractor-mounted A
Worker exposure	–	–
Bystander/resident exposure	–	(Available RMMs are insufficient)
Risk to aquatic organisms	RMM of 20 m no-spray buffer zone combined with a 20-m vegetated buffer was sufficient for only 1/6 scenarios[(a)]	

(a): D3.

8.2. Particular conditions proposed for the maximum residue level applications

No particular conditions are proposed for the MRL applications.

9. Concerns and related data gaps

9.1. Concerns and related data gaps for the representative uses evaluated

9.1.1. 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[31] 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 consumer dietary risk assessment could not be finalised since the residue definition for risk assessment proposed as dimoxystrobin in rotational crops is provisional pending data to address the genotoxic potential of metabolites observed in high proportions in several crop parts of the rotational crops. Although a livestock exposure assessment is not triggered considering the representative uses, the risk assessment residue definition for products of animal origin could also not be finalised pending a complete toxicological assessment of 505M76 (see Section 3.1).
    a) The aneugenicity potential of metabolite **505M01** should be addressed in view of the high proportions of this compound observed in rotational crops (> 10% TRR) (relevant for all representative uses evaluated, see Sections 2 and 3.1).
    b) The aneugenicity and clastogenicity potential of metabolites **505M88 and 505M33** should be addressed in view of the high proportions of these compounds observed in rotational crops (> 10% TRR) (relevant for all representative uses evaluated, see Sections 2 and 3.1).
    c) The aneugenicity and clastogenicity potential and data on the general toxicity profile of **505M76** should be addressed (relevant for all representative uses evaluated, see Sections 2 and 3.1).
2) The risk assessment to honey bee larvae could not be finalised due to the lack of reliable information (applicable for all representative uses, see Section 5).
    a) A chronic toxicity study with honey bee larvae in line with OECD Guidance No 239 is required (applicable for all representative uses, see Section 5).
3) The ED assessment for the EAS-modalities for non-target organisms other than mammals could not be finalised and further data would be needed (see Section 6).
    a) In line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018), a fish short-term reproduction assay (FSTRA, in line with OECD TG 229) or a 21-day fish screening toxicity assay (in line with OECD TG 230) including gonad histopathology assessments should be submitted. In case of positive evidence from that study, additional testing might be necessary to further investigate adversity (i.e. level 4–5 studies) (relevant for all representative uses evaluated, see Section 6).

[31] 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.

9.1.2. 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:

4) High acute risk to aquatic invertebrates for 5/6 scenarios for the use on winter oilseed rape and all scenarios for the use on sunflower when also considering the implementation of the assessed mitigation measures that reduced exposure (20 m no-spray buffer zone +20 m vegetated filter strip)[32] (see Section 5).
5) High potential for groundwater contamination by groundwater relevant metabolites in geoclimatic conditions represented by all the relevant FOCUS groundwater scenarios for all the representative uses assessed (see Sections 2, 4 and 7).

9.1.3. 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		Oilseed rape Foliar spray	Sunflower Foliar spray
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified		X (see Section 2)
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised	X[1]	X[1]
Risk to wild non-target terrestrial vertebrates	Risk identified		
	Assessment not finalised		

[32] With these risk mitigation measures, the exposure reduction is just below the limit of 95% (92.5%) for spray drift that is recommended by the FOCUS Landscape and mitigation guidance (FOCUS, 2007). While theoretically there is a small margin, it is unlikely that with the absolute 95% drift reduction (i.e. with a 30-m no spray buffer zone resulting in 94.94% drift reduction; also using 50% drift reducing nozzle +10 m buffer zone is essentially the same) any additional scenario would pass, nevertheless the risk assessment to absolutely confirm the situation is not available from the peer review. Nonetheless, it is unlikely that the critical area of concern would change.

