Approved: 28 January 2025

DOI: 10.2903/j.efsa.2025.9257

CONCLUSION ON PESTICIDES PEER REVIEW

efsa JOURNAL

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

European Food Safety Authority (EFSA) | Fernando Álvarez | Maria Arena | Domenica Auteri | Sofia Batista Leite | Marco Binaglia | Anna Federica Castoldi | Arianna Chiusolo | Angelo Colagiorgi | Mathilde Colas | Federica Crivellente | Chloe De Lentdecker | Isabella De Magistris | Mark Egsmose | Gabriella Fait | Franco Ferilli | Monica Fittipaldi Broussard | German Giner Santonja | Varvara Gouliarmou | Katrin Halling | Alessio Ippolito | Frederique Istace | Samira Jarrah | Dimitra Kardassi | Aude Kienzler | Anna Lanzoni | Roberto Lava | Renata Leuschner | Alberto Linguadoca | Jochem Louisse | Christopher Lythgo | Oriol Magrans | Iris Mangas | Andrea Mioč | Ileana Miron | Tunde Molnar | Laura Padovani | Vincenzo Padricello | Martina Panzarea | Juan Manuel Parra Morte | Alexandra Piti | Simone Rizzuto | Anamarija Romac | Agnès Rortais | Miguel Santos | Rositsa Serafimova | Rachel Sharp | Csaba Szentes | Anne Theobald | Manuela Tiramani | Giorgia Vianello | Laura Villamar-Bouza

Correspondence: pesticides.peerrevieew@efsa.europa.eu

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

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Germany and co-rapporteur Member State Hungary for the pesticide active substance pyraclostrobin and the assessment of applications for maximum residue levels (MRLs) are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of pyraclostrobin as a fungicide and plant growth regulator on cereals (wheat, barley, oats, rye, triticale), maize (forage and grain) and potatoes. MRLs were assessed in sweet corn and fish. 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 reported where identified.

KEYWORDS

fungicide, MRL Article 10, peer review, pesticide, plant growth regulator, pyraclostrobin, risk assessment

CONTENTS

SUMMARY

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

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Germany and co-rapporteur Member State (co-RMS), Hungary, received an application from BASF SE for the renewal of approval of the active substance pyraclostrobin. In addition, BASF SE submitted applications for maximum residue levels (MRLs) for sweet corn and fish, as referred to in Article 7 of Regulation (EC) No 396/2005.

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

The uses of pyraclostrobin according to the representative uses as a fungicide and plant growth regulator on cereals (wheat, barley, oats, rye, triticale), maize (forage and grain) and potatoes, as proposed at EU level, result in a sufficient efficacy.

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

With regard to the mammalian toxicology section, no critical area of concern or issue not finalised were identified on the basis of the available data.

Regarding the residue section, the residue definitions for plant and animals are subject to a data gap for toxicity profile for metabolite 500M07 leading to the consumer dietary risk assessment not finalised. The MRL requests for sweet corn and fish were fully supported by the available data.

In the area of environmental fate and behaviour information is missing regarding the surface water and sediment exposure assessments for the aqueous photolysis metabolites BF 500-15 and 500M58. A data gap was also identified for information on the effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface water, when surface water is abstracted for drinking water. This gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses.

High risk was concluded for mammals for the representative uses to cereal and maize (with the exception of the cereal uses in the central zone, for which a low risk to mammals has been identified). Risk mitigation measures need to be implemented to reach low risk to aquatic organisms for the use in potatoes. For aquatic invertebrates, high risk was reached for the representative uses to cereal and maize even considering suitable mitigation measures. The risk assessment to several aquatic metabolites could not be finalised.

Regarding to the endocrine disrupting properties, it could be concluded that pyraclostrobin does not meet the ED criteria as laid down in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

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 Germany and co-RMS Hungary received an application from BASF SE for the renewal of approval of the active substance pyraclostrobin. 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] Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Hungary), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on pyraclostrobin in the RAR, which was received by EFSA on 19 February 2018 (Germany, 2018). The RAR included a proposal to set MRLs, submitted under Article 7 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 10 July 2018. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 9 September 2018. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS and the co-RMS on 6 May 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, residues, environmental fate and behaviour, and ecotoxicology.

In addition, following a consultation with Member States in the Pesticides Peer Review Expert meeting 24 (February 2020), it was considered necessary to apply an additional clock stop of 22 month in accordance with Commission Implementing Regulation (EU) No 2018/1659, to be able to conclude whether the approval criteria for endocrine disruption in line with the scientific criteria for the determination of endocrine disrupting properties, as laid down in Commission Regulation (EU) 2018/605,[5] are met.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposed MRLs took place with the RMS in June 2023 and then with all Member States via a written procedure in September–November 2024.

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

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

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

[4]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, p. 1–16.

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

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation, evaluated on the basis of the representative uses of pyraclostrobin as a fungicide and plant growth regulator on cereals (wheat, barley, oats, rye, triticale), maize (forage and grain) and potatoes, 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 for sweet corn and for fish.

A list of the relevant end points for the active substance and the formulation for representative uses and the proposed MRLs is provided in Appendix B.

A key supporting document to this conclusion is the peer review report (EFSA, 2025), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting tables (10 May 2019 and 21 November 2022[6]);
- the evaluation table (9 December 2024);
- 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 revisions (including the Addendum to the RAR assessing the MRL application form) (Germany, 2024), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

THE ACTIVE SUBSTANCE AND THE FORMULATION FOR REPRESENTATIVE USES

Pyraclostrobin is the ISO common name for methyl 2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy}methyl)-*N*-methoxycarbanilate (IUPAC).

The formulated products for the representative uses in the context of the evaluation were 'BAS 500 06 F' an emulsifiable concentrate (EC) containing 200 g/L pyraclostrobin and 'BAS 516 07 F' water-dispersible granules (WG) containing 67 g/kg pyraclostrobin and 267 g/kg boscalid (for which the peer review for the renewal of the approval is ongoing).

The information on the active substances and the formulations for representative uses, including the co-formulants in these formulations, was considered in the overall assessment during the peer review. For BAS 500 06 F one of the components of co-formulants is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009[7] (below the level set in Regulation (EU) 2021/383 paragraph (14) for acceptable unintentional impurity), two components of co-formulants are not approved active substances under Regulation (EC) 1107/2009.[8] For BAS 516 07 F one of the components of a co-formulant is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009 (below the level set in Regulation (EU) 2021/383 paragraph (14) for acceptable unintentional impurity), one component of a co-formulant is an approved active substance, one co-formulant and three components of co-formulants are not approved active substances under Regulation (EC) 1107/2009. Details on the composition of the formulations cannot be reported in conclusions because of the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009, however this information was fully available and evaluated during the peer review. A proposal for classification of the formulations according to the Regulation (EC) 1272/2008 was provided by the applicant and assessed by the RMS (please see Volumes 3 CP of the RAR).

The representative uses evaluated for 'BAS 500 06 F' were broadcast foliar spray applications for control of a broad range of pathogens causing fungal diseases in cereals (wheat, barley, oats, rye, triticale) and maize (forage and grain) and for some beneficial physiological effects on the same crops (e.g. a reduction of nonparasitic leaf spots in cereals and delay senescence and improving of the total greenness of the crop towards the end of the growing season in maize). The representative uses evaluated for 'BAS 516 07 F' was broadcast foliar spray application for control of *Alternaria* spp. on potatoes. Full details of the GAPs can be found in the list of end points in Appendix B.

Data were submitted to conclude that the use of pyraclostrobin according to the representative uses proposed at EU level results in a sufficient fungicidal and plant growth regulator efficacy, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

[6]Reporting table following consultation on the revised RAR on the assessment of the endocrine-disrupting properties made available after the 22-month clock stop.

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

[8]Please see Regulation (EC) No 1107/2009 for acceptability criteria for co-formulants and Section 2.13.6 of the Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. EFSA Supporting Publications, 2019, EN-1623. https://doi.org/10.2903/sp.efsa.2019.EN-1623.

CONCLUSIONS OF THE EVALUATION

General Aspects

With regard to the mammalian toxicity information available for the formulation for representative uses 'BAS 500 06 F', studies were performed for the acute toxicity endpoints. With regard to the co-formulants contained in 'BAS 500 06 F', sufficient toxicological data were available for all components, but one (present in significant amount in the final formulation). For this co-formulant, the available toxicological information does not sufficiently address the genotoxicity, short- and long-term toxicity of 'BAS 500 06 F' and this might be considered for further assessment (see Section 10). It is noted that another co-formulant present in significant amount was identified as a photoirritant compound.

Regarding the mammalian toxicity information available for the formulation for the representative uses'BAS 516 07 F', studies were performed for the acute toxicity and genotoxicity endpoints. With regards to the co-formulants contained in'BAS 516 07 F', sufficient toxicological data were available for all components, but three (present in significant amount in the final formulation). For one co-formulant, insufficient information about its specification/composition was available and for these three co-formulants the available toxicological information is insufficient to address the genotoxicity and/or repeated-dose toxicity potential of 'BAS 516 07 F' over the short- and long-term and they might be considered for further assessment (see Section 10).

The collected information (not covering all endpoints), including the existing uses other than plant protection products, under regulated EU frameworks, did not highlight any additional concern.

Suitable ecotoxicity data were available for the assessment of non-target organisms according to the requirements of Regulation (EU) No 284/2013.[9] No chronic data with the formulations for representative uses were available except for algae, earthworms and soil macroorganisms. Based on the available toxicity data, it is noted that the formulations for representative uses are not acutely more toxic than the active substance. For those groups of organisms for which chronic data were not available, available data for the individual components of the formulations for representative uses were retrieved. Data on single components were in general limited with the exception of one of the components of the formulation 'BAS 516 07 F' which is an active substance. Nevertheless, from the available datasets no concerns were identified for non-target organisms other than mammals. However, pending on the outcome on the data gap identified in mammalian toxicology for several components of the formulations for representative uses as described in previous paragraphs, further consideration to non-target organisms may be necessary.

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

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

The proposed specification for pyraclostrobin is based on batch data from industrial plant production and quality control data. The proposed minimum purity of the technical material is 980 g/kg. Toluene and dimethyl sulfate are considered as relevant impurities with a maximum content of 8 g/kg and 0.001 g/kg, respectively. Based on data submitted for the renewal, an update of the reference specification is proposed (i.e. higher minimum purity of the active substance, new relevant impurity (toluene) and some changes for the significant impurities). The batches used in the mammalian toxicological assessment support the updated reference specification but not the original one (see Section 2). Batches used in the ecotoxicological assessment are in compliance with proposed updated reference specification (see Section 5). There is no FAO specification available for pyraclostrobin.

The main data regarding the identity of pyraclostrobin and its physical and chemical properties are given in Appendix B. A data gap was set for the partition coefficient *n*-octanol–water (log P_{OW}) for some of the components of the residue definitions for risk assessment (for the environmental compartments) (see Section 10).[10]

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

Pyraclostrobin residues can be monitored in food and feed of plant origin by liquid chromatography with tandem mass spectrometry (LC–MS/MS) with limit of quantification (LOQ) of 0.02 mg/kg in each commodity group. However, matrix effects were not investigated, therefore a data gap was set (see Section 10). The RMS disagreed with this data gap. The efficiency of the extraction procedure used in the method for commodities with high-water and high-acid content and for dry crops was demonstrated. Extraction efficiency for commodities with high-oil content was not addressed because of lack of metabolism study in these commodities (not required considering the representative uses). Pyraclostrobin residues in food/feed of animal origin can be determined by LC–MS/MS with LOQ of 0.01 mg/kg in all animal matrices.

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

[10]See Data requirement 1.4 of the Evaluation table (EFSA, 2025).

Pyraclostrobin residues in soil and water can be monitored by LC–MS/MS with LOQs of 0.001 mg/kg and 0.003 µg/L, respectively. LC–MS/MS method exists for monitoring of pyraclostrobin residues in air with a LOQ of 0.5 µg/m^3.

LC–MS/MS method can be used for monitoring of pyraclostrobin residues in body fluids (blood) with 0.01 mg/L. Residue of metabolite 500M106 in body fluids can be monitored by LC-HRMS with a LOQ of 0.05 mg/L, however a confirmatory method is missing (data gap, see Section 10). It was decided that also metabolite 500M104/500M46 should be monitored in body fluids for which there is not a validated method (data gap, see Section 10). Pyraclostrobin residue in body tissues can be determined by using the monitoring methods for residue in food of animal origin.

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance pyraclostrobin and its metabolites was discussed at the Pesticides Peer Review Experts' meeting 22 in January 2020. The following guidance documents were followed in the production of this conclusion: European Commission (2003, 2012), EFSA (2014b), EFSA PPR Panel (2012) and ECHA (2017).

In the technical specifications, toluene and dimethyl sulfate are identified as relevant impurities, however they are of no concern at the specified levels (8 g/kg and 0.001 g/kg, respectively). The new proposed reference specification (and not the current reference specification) with minimum purity of 980 g/kg is considered covered by batches used in the toxicity studies. The analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicity studies are overall considered fit-for-purpose/validated.

Oral absorption of pyraclostrobin is 50%, based on urinary and biliary excretion in rat metabolism studies. Pyraclostrobin is widely distributed with highest concentrations in gastrointestinal tract (GIT) and liver, with no evidence for bioaccumulation. It is rapidly and extensively metabolised, mainly via faeces including biliary excretion, forming a large number of metabolites individually accounting for only a small percentage of the applied dose.

Based on the comparative in vitro metabolism study in human, rat, dog and rabbit cells, two metabolites (500M02 and 500M106) were only found in human and rabbit (see below) and their (geno)toxicity profile has been considered covered by the parent (see below).

The residue definition for body fluids (for human monitoring purposes) includes pyraclostrobin and the metabolites 500M106 and 500M104/500M46 (see also Section 1 for the analytical methods).

With regard to acute toxicity, pyraclostrobin has the following harmonised classification[11]: harmful if swallowed (Category 4), toxic by inhalation (Category 3), causes skin irritation (Category 2) and may cause respiratory irritation after single exposure (STOT SE 3) based on human data. It is not irritating to the eyes and not a skin sensitiser. Pyraclostrobin has not been shown to be phototoxic in the 3T3 NRU-PT test (OECD TG 432).