Representative use		Oilseed rape Foliar spray	Sunflower Foliar spray
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised	X[2]	X[2]
Risk to aquatic organisms	Risk identified	X[4(b)] (5/6)	X[4(c)] (4/4)
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure to metabolites	Legal parametric value breached	X[5]	X[5]
	Parametric value of 10 μg/L[(a)] breached		
	Assessment not finalised		

The superscript numbers relate to the numbered points indicated in Sections 9.1.1 and 9.1.2. Where there is no superscript number, see Sections 2–7 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).
(b): High acute risk to aquatic invertebrates (5/6 scenarios); high acute and chronic risk to fish (2/6 scenarios); high risk to algae (2/6 scenarios), high risk to sediment dwelling organisms (3/6), high chronic risk to aquatic invertebrates (1/6 scenarios).
(c): High acute risk to aquatic invertebrates (4/4 scenarios).

9.2. Issues related to the maximum residue level applications

9.2.1. Issues not finalised under the maximum residue level applications

- The consumer dietary risk assessment could not be finalised with regard to the intended uses on oilseed rape seeds, mustard seeds, poppy seeds and Gold of pleasure seeds as these uses are also impacted by the outstanding aneugenicity and clastogenicity data to conclude on the genotoxic potential for several metabolites to finalise the risk assessment residue definition for rotational crops (see Sections 3.1 and 3.2).

9.2.2. Consumer risk identified under the maximum residue level applications

- None identified.

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 and/or as regards the MRL application assessed and are listed in the order of the sections:

- A new validated monitoring method including sufficient extractability for high oil content commodities is required (relevant for all representative uses evaluated; see Section 1).
- Sufficient residue trials on oilseed rapeseeds conducted in the southern zone of Europe are required to definitively conclude on the residue levels of dimoxystrobin in honey and other bee products (relevant for all representative uses evaluated; see Section 3.1).
- 4 residue trials compliant with the SEU outdoor GAP on sunflower (2 × 100 g a.s./ha, BBCH 20–65, PHI: 28 days) (relevant for the confirmatory data identified during the MRL review (Art.12), see Section 3.2).
- No information was available to confirm whether the batches used in the ecotoxicology studies are compliant with the reference specification of the active substance (relevant for all representative uses, see Section 5).
- No aquatic risk assessment for sediment dwellers was provided for the metabolites 505M08, 505M09, 505M01 and 505M96 (relevant for all representative uses, see Section 5).
- Acute contact toxicity data with dimoxystrobin for bees were not available (relevant for all representative uses, see Section 5).

- Further data were not available to address the risk to honey bees from sublethal effects and via exposure to plant metabolites formed in pollen and nectar (relevant for all representative uses, see Section 5).
- Chronic toxicity data for honey bee (adults and larvae) with the formulation for representative uses containing more than one active substance are necessary (applicable for all representative uses, see Section 5).
- Final report for the Xenopus Eleutheroembryo Thyroid Assay (XETA, OECD TG 248) should be provided (relevant for all representative uses, see Section 6).

References

ECHA (European Chemicals Agency), 2017. Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 5.0 July 2017. Reference: ECHA-17-G-21-EN; ISBN: 978-92-9020-050-5. Available online: https://echa.europa.eu/guidance-documents/guidance-on-clp

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 AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and 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 2018;16(6):5311,135 pp. https://doi.org/10.2903/j.efsa.2018.5311

ECHA (European Chemicals Agency), 2020. Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of dimoxystrobin (ISO); (2E)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-N-methylacetamide; (E)-2-(methoxyimino)-N-methyl-2-[α-(2,5-xylyloxy)-otolyl]acetamide. CLH-O-0000006865-62-01/F. Adopted 8 October 2020. Available online: www.echa.europa.eu

EFSA (European Food Safety Authority), 2008. Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. EFSA Journal 2008;6 (1):622, 32 pp. https://doi.org/10.2903/j.efsa.2008.622

EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. https://doi.org/10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2013a. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for dimoxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11 (11):3464, 41 pp. https://doi.org/10.2903/j.efsa.2013.3464

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 2013;11(7):3295, 268 pp., https://doi.org/10.2903/j.efsa.2013.3295

EFSA (European Food Safety Authority), 2014a. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., https://doi.org/10.2903/j.efsa.2014.3662

EFSA (European Food Safety Authority), 2014b. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12 (7):3799, 127 pp. https://doi.org/10.2903/j.efsa.2014.3799

EFSA (European Food Safety Authority), 2014c. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., https://doi.org/10.2903/j.efsa.2014.3874

EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. https://doi.org/10.2903/j.efsa.2017.4873

EFSA (European Food Safety Authority), 2022. Statement concerning the assessment of environmental fate and behaviour and ecotoxicology in the context of the pesticides peer review of the active substance dimoxystrobin. EFSA Journal 2022;20(10):7634, 119 pp. https://doi.org/10.2903/j.efsa.2022.7634

EFSA (European Food Safety Authority), 2023. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance dimoxystrobin. Available online: www.efsa.europa.eu

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 2013;11(7):3290, 186 pp. https://doi.org/10.2903/j.efsa.2013.3290

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2018. Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA Journal 2018;16(8):5377, 188 pp. https://doi.org/10.2903/j.efsa.2018.5377

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, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.
European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2011. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95-rev. 9 March 2011, pp. 1–46.
European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.
European Commission, 2014a. 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.
European Commission, 2014b. Guidance document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012. SANCO/2012/11251-rev. 4, 12 December 2014.
European Commission, 2006. Review report for the active substance dimoxystrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 4 April 2006 in view of the inclusion of dimoxystrobin in Annex I of Council Directive 91/414/EEC. SANCO/10531/05 – final, 4 April 2006.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2001. FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev. 2, 245 pp., as updated by Generic guidance for FOCUS surface water scenarios, v. 1.3 December 2014.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp., as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, v. 1.1 December 2014.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2007. Landscape and mitigation factors in aquatic risk assessment. Volume 1. Extended summary and recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. EC Document Reference SANCO/10422/2005 v. 2.0, 169 pp.
Hungary, 2017. Renewal Assessment Report (RAR) on the active substance dimoxystrobin prepared by the rapporteur Member State Hungary, in the framework of Commission Implementing Regulation (EU) No 844/2012, August 2017. Available online: www.efsa.europa.eu
Hungary, 2022. Revised Renewal Assessment Report (RAR) on dimoxystrobin prepared by the rapporteur Member State Hungary in the framework of Commission Implementing Regulation (EU) No 844/2012, July 2022. Available online: www.efsa.europa.eu
JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004, 383 pp.
JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 18–27 September 2007, 164 pp.
McCall PJ, Laskowski DA, Swann RL and Dishburger HJ, 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). Oct 21–22, Washington, D.C. pp. 89–109.
OECD (Organisation for Economic Co-operation and Development), 2009. Guidance document on overview of residue chemistry studies. ENV/JM/MONO(2009)31, 28 July 2009.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: www.oecd.org
SETAC (Society of Environmental Toxicology and Chemistry), Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet MC, Lewis G, Oomen PA, Schmuck R and Vogt H (eds.), 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT 2 workshop.

Abbreviations

1/n	slope of Freundlich isotherm
a.s.	active substance
ADI	acceptable daily intake
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
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
ECHA	European Chemicals Agency
ERO	ecological recovery option
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSTRA	Fish Short-Term Reproduction Assay
GAP	Good Agricultural Practice
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC–MS	high-pressure liquid chromatography–mass spectrometry
HR	hazard rate
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
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)
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC–MS	liquid chromatography–mass spectrometry
LC–MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue level
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
Pa	pascal
PEC	predicted environmental concentration
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PHI	preharvest interval
QSAR	quantitative structure–activity relationship
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
SC	suspension concentrate
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TMDI	theoretical maximum daily intake
TRR	total radioactive residue

UF	uncertainty factor
WHO	World Health Organization
ε	decadic molar extinction coefficient
λ	wavelength

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

Properties		Conclusion[a]
CMR	Carcinogenicity (C)	Dimoxystrobin is classified as a Carc. Cat 2 (H351) (ECHA RAC, 2020)[b]
	Mutagenicity (M)	Dimoxystrobin is not classified as Mutag. Cat 1A, B Dimoxystrobin is not considered to be a mutagen according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009
	Toxic for Reproduction (R)	Dimoxystrobin is classified as Repr. 2 (H361d) (ECHA RAC, 2020)
Endocrine disrupting properties		Dimoxystrobin is not considered to meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605. The same conclusion applies concerning the ED criteria for the T- modality for non-mammalian species. A conclusion for the EAS-modalities for non-target organisms other than mammals according to point 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605 could not be drawn.
POP	**Persistence**	Dimoxystrobin is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Dimoxystrobin 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
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Dimoxystrobin 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
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).
(b): ATP18 – (16/02/2022), 23/11/2023: Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0692&qid=1667995782196.