For the overall short-term oral toxicity, the no observed adverse effect level (NOAEL) is 6 mg/kg bw per day based on effects on food intake, body weight, clinical chemistry and haematological changes and clinical signs observed in both 90-day and 1-year dog studies as well as effects on duodenal mucosa observed in the 90-day dog study. The NOAEL by inhalation is 0.9 mg/kg bw per day, calculated on the basis of a NOAEC of 3 mg/m^3 in the 28-day rat study, based on systemic effects in the blood, spleen and duodenum. Pyraclostrobin is also classified STOT RE 2[12] based on effects in liver, gastrointestinal tract and the nasal cavity through prolonged or repeated exposure.

Pyraclostrobin is negative for gene mutations in bacterial and mammalian cells and in an in vitro chromosome aberration test in mammalian cells. It is positive in a non-guideline in vitro micronucleus assay in human lymphocytes but negative in a guideline in vitro micronucleus assay in human lymphocytes (OECD TG 487) as well as in an in vivo micronucleus assay in mouse bone marrow, with proof of tissue exposure. Based on this, pyraclostrobin is concluded as unlikely to be genotoxic.

In rat, the long-term toxicity NOAEL is 3.4 mg/kg bw per day based on effects on body weight, reduced food consumption and liver effects in the 2-year studies. No evidence for carcinogenicity was observed up to 9.2 mg/kg bw per day. In mouse, the long-term toxicity NOAEL is 4.1 mg/kg bw per day, based on effects on body weight with no evidence for carcinogenicity up to 17.2 mg/kg bw per day.

In the two-generation reproductive toxicity study in rat, the parental NOAEL is 8.2 mg/kg bw per day based on reduced food consumption and body weight (gain) and supported by an increase in relative kidney weight in F0 and F1 males. The reproductive NOAEL is 32.5 mg/kg bw per day (highest tested dose). The offspring NOAEL is 8.2 mg/kg bw per day based on reduced body weight gain in F1 and F2 pups and supported by delayed vaginal opening (F1 only). With regard to teratogenicity studies, the maternal NOAEL in rat is 10 mg/kg bw per day based on reduced food consumption and body weight gain; the developmental NOAEL is 25 mg/kg bw per day based on increase in soft tissue (urogenital tract) and skeletal variations. In rabbit, the overall maternal NOAEL is 3 mg/kg bw per day based on reduced food consumption and body weight gain; the overall developmental NOAEL is 5 mg/kg bw per day based on increased post-implantation losses/early resorptions. It is noted that pyraclostrobin has a harmonised classification for developmental toxicity (Category 2)[13] based on the observed developmental findings in rabbit pups.

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

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

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

Pyraclostrobin did not show evidence of adverse effect on the immune system in the specific study in mice or in other available studies. For neurotoxicity, no specific effects were observed in acute and repeated-dose studies.

The **acceptable daily intake** (ADI) is established at 0.03 mg/kg bw per day, based on the NOAEL for systemic toxicity from the long-term/carcinogenicity studies in rats and on the maternal NOAEL from the developmental toxicity study in rabbit, and using an uncertainty factor (UF) of 100 (same ADI as set by European Commission, 2004).

The **acute reference dose** (ARfD) is established at 0.03 mg/kg bw, based on the maternal NOAEL in the developmental toxicity study in rabbit, and applying an UF of 100 (same ARfD as set by European Commission, 2004).

The systemic **acceptable operator exposure level** (AOEL) is established at 0.015 mg/kg bw per day, based on the maternal NOAEL from the developmental toxicity study in rabbit and supported by the NOAEL in the 90-day rat neurotoxicity study, applying the UF of 100 and a correction for oral absorption value of 50% (same AOEL as set by European Commission, 2004).

The **inhalation AOEL** is established at 0.009 mg/kg bw per day, based on the systemic NOAEC of 3 mg/m^3 converted to mg/kg bw from the subacute 28-day inhalation study in rats and applying the UF of 100. No inhalation AOEL was established previously.

The **acute AOEL** (AAOEL) is established at 0.015 mg/kg bw, on the same basis as the ARfD, applying the UF of 100 and a correction for oral absorption value of 50%. No AAOEL was established previously.

The **inhalation AAOEL** is established at 0.009 mg/kg bw, on the same basis as the inhalation AOEL and applying the UF of 100. No inhalation AAOEL was established previously.

Toxicological studies and information have been provided for several pyraclostrobin metabolites (see also Appendix B). Genotoxic potential could be excluded for the plants and livestock metabolites **500M04** (and its glycoside **500M55**), **500M24**, **500M49**, **500M51** and for the human/rabbit in vitro metabolites **500M02** and **500M106**. For metabolite **500M04** an ADI of 0.1 mg/kg bw per day was established based on the 90-day rat study, using an UF of 100 and an additional factor of 10 (for limited database). For metabolites **500M02** and **500M106**, reference values of the parent substance may apply. For the other metabolites (including among others, **500M54, 500M07** (covering also **500M67, 500M64** and related glycosides), **500M66** and **500M85** no data were available for genotoxicity and general toxicity (see Sections 3 and 9.1.1).

The **dermal absorption** values for pyraclostrobin in the formulation 'BAS 500 06 F' are 3% for concentrate, 6% for the 1:200 dilution and 7% for the 1:400 dilution. The dermal absorption values for pyraclostrobin in the formulation 'BAS 516 07 F' are 0.2% for the concentrate (1:2 dilution), 5% for the 1:150 dilution and 4% for the 1:600 dilution. The dermal absorption values for boscalid in the formulation 'BAS 516 07 F' are 0.3% for the concentrate (1:2 dilution), 2% for the 1:150 dilution and of 4% for the 1:1200 dilution.

The **non-dietary exposure** estimates for the operators are below the (A)AOEL with the use of gloves during mixing/loading and application for the use on cereals, and without use of gloves (only standard workwear) for the use on potatoes. For the workers, residents and bystanders, the predicted exposure estimates are below the (A)AOEL without particular risk mitigation measure for both formulations. In addition, the combined exposure to pyraclostrobin and boscalid in the product 'BAS 516 07 F' does not raise any concern (based on the sum of hazard quotients).

3 | RESIDUES

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

Pyraclostrobin was discussed at the Pesticides Peer Review Experts' meeting 23 in January 2020.

3.1 | Representative use residues

Metabolism was studied in grape (fruit), wheat and paddy rice (cereals/grass crop), Chinese cabbage (leafy crop) and potato (tuber crop) after foliar treatment and in wheat upon seed treatment. The valid studies were GLP and guideline compliant, employed two different label positions (tolyl-^{14}C and chlorophenyl-^{14}C) and covered the critical GAP conditions for the representative uses. After foliar treatment pyraclostrobin is intensively metabolised to numerous minor metabolites but it remains the predominant residue (at least 8% TRR or 0.034 mg eq/kg in wheat grain) in all investigated plant parts. The only other major residue common to all plant parts is metabolite 500M07. Toxicity data have not been submitted (see Section 2). Based on the high exposure potential via grape fruits (2.9% TRR; 0.045 mg eq/kg) for which uses are authorised in EU (EFSA, 2011) but which there is not a representative use in this assessment, it is suggested to investigate the genotoxic potential of metabolite **500M54**. As the metabolism is similar in all four investigated crop categories both for foliar and seed treatment, a general **plant residue definition for risk assessment (provisional)** applicable to foliar and seed treatment is set as pyraclostrobin and its metabolite 500M07. The expression is provisional pending on the toxicity profile for metabolite **500M07** (see Section 2 and also Section 9.1.1). Three new studies with Chinese cabbage, paddy rice and seed treated wheat revealed the relevance of the metabolite 500M07 for inclusion in the risk assessment residue definition. These new studies, the new data requirements and the currently applicable guidance on metabolism OECD TG 501 differ from those applicable during the previous evaluations (EFSA, 2011). This led to the proposed change of the residue definition. Pyraclostrobin was recovered in all edible parts and is considered as good marker and therefore confirmed as **plant residue definition for enforcement purposes**. In a valid confined rotational crop study, covering the maximal seasonal rate and the plateau of the persistent soil metabolites 500M01 and 500M02, the absolute levels of radioactivity in edible commodities reached from 0.02 mg/kg in leafy crops to 0.09 mg/kg

in cereals and consisted mainly of parent and 500M07. Therefore, the **plant residue definition** is also applicable to **rotational crops**. To support the representative uses, a sufficient number of valid residue field trials for all representative uses and covered by storage stability data was presented. The stability of pyraclostrobin was investigated and confirmed under standard hydrolysis conditions. A non-standard hydrolysis study intended to mimic the conditions for the oil processing (deodorisation) was also presented and was found supportive. 500M07 was formed under harsh conditions (190°C and 12 bar) indicating that it would be similarly stable as parent under less severe standard hydrolysis conditions. Therefore, a separate study for the metabolite is not necessary. The **residue definition for processing** is proposed as pyraclostrobin. Processing factors for cereal were derived from valid residue trials for pyraclostrobin and the sum of pyraclostrobin and 500M07 awaiting the finalisation of the plant residue definition. Given the residues were below LOQ in potato, no processing studies are required.

The dietary burden calculation exceeds the trigger for metabolism studies for all livestock categories and for fish. Valid metabolism studies were conducted in poultry and ruminants with tolyl-^{14}C and chlorophenyl-^{14}C labelled pyraclostrobin. The dose rate of the studies covers the estimated dietary burden with respect to the representative uses. Plateau was reached in milk 4 days after the first dose, but not in eggs. Pyraclostrobin metabolised extensively but was still recovered in all matrices except poultry liver. The plant metabolite **500M07** was present in all tissues and egg but it was major only in fat. Among several other minor metabolites, the three metabolites **500M66, 500M67 and 500M85**, were detected in edible matrices. It is noted that they are not reported to occur in rats and no toxicological information is available for them. Using the common moiety analytical method, 500M66 and 500M67 will be converted to and analysed as 500M85. The metabolites **500M24, 500M49 and 500M51**, which contain the tolyl moiety and for which a genotoxicity potential is unlikely, are not covered by this analytical method. However, their contribution to overall exposure is considered low. A supportive in vitro study showed that pyraclostrobin is qualitatively similarly metabolised by liver microsomes of cow and goat. However quantitative differences were observed with goat samples exhibiting higher rate of metabolic activity. In the light of the available data the **residue definition for risk assessment for poultry and ruminant** matrices is pyraclostrobin and its metabolites analysed as 500M04 and 500M85, sum expressed as pyraclostrobin. This is in line with the residue definition set under Article 12 procedure as 'sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin' (EFSA, 2011). The latter allows more flexibility with regard to the analyte measured by a common moiety method. This should be regarded as **provisional** pending the toxicity profile for metabolite 500M07 (data gap in Section 2) which is occurring at relevant levels in all matrices and it is a precursor of 500M04. It is assumed that these data on 500M07 can cover also the toxicity of its hydroxylation products, **500M64** and **500M67**, and their glycosides, **500M06 and 500M32**, of which some occur only at levels slightly above 10% TRR in poultry liver and fat. As the parent molecule is occurring in all matrices (except for poultry liver which is less relevant as food item), it is considered as a good marker and the **animal residue definition for enforcement purposes** is set as pyraclostrobin. A separate metabolism study with 500M07 was not presented. As it is a precursor of several other metabolites occurring also in animals, separate feeding studies are in principle not deemed necessary. However, this will be subject to the outcome of toxicological studies on 500M07 and the expression of the plant residue definition. In addition to a bioaccumulation and metabolism study via aqueous treatment of bluegill sunfish (see Section 5), a recent GLP compliant fish metabolism study was available (see Section 3.2). Parent was the predominant residue and the only identified metabolite, **500M89**, occurred in very low level. The **residue definition for risk assessment and enforcement for fish** is proposed as pyraclostrobin. As the fish study is highly overdosed, residues in fish are not expected and a feeding study is not necessary.

Valid feeding studies with poultry and ruminants are available to derive MRLs. Analysis of the egg and hen tissue samples were carried out with a valid common moiety method covering pyraclostrobin and 500M77, a 1-(4-hydroxy-3-chlorophenyl) moiety containing poultry specific metabolite, which were hydrolysed to 500M04 and 500M85, respectively, and measured in addition to pyraclostrobin. No quantifiable residues were found at all dose groups. A study investigating the residues in honey and bee products upon application to sunflowers was submitted. The study showed several shortcomings which could lead to the conclusion that the residues of parent and 500M007 (both below LOQ of 0.05 mg/kg) may be incorrectly estimated. Given that the representative uses are on the non-melliferous crops, a further study is not required.

The consumer risk assessment for the representative uses calculated with PRIMo 3.1 is provisional (see Section 9.1.1) and subject to finalisation of the plant residue definition which includes a data gap on the toxicity profile of metabolite 500M07. Also, the consumer risk assessment for drinking water is not finalised (see Section 4). In addition, it is suggested to investigate the genotoxic potential of the metabolite 500M54.

Indicatively the highest TMDI was calculated for the DK child resulting in 9% of the ADI and the highest acute exposure was calculated for potatoes, representing 21% of the ARfD. Exposure to the second active substance, boscalid, in the representative formulation for use on potatoes could not be estimated as no data were present in the RAR. EFSA evaluated the safety of boscalid (EFSA, 2014c) and concluded using PRIMo revision 2 that the highest chronic exposure for boscalid represented 39.6% of the ADI (German children), considering residue levels in primary crops only and 42.9% of the ADI (WHO Cluster diet B) considering both primary crop use and incorporation of residues from previously treated soil. This calculation for boscalid considered all authorised uses including on cereals and potatoes with more conservative GAPs.

3.2 | Maximum residue levels

A MRL application for increasing the MRL of sweet corn and fish has been submitted.

To support this application a sufficient number of valid residue field trials with maize analysing maize at milky stage was provided. The trials were the same ones as discussed under Section 3.1 as the GAP for maize and sweet corn are identical

except that for the use on sweet corn a PHI of 28 days was defined. An increase of the existing MRL (0.04 mg/kg) to 0.09 mg/kg can be proposed.

A recent GLP compliant metabolism study with fish was submitted (see Section 3.1). Rainbow trouts were dosed orally via feed and residues of pyraclostrobin accounted to 0.3 mg/kg representing 93% TRR in fish filet and 0.4 mg/kg representing 73% TRR in fish liver. As the fish study is with 10 mg/kg feed dry matter highly overdosed, residues in fish are not expected and a feeding study is not necessary. On the basis of this metabolism study, MRL in edible fish commodities can be proposed at the LOQ of 0.01 mg/kg.

In the latest reasoned opinions by EFSA (EFSA, 2018, 2019, 2023) when using the existing MRLs with PRIM0 3.1, a slight exceedance of the ARfD in lettuces (103% of the ARfD) and wine grapes (100.4% of ARfD) was observed which is confirmed in this peer review. For the chronic exposure no risk was identified.