Appendix B – List of end points for the active substance and the formulation 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.2023.8329.

Appendix C – Wording EFSA used in Section 4 of this conclusion, in relation to DT and K_{oc} 'classes' exhibited by each compound assessed

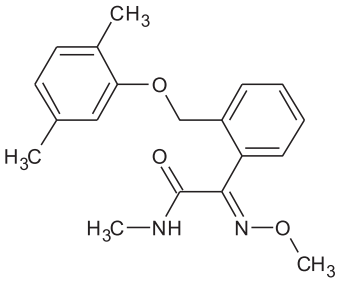
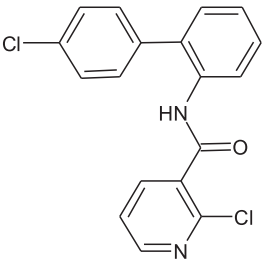
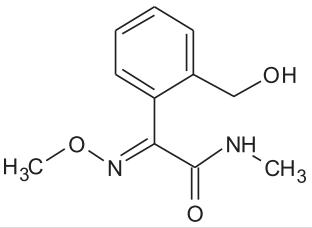
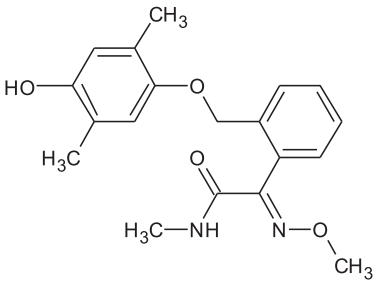
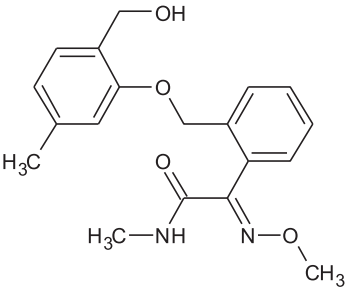
Wording	DT_{50} normalised to 20°C for laboratory incubations[(a)] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT_{50} when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1 to < 10 days
Moderate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

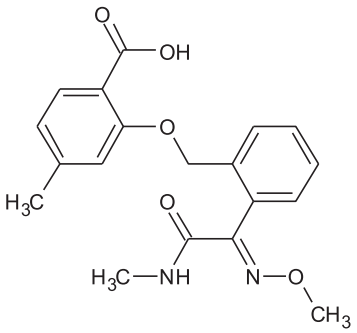
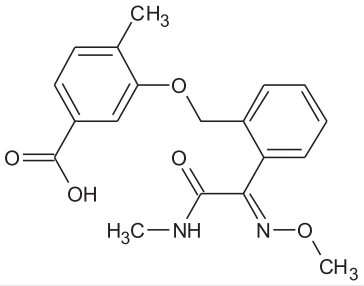
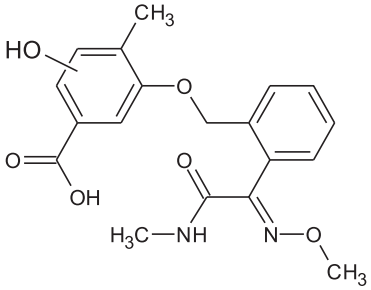
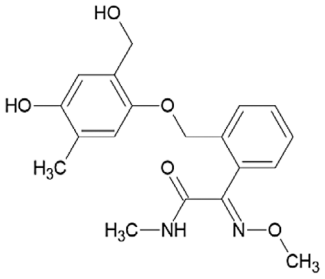
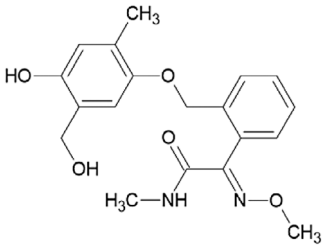
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.
(a): For laboratory soil incubations, normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