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Pyraclostrobin was discussed at the Pesticides Peer Review Experts' TC 11 in January 2020.

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, pyraclostrobin exhibited moderate to medium persistence, forming the major (> 10% applied radioactivity (AR)) metabolites **BF 500–6** (500M01, max. 31% AR) and **BF 500–7** (500M02, max. 13% AR), both exhibiting moderate to very high persistence. Mineralisation of the pyrazole, tolyl and chlorophenyl ring ^{14}C radiolabel to carbon dioxide accounted for 2%–8% AR after 120–180 days. The formation of unextractable residues (not extracted by sodium hydroxide or acetonitrile/water and/or methanol and/or methanol/water) for these radiolabels accounted for 37%–59% AR after 120–180 days. In anaerobic soil incubations pyraclostrobin degraded quickly, forming the major metabolite **BF 500-3** (500M07, max. 96% AR at day 7), which triggered further exposure assessment for the representative use on winter cereals only.[14] Pyraclostrobin and its soil metabolites BF 500-6 and BF 500-7 can be considered immobile in soil. The metabolite BF 500-3 exhibited medium mobility or to be immobile in soil. It was concluded that the adsorption of pyraclostrobin and its soil metabolites BF 500-6 and BF 500-7 was not pH dependent. In satisfactory field dissipation studies carried out at four sites in Germany, two sites in Spain, one site in Sweden, one site in Denmark, one site in Italy and one in the France (spray application to the soil surface on bare soil plots) pyraclostrobin exhibited moderate to very high persistence. Sample analyses were carried out for the parent pyraclostrobin and in four sites also for its metabolites BF 500–6, BF 500–7 and BF 500–3. Under field conditions metabolites BF 500–6 and BF 500–7 exhibited very high persistence in soil, while for metabolite BF 500–3 no reliable endpoints could be derived. Field study DegT50 values were derived following normalisation to FOCUS reference conditions (20°C and pF2 soil moisture) following the EFSA (2014a) DegT50 guidance. The field data endpoints were not combined with laboratory values to derive modelling endpoints for pyraclostrobin, while combined laboratory and field kinetic endpoints for metabolites BF 500–6 and BF 500–7 were used for modelling.

In laboratory incubations in dark aerobic natural sediment water systems, pyraclostrobin exhibited moderate persistence, forming the major metabolites BF 500–3 (max. ca. 66% AR in sediment) and BF 500–6 (max. ca 7% AR in sediment). The unextractable sediment fraction accounted for 54%–62% AR at study end (100 days). Mineralisation of both radiolabels accounted for only 4.1%–4.6% AR at the end of the study. The rate of decline of pyraclostrobin in a laboratory sterile aqueous photolysis experiment was faster compared to that occurred in the aerobic sediment water incubations. Chromatographically resolved components accounting for > 10% AR were: BF 500–11 (max. 45% AR), BF 500–13 (max 17% AR), BF 500–14 (max 21% AR), BF 500–15 (max 27% AR) and 500M58 (max 23% AR). Two irradiated water/sediment studies confirmed the formation of the photodegradates BF 500–11 (max. 11% AR), BF 500 13 (max 15% AR) and BF 500–14 (max 11% AR) in the water phase and BF 500–3 (max. 17% AR) in the sediment. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for the metabolites BF 500–3, BF 500 6, BF 500–7, BF 500–11, BF 500–13 and BF 500–14, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). However, a data gap[15] is identified for PEC values for the photodegradates BF 500–15 and 500M58 (see Sections 5 and 9.1.1). For the active substance pyraclostrobin, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available.[16] The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m and drift reducing nozzles up to 90% being implemented for the drainage scenarios (representing a 91%–93% 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 runoff of mass adsorbed to soil by 95%) being implemented for the run-off scenarios. The SWAN tool (version 4.0.1) was appropriately used to implement these mitigation measures in the simulations. Arithmetically correct PEC surface water values that have drift mitigation greater than 95% (combining buffer zones and nozzles) are available in the RAR but they have not been relied on for this conclusion (and have not been included in Appendix B), as using them contravenes the relevant FOCUS (2007) guidance.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3,[17] with the exception that MACRO model was

[14]See experts' consultation point 4.2 in the report of Pesticides Peer Review Experts' TC 11 (EFSA, 2025).

[15]See data requirement 4.15 in the Evaluation Table – Section 4, Environmental fate and behaviour (EFSA, 2025).

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

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

not run for the Châteaudun scenario (data gap, see Section 10). The potential for groundwater exposure from the representative uses by pyraclostrobin and its soil metabolites BF 500–6, BF 500–7 and BF 500–3 above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. Based on these results, it is unlikely that the PEC groundwater values resulting from simulations with FOCUS MACRO model and the relevant FOCUS Châteaudun scenario will be above the trigger of 0.1 μg/L.

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues of both the active substance and its identified metabolites potentially present in surface water that might be present in surface water, when surface water is abstracted for drinking water. The applicant proposed the use of a dilution factor justified by the fact that this approach was accepted for other active substances. However, the use of dilution factor in isolation is not considered acceptable, unless it is also demonstrated that the substance is stable following water treatment processes. This has led to the identification of a data gap[18] and results in the consumer risk assessment not being finalised (see Sections 3 and 9.1.1).

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix B of this conclusion. A key to the wording used to describe the persistence and mobility of the compounds assessed can be found in Appendix C of this conclusion. PEC for boscalid, included as a second active substance in the formulation for representative uses, and its transformation products are not available, leading to an assessment not finalised (see Section 9.1.1).

5 | ECOTOXICOLOGY

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

Several aspects pertaining to the ecotoxicological risk assessment of pyraclostrobin were discussed at the Pesticides Peer Review Experts' Meeting 24 and its follow-up teleconference held in January/April 2020 and reflected below in the specific sections.

The information to support the compliance of the batches used in the ecotoxicological studies with the updated reference specification was considered sufficient.

The representative formulation 'BAS 516 07 F' contains a second active substance i.e. boscalid. Considering the lack of PECs in waters and soils as stated in Section 4 and a mixture risk assessment considering the two active substances in the formulation has not been presented, an assessment not finalised is identified for the risks related to the uses with this representative formulation (see Sections 3 and 9.1.1). It must be noted that the conclusions reported below related to the uses in potatoes, considered exposure estimates to pyraclostrobin only.

Suitable acute and reproductive data with pyraclostrobin were available for **birds and mammals**. In addition, acute studies were available with the two formulations for representative uses ('BAS 500 06 F' and 'BAS 516 07 F').

The geometric mean of the available acute toxicity studies with **birds** for the active substance was used for the acute risk assessment. Low acute and long-term risk to birds was concluded for all the representative uses for the active substance.

Low acute risk to **mammals** was indicated in the screening step for all the representative uses of pyraclostrobin by using the lower available endpoint with the active substance (LD_{50} in mouse was 450 mg/kg). However, the available acute data with mammals raised a concern on the sensitivity of rat versus mouse when pyraclostrobin is formulated. Available acute data with the formulated product and the same tested species (*Rattus rattus*) showed that pyraclostrobin is more toxic when formulated in line with 'BAS 500 06 F' (i.e. $500 > LD_{50\ \text{formulated product, rat}} < 2000$ mg/kg bw vs. $LD_{50\ \text{active substance, rat}} > 5000$ mg/kg bw); therefore, it is unknown whether the lowest endpoint with the active substance ($LD_{50\ \text{active substance, mouse}} = 450$ mg/kg bw) is protective enough for certain mammalian species when formulated based on the evidence from the mouse acute endpoint. Based on this, experts at the Pesticides Peer Review Experts' meeting 24[19] agreed to present a conservative acute risk assessment for pyraclostrobin-based product 'BAS 500 06 F' as included below. This was not further challenged in the next steps of the process.

Considering the lowest unbounded value from the study with rat and the formulated product, high acute risk to small and large herbivorous mammals was indicated for the uses of 'BAS 500 06 F' following 1 and 2 applications in cereals at the maximum application rate of 250 g a.s. /ha, and to small herbivorous mammals for all the uses in maize and in cereals following two applications with an application rate of 220 g a.s./ha. To refine the acute risk, valid residue decline studies[20] on wheat in the CEU and SEU[21] as well as a body burden model were available and discussed at the Pesticides Peer Review Experts' meeting 24.[22] A refinement of the risk based on the available body burden model was not carried out since it was agreed that the model was not sufficiently validated, and model key parameters were not fully supported.

Based on a refined risk assessment using a specific MAF following new residue data submitted, the acute risk could be considered low to small herbivorous mammals for cereals following 2 applications at 220 g a.s./ha. In addition, for the uses

[18]See data requirement 4.16 in the Evaluation Table – Section 4, Environmental fate and behaviour (EFSA, 2025).

[19]See experts' consultation point 5.3 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

[20]A refined DT_{50} of 3.94 days and 1.74 days in the Southern EU and Central EU were agreed, respectively. Since no residue data were available for the Northern Zone, a refined DT_{50} could not be calculated.

[21]No residue trials were available for the NEU, therefore, a refinement of the MAF by applying a specific DT_{50} could not be possible for the NEU uses.

[22]See experts' consultation point 5.3 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

where the acute TER was marginally less than the trigger, a low acute risk is concluded for small and large herbivorous mammals for the uses on cereals in CEU and SEU owing to the conservative endpoint that was selected for the risk assessment. Overall, for the acute scenario low risk could be concluded to mammals for the uses in potatoes with the formulation 'BAS 516 07 F' and in cereals in the CEU and SEU with the formulation 'BAS 500 06 F'.

The ecotoxicological relevant endpoint for long-term risk assessment for wild mammals was discussed and agreed at the Pesticides Peer Review Experts' meeting 24.[23] A high long-term risk was concluded at the tier 1 to small omnivorous, small and large herbivorous mammals for uses in cereals following 1 and 2 applications with an application rate of 250 g a.s./ha, to small and large herbivorous mammals for the uses on cereals following 2 applications at 220 g a.s./ha and to small herbivorous mammals for the uses in maize. Low long-term risk was concluded to small insectivorous mammals for all representative uses as well as to small omnivorous mammals for the uses on cereals following 2 applications at 220 g a.s./ha and the uses in maize. Likewise, low long-term risk could be concluded for all relevant feeding guilds for uses in potatoes when the risk assessment considers only pyraclostrobin.

For refining the identified risk, appropriate residue data as indicated previously and field effects studies[24] with mammals were available. At the meeting, it was agreed that the available field studies were not suitable for demonstrating low risk in a long-term scenario; therefore, this refinement was not further considered for risk assessment purposes. Overall, low long-term risk to mammals could be concluded for all the uses[25] in potatoes, for all the uses in the central zone in cereals and in maize. For the remaining uses, the long-term risk to mammals remains high. Table 1 summarising the risk assessment for mammals is included below.

TABLE 1 Overview of the risks identified for wild mammals.

	Acute risk assessment LD_{50} = 500 mg prod./kg bw		**Refined acute risk assessment**	**Long-term risk assessment NOAEL = 5 mg a.s./kg bw per day**		**Refined long-term risk assessment**
Uses	**Tier 1**		**Higher tier**	**Tier 1**		**Higher tier**
Cereals 2 × 250 g a.s/ha NEU CEU SEU	Small insectivorous mammals	LR	/	Small insectivorous mammals	LR	/
	Small omnivorous mammals	LR	/	Small omnivorous mammals	**HR**	**HR** for NEU uses LR for CEU uses LR for SEU use
	Small herbivorous mammal	**HR**	**HR** for NEU uses LR for CEU uses* LR for SEU use*	Small herbivorous mammal	**HR**	**HR** for NEU uses LR for CEU uses **HR** for SEU use
	Large herbivorous mammal	**HR**	**HR** for NEU uses LR for CEU uses* LR for SEU use*	Large herbivorous mammal	**HR**	**HR** for NEU uses LR for CEU uses **HR** for SEU use
Cereals 1 × 250 g a.s/ha NEU CEU	Small insectivorous mammals	LR	/	Small insectivorous mammals	LR	/
	Small omnivorous mammals	LR	/	Small omnivorous mammals	**HR**	**HR** for NEU use LR for CEU use
	Small herbivorous mammal	**HR**	**HR** for NEU use LR for CEU use*	Small herbivorous mammal	**HR**	**HR** for NEU use LR for CEU use
	Large herbivorous mammal	**HR**	**HR** for NEU use LR for CEU use*	Large herbivorous mammal	**HR**	**HR** for NEU use LR for CEU use
Cereals 2 × 220 g a.s/ha SEU	Small insectivorous mammals	LR	/	Small insectivorous mammals	LR	/
	Small omnivorous mammals	LR	/	Small omnivorous mammals	LR	/
	Small herbivorous mammal	**HR**	LR for SEU use	Small herbivorous mammal	**HR**	**HR** for SEU use
	Large herbivorous mammal	LR	/	Large herbivorous mammal	**HR**	**HR** for SEU use

[23]See experts' consultation point 5.2 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025). A NOAEL of 5 mg/kg bw per day was agreed based on the effects observed (i.e. increase of post-implantation losses, early/ total resorptions) in a developmental study with rabbit.

[24]See experts consultation point 5.3 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

[25]All uses in potatoes comprises the same use pattern 4x17 g/ha with uses in the NEU, CEU, SEU.

TABLE 1 (Continued)

	Acute risk assessment LD_{50} = 500 mg prod./kg bw		Refined acute risk assessment	Long-term risk assessment NOAEL = 5 mg a.s./kg bw per day		Refined long-term risk assessment
Uses	**Tier 1**		**Higher tier**	**Tier 1**		**Higher tier**
Maize 1 × 200 g a.s/ha NEU CEU SEU	Small insectivorous mammals	LR	/	Small insectivorous mammals	LR	/
	Small omnivorous mammals	LR	/	Small omnivorous mammals	LR	/
	Small herbivorous mammal	**HR**	**HR** for NEU use **HR** for CEU uses **HR** for SEU use	Small herbivorous mammal	**HR**	**HR** for NEU use LR for CEU uses **HR** for SEU use
'BAS 516 07 F' Potatoes 4 × 17 g a.s./ha NEU CEU SEU (for pyraclostrobin only)	Small herbivorous mammal vole at the screening step	LR for using the endpoint for pyraclostrobin	/	Small insectivorous mammals	LR	/
				Small omnivorous mammals	LR	/
				Small herbivorous mammal	LR	/

Abbreviations: HR, high risk; LR, low risk.