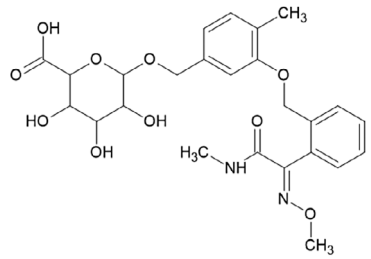
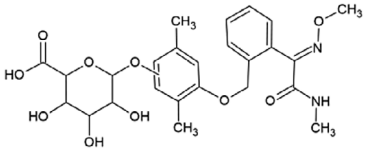
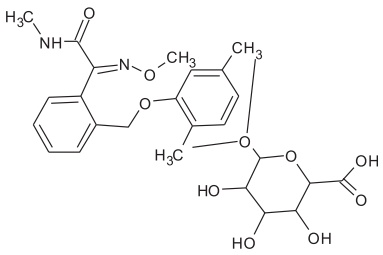
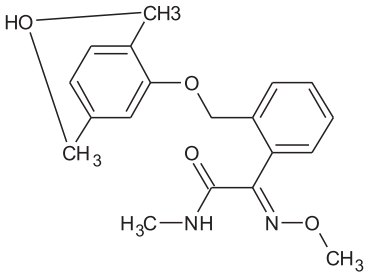
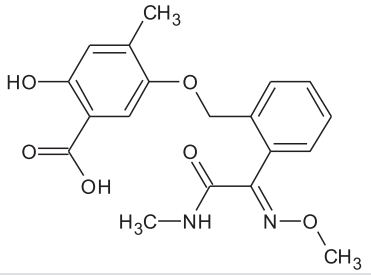
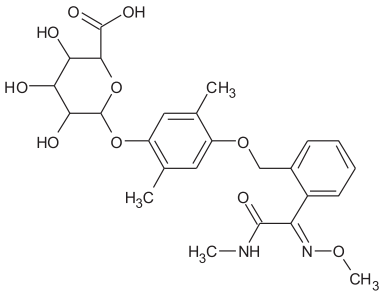
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2,000
Slight mobility	2,001–5,000
Immobile	> 5,000

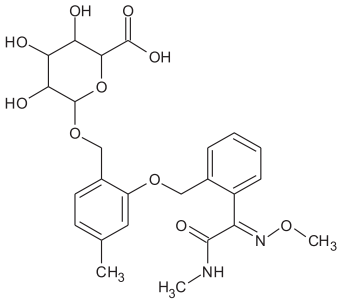
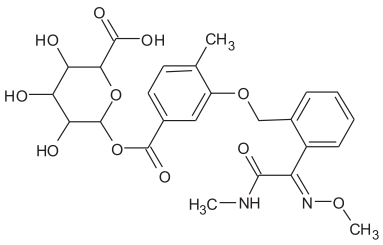
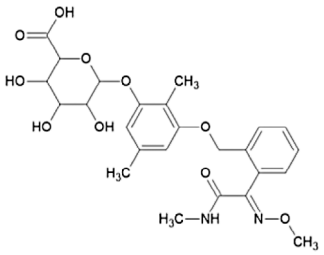
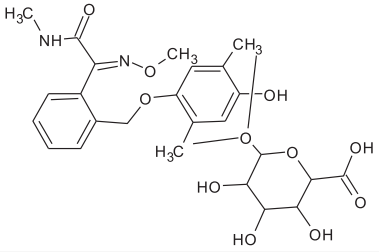
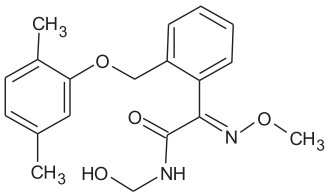
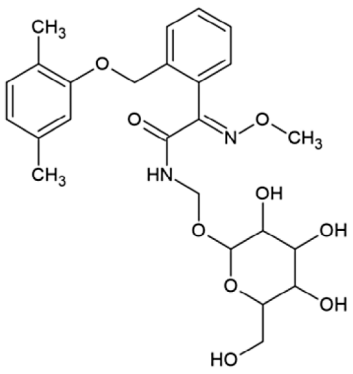
Based on McCall et al. (1980).