*Low risk was concluded, although the TER was slightly below the trigger and considering the conservative assumptions for the selection.

Low risk was concluded to birds and mammals from the exposure to pertinent plant metabolites of pyraclostrobin (i.e. BF 500–3) for all representative uses. The risk from secondary poisoning was triggered for pyraclostrobin and the metabolite BF 500–3 since log Pow is greater than 3. Low acute and chronic risk was concluded for fish-eating and earthworms-eating birds and mammals for pyraclostrobin for all representative uses. Although it is expected that the risk from secondary poisoning from the exposure to additional metabolites of pyraclostrobin would be low, this part of the risk assessment would need to be updated when new information become available (e.g. log Pow for those metabolites for which this information is not currently available (see data gap in Section 10)).

Open literature acute studies and semi-field studies with the **amphibians** *Rana temporaria* and *Bufo bufo* with the representative formulation 'BAS 500 06 F' were available. In addition, acute studies with both species and 'BAS 516 07 F' were available. Other studies conducted with a formulation which is not the representative formulation were also available but considered supportive information. In addition, two generic monitoring field studies conducted in Germany for addressing the behaviour of amphibians in agricultural landscapes were provided. The available information, together with an illustrative risk assessment performed by the RMS, was discussed at the Pesticides Peer Review Experts' meeting 24.[26,27] At the meeting, it was agreed that the available information suggested that amphibians might likely be affected acutely via spray application of pyraclostrobin-containing representative formulations; however, in absence of a risk assessment scheme, a firm conclusion could not be drawn related to the risk to amphibians.

For **aquatic organisms** reliable data for acute toxicity with the active substance were available for fish and for aquatic invertebrates. In addition, toxicity data with the two representative formulations ('BAS 500 06 F' and 'BAS 516 07 F') were available for fish (acute), aquatic invertebrates (acute) and algae. Based on the acute ecotoxicity data, it can be concluded that when formulated in line with the formulations for representative uses, the formulation for representative use does not result in a higher acute toxicity than the technical active substance. Chronic toxicity data with the active substance were available for fish, aquatic invertebrates, algae, aquatic macrophytes and sediment dwelling organisms. Several aspects of the aquatic risk assessment were discussed in the Pesticides Peer Review Experts' meeting 24 with regard to the fish chronic endpoint,[28] the suitability of the endpoint from a mesocosm study[29] and the endpoint derived from a sensitive species distribution (SSD) calculation considering five fish species[30] which was further used for risk assessment purposes.

Low acute risk to fish and aquatic invertebrates could be concluded at FOCUS Step 4 for the uses in potatoes. By considering mitigation measures, low chronic risk could also be concluded to aquatic invertebrates for the uses in potatoes and for algae, sediment dwelling organisms and chronic scenario for fish, the risk was already considered low at FOCUS Step 2. For the uses in maize, low acute and chronic risk to fish and algae could be achieved at FOCUS Step 4 by implementing 10 m vegetative buffer strips (only for fish) and 5 m buffer strips (only for algae) respectively. However, high acute and chronic risk to aquatic invertebrates was concluded for all scenarios (eight out of eight) at FOCUS Step 4 even considering the

[26]See experts' consultation point 5.1 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

[27]See CP BAS 516 07 F and CP BAS 500 06 F for the RMS's illustrative risk assessment where the available endpoints are compared with a simple exposure estimate.

[28]See experts' consultation point 5.5 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

[29]See experts' consultation point 5.6 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

[30]See experts' consultation point 5.4 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025).

highest possible mitigation measures (i.e. 20 m vegetative buffer strips and 50% nozzle reduction). The same situation was observed for aquatic invertebrates for the uses in cereals. High acute and chronic risk was concluded to aquatic invertebrates for all scenarios even including the highest possible mitigation measures (i.e. 20 m vegetative buffer zones and 50% nozzle reduction) for spring cereals following 1 and 2 applications (five out of five water scenarios failing) and for winter cereals following 1 and 2 applications (nine out of nine water scenarios failing) (see Table 8 in Section 9.1.3). A summary of the aquatic risk assessment for the representative uses of pyraclostrobin is presented below (Table 2).

TABLE 2 Overview of the risks identified and the mitigation measures needed for aquatic organisms.

Uses/aquatic taxa	Acute fish (SSD)	Chronic fish (ELS)	Invertebrates acute	Invertebrate chronic	Algae
Winter cereals 1 × 250 g a.s./ha BBCH < 69	LR (10 m vegetative buffer strip)	LR (20 m vegetative buffer strip)	**HR** (9 out of 9 scenarios)	**HR** (9 out of 9 scenarios)	LR (5 m buffer strip)
Winter cereals 2 × 250 g a.s./ha BBCH < 69	LR (10 m vegetative buffer strip)	LR (20 m vegetative buffer strip)	**HR** (9 out of 9 scenarios)	**HR** (9 out of 9 scenarios)	LR (5 m buffer strip)
Spring cereals 1 × 250 g a.s./ha BBCH 25	LR (10 m vegetative buffer strip)	LR (20 m vegetative buffer strip)	**HR** (5 out of 5 scenarios)	**HR** (5 out of 5 scenarios)	LR (5 m buffer strip)
Spring cereals 2 × 250 g a.s./ha BBCH 25	LR (10 m vegetative buffer strip)	LR (20 m vegetative buffer strip)	**HR** (5 out of 5 scenarios)	**HR** (5 out of 5 scenarios)	LR (5 m buffer strip)
Maize 1 × 200 g a.s./ha	LR (10 m vegetative buffer strip)	LR (10 m vegetative buffer strip)	**HR** (8 out of 8 scenarios)	**HR** (8 out of 8 scenarios)	LR (5 m buffer strip)
Potatoes (for pyraclostrobin only) 4 × 17 g a.s./ha	LR[31]	/	LR	LR (10 m vegetative buffer strip)	/

Abbreviations: HR, high risk; LR, low risk; when mitigation measures are needed, this is included in brackets. Likewise, when high risk is identified, the number of scenarios failing is included in brackets.

For sediment dwelling organisms, low chronic risk was achieved at FOCUS Step 3 for all the uses in cereals (winter and spring) and at FOCUS Step 2 for uses in maize. Low chronic risk was concluded at FOCUS Step 1 for macrophytes for all representative uses.

Suitable acute studies with relevant surface water and sediment metabolites (i.e. BF 500–6, BF 500–7, BF 500–3, BF 500–11, BF 500–13, BF 500–14, BF 500–15, 500M58) were available for several metabolite/taxa combination.[32] The risk assessment was conducted only for the surface water compartment for metabolites BF 500–11, BF 500–13, BF 500–14 and only for sediments for the metabolites BF 500–3, BF 500–6 and BF 500–7. For those metabolites for which risk assessment was available, low acute risk could be concluded at different FOCUS Steps without the need of implementing mitigation measures. Although, exposure estimates were available, for the metabolites BF 500–6 and BF 500–7 no ecotoxicity data was available for the organisms living in the water column, risk assessment was not conducted (see Section 9.1.1). For the metabolite BF 500–3, although data were available, the risk assessment for organisms living in the water column was not included in the RAR (data gap, see Section 10). In addition, no PECs estimation was provided for metabolites BF 500–15 and 500M58 (see Section 4), therefore the risk assessment for those metabolites is considered an issue that could not be finalised (see Section 9.1.1).

Acute (oral and contact) data for honey **bees** were available with technical pyraclostrobin and both representative formulations. In addition, chronic studies with adult honey bees and a 22-day study with honey bee larvae were available with technical active substance. Additional studies (i.e. a tunnel study in line with EPPO 170/OECD 75 and field monitoring studies for determining residues in bee relevant matrices) were available. In line with the EU data requirements, when a representative formulation contains more than one active substance (i.e. 'BAS 516 07 F' contains boscalid), further testing with the formulation is necessary (data gap, see Section 10).

Acute studies with technical pyraclostrobin were also available with the bumble bee *Bombus terrestris*. No regulatory toxicity data was available on solitary bees.

Furthermore, specific literature studies for non-*Apis* bees, relevant for the formulation 'BAS 516 07 F' were requested from the applicant but they were not provided since the applicant assessed the papers as not relevant. Nevertheless, the studies were evaluated by the RMS. This data gap is extended for those literature papers on honey bees requested in the framework of the peer-review, but not provided (data gap, see Section 10). Based on the information available in the RAR, the available information suggests the need of further investigating effects of the formulated product on this bee group.

A risk assessment in line with the SANCO guidance on terrestrial ecotoxicology (European Commission, 2002) was available in the RAR. EFSA has also conducted the risk assessment to honey bees for pyraclostrobin in line with the EFSA Bee guidance (EFSA, 2013). Low acute oral and contact risk to honey bees and bumble bees was concluded for all the uses. The same conclusion as the one for honey bees could be reached for the acute scenario by using the SANCO guidance. For the chronic scenario, low risk to honey bee adults and larvae could be concluded for all representative uses for pyraclostrobin parent compound.

[31]Low risk was achieved by using Tier 1 data.

[32]Acute ecotoxicity data were available for fish, aquatic invertebrates and algae for the following metabolites: BF 500-3, BF 500-5, BF 500-11, BF 500-13 and BF 500-14 and for sediment dwelling organisms for the metabolites BF 500-3, BF 500-6 and BF 500-7. It must be noted that BF 500-05 is not considered a relevant aquatic metabolite.

A suitable assessment for accumulative effects was not available for any of the representative uses. In addition, a risk assessment due to the potential occurrence of pyraclostrobin metabolites in pollen and nectar and an assessment of sublethal effects were not available (data gap, see Section 10).

Toxicity data from tier 1 (glass plate) with the standard species *Aphidius rhopalosiphi, Typhlodromus pyri* were available for both representative formulations 'BAS 500 06 F' and 'BAS 516 07 F' to evaluate the risk for **non-target arthropods (NTAs)** other than bees. Moreover, additional tier 1 testing was conducted with other species (*Aleochara bilineata*, *Chrysoperla carnea*, *Poecilus cupreus* and *Pardosa* spp.) and the representative formulation 'BAS 516 07 F' used on potatoes.

Toxicity data from extended laboratory studies for both representative formulations were available with the two standard species and *A. bilineata* and *C. carnea*. In addition, an aged residue study with *C.carnea* was also available.

Tier 1 risk assessment indicated low in-field risk to both indicator species for all the uses on potatoes. By using additional information (i.e. extended lab studies and an aged residue study), low in-field risk was concluded at tier 2 for all the uses in maize and cereals. The off-field risk was considered low for all representative uses.

Chronic toxicity studies were conducted with **earthworms**, **soil meso- and macrofauna** (the collembola *Folsomia candida* and the predatory mite *Hypoaspis aculeifer*) and for soil microorganisms for both representative formulations. Furthermore, chronic toxicity studies with *Eisenia fetida*, *Folsomia candida* and soil microorganisms were provided with two out of the three pertinent soil metabolites (i.e. BF 500–6 and BF 500–7) of pyraclostrobin. For the third pertinent soil metabolite identified (i.e. BF 500–3) (see Section 4), no ecotoxicity data with soil organisms were available. For this metabolite, a screening risk assessment considering that it is 10 times more toxic than the parent pyraclostrobin was considered. Field studies with earthworms were available with the two representative formulations.

Low chronic risk to earthworms, soil meso- and macrofauna and soil microorganisms was concluded for all the uses except for the use of 'BAS 500 06 F' in cereals following two applications with an application rate of 250 g/ha where the trigger of 5 was slightly breached (TER of 4.7). Considering that this TER is slightly below the trigger value of 5 and that the available field studies did not show effects on the earthworms populations, low risk could also be concluded for this use with the formulated product.

In addition, low chronic risk to soil organisms could also be concluded for metabolites BF 500–6 and –7; however, the TERs for the metabolite BF 500–3 for soil macro and mesofauna were below the trigger value (TER of 3.5 and 2.6 for *Folsomia* and *Hypoaspis*, respectively); therefore, it was not possible to conclude low risk for the use of pyraclostrobin in winter cereals following two applications with an application rate of 250 g/ha. Considering that (i) no effects have been seen in soil organisms in those tests conducted with other relevant soil metabolites and (ii) an assumption of 10-times more toxic than the parent in absence of specific data was conducted, a low risk to soil macro and mesofauna could be concluded for metabolite BF 500–3 considering the available evidence and the worst-case assumptions made for risk assessment purposes.

Appropriate ecotoxicity data (i.e. vegetative vigour and seedling emergence tests) were submitted with the representative formulations and the risk to **non-target terrestrial plants** was assessed as low for all the representative uses.

The risk to **organisms involved in sewage treatment processes** was also concluded to be low for all the representative uses of pyraclostrobin.

6 | ENDOCRINE DISRUPTION PROPERTIES

An assessment of the endocrine disruption (ED) potential of pyraclostrobin **for humans and non-target organisms** according to the ECHA/EFSA ED guidance (ECHA/EFSA, 2018) has been available. This assessment was discussed at the Pesticides Peer Review Experts' meeting 22 for Mammalian Toxicology and Pesticides Peer Review Experts' meeting 24[33] and TC 93 for the Ecotoxicology section.

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

The dataset was considered complete in line with the ECHA/EFSA ED guidance and no EATS-mediated adversity was observed. Therefore, scenario 1a is applicable and it can be concluded that pyraclostrobin has no ED potential.

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

For **non-mammalian species**, a fish short-term reproduction assay (FSTRA, OECD TG 229) and a xenopus eleutheroembryonic thyroid assay (XETA, OECD TG 248) were available. The FSTRA did not show any evidence suggesting EAS-mediated endocrine activity. Therefore, in line with the ECHA/EFSA ED guidance, it was concluded that the ED criteria were not met

[33]See experts' consultation point 5.7 in the report of Pesticides Peer Review Experts' meeting 24 (EFSA, 2025). Based on the lack of appropriate data for the ED assessment for non-target organisms other than mammals, the testing strategy in line with the ECHA/EFSA ED guidance was agreed at the meeting.

for the EAS modalities. For the T-modality, the available XETA was extensively discussed in the TC 93.[34] An inhibition of fluorescence greater than 12% was observed at all tested concentrations in the spiked mode of the test, however, not in a dose–response manner. In addition, the statistical analysis did not highlight those differences as statistically significant different. The experts at the meeting considered the XETA assay as negative and concluded that, overall, the weight of evidence did not indicate any positive evidence of thyroidal endocrine activity for non-mammalian species.

Overall, it was concluded that pyraclostrobin does not meet the ED criteria as laid down in point 3.6.5. and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 3–6)

TABLE 3 Soil