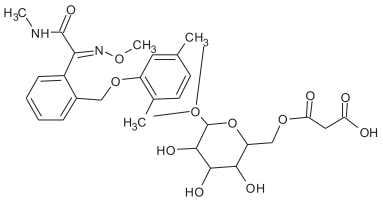
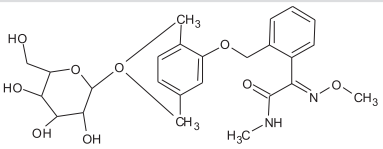
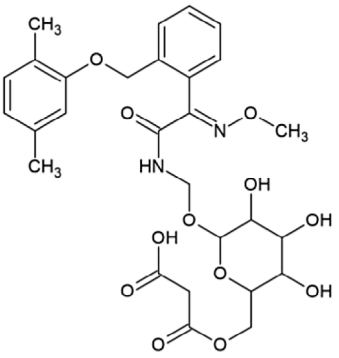
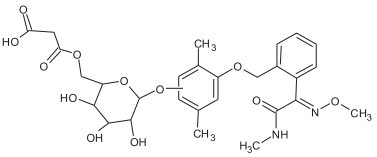
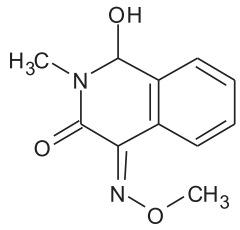
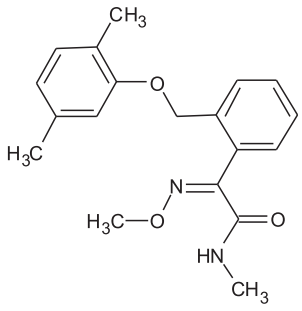
Appendix D – Used compound codes

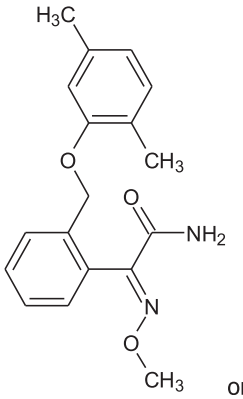
Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Dimoxystrobin	(2*E*)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-N-methylacetamide CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)ccc1C WXUZAHCNPWONDH-DYTRJAOYSA-N	
Boscalid	2-chloro-N-(4′-chlorobiphenyl-2-yl)pyridine-3-carboxamide O=C(Nc1ccccc1c1ccc(Cl)cc1)c1cccnc1Cl WYEMLYFITZORAB-UHFFFAOYSA-N	
505M01 BF 505-4 M505F001	(2*E*)-2-[2-(hydroxymethyl)phenyl]-2-(methoxyimino)-N-methylacetamide OCc1ccccc1/C(=N\OC)C(=O)NC XJIRPXWWLNGHSS-JLHYYAGUSA-N	
505M02	(2*E*)-2-{2-[(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-*N*-methylacetamide CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)c(O)cc1C ICVNEAGHTDPIRM-DYTRJAOYSA-N	
505M03	(2*E*)-2-(2-{[2-(hydroxymethyl)-5-methylphenoxy]methyl}phenyl)-2-(methoxyimino)-*N*-methylacetamide CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)ccc1CO WVOTVVNGUPJGGI-DYTRJAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
505M08 BF 505-7 M505F008	2-({2-[(1*E*)-*N*-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-4-methylbenzoic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)ccc1C(=O)O VVBFFEYXSJKVET-HEHNFIMWSA-N	
505M09 BF 505-8 M505F009	3-({2-[(1*E*)-*N*-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-4-methylbenzoic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(ccc1C)C(=O)O RKECPZYSBKSRJM-HEHNFIMWSA-N	
505M33 and aglycon of 505M33	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M47	(2E)-2-(2-{[4-hydroxy-2-(hydroxymethyl)-5-methylphenoxy]methyl}phenyl)-2-(methoxyimino)-N-methylacetamide CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)c(O)cc1CO KXAJIFJGLZBIDE-DYTRJAOYSA-N	
505M48	(2E)-2-(2-{[4-hydroxy-5-(hydroxymethyl)-2-methylphenoxy]methyl}phenyl)-2-(methoxyimino)-N-methylacetamide CNC(=O)\C(=N\OC)c1ccccc1COc1cc(CO)c(O)cc1C QVYXROKIHCASJA-DYTRJAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
505M49	[3-({2-[(1E)-N-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-4-methylphenyl] methyl hexopyranosiduronic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(COC2OC(C(O)C(O)C2O)C(=O)O)ccc1C ZJKVZJHUTRDZHR-OVVQPSECSA-N	
505M50	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M51	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M63 (M505F063)[d]	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M76	2-hydroxy-5-({2-[(1*E*)-*N*-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-4-methylbenzoic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(c(O)cc1C)C(=O)O AUAVCNJVDDPJIJ-HEHNFIMWSA-N	
505M78	4-({2-[(1*E*)-*N*-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-2,5-dimethylphenyl hexopyranosiduronic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)c(OC2OC(C(O)C(O)C2O)C(=O)O)cc1C VZLCFDLOJGDZFZ-OVVQPSECSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
505M79 (glucuronide conjugate of 505M03)	[2-({2-[(1*E*)-*N*-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-4-methylphenyl] methyl hexopyranosiduronic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)ccc1COC1OC(C(O)C(O)C1O)C(=O)O CYGPEJWZLVJUKQ-OVVQPSECSA-N	
505M81 (glucuronide conjugate of 505M09)	1-*O*-[3-({2-[(1*E*)-*N*-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-4-methylbenzoyl] hexopyranuronic acid O=C(OC1OC(C(O)C(O)C1O)C(=O)O)c1ccc(C)c(OCc2ccccc2C(=N\OC)/C(=O)NC)c1 MUMXFZDWRJJYFQ-WPWMEQJKSA-N	
505M84	3-({2-[(1E)-N-methoxy-2-(methylamino)-2-oxoethanimidoyl]phenyl}methoxy)-2,5-dimethylphenyl hexopyranosiduronic acid CNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)cc(OC2OC(C(O)C(O)C2O)C(=O)O)c1C SRIKQKWBTCNGLN-OVVQPSECSA-N	
505M86	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M88	(2*E*)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-*N*-(hydroxymethyl)-2-(methoxyimino)acetamide OCNC(=O)\C(=N\OC)c1ccccc1COc1cc(C)ccc1C VLFCVNAQVOXVSB-DYTRJAOYSA-N	
505M89	(2E)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-N-[(hexopyranosyloxy)methyl]-2-(methoxyimino) acetamide Cc1cc(OCc2ccccc2/C(=N\OC)C(=O)NCOC2OC(CO)C(O)C(O)C2O)c(C)cc1 AHAHTFLDNJECBR-NHFJDJAPSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
505M91	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M93	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M94	{[(2E)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)acetyl]amino}methyl 6-O-(carboxyacetyl)hexopyranoside Cc1cc(OCc2ccccc2/C(=N\OC)C(=O)NCOC2OC(COC(=O)CC(=O)O)C(O)C(O)C2O)c(C)cc1 UTVRKHMYXRNATA-JJKYIXSRSA-N	
505M95	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
505M96 M505F096	(4*E*)-1-hydroxy-4-(methoxyimino)-2-methyl-1,4-dihydroisoquinolin-3(2*H*)-one O=C1\C(=N\OC)c2ccccc2C(O)N1C RVPXDOSJHGHSKY-FMIVXFBMSA-N	
505M098	(2*Z*)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-*N*-methylacetamide CNC(=O)/C(=N\OC)c1ccccc1COc1cc(C)ccc1C WXUZAHCNPWONDH-UZYVYHOESA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
(M505F108)[d]	(2*E*)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)acetamide NC(=O)\C(=N\OC)c1ccccc1Coc1cc©ccc1C RAVZLEBNRHEGFV-LVZFUZTISA-N	 or isomer

(a): The name in bold is the name used in the conclusion. In addition, metabolites without bold font appear in the list of endpoints in Appendix B.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).
(d): See data requirement 2.1 in the mammalian toxicology evaluation table (EFSA, 2023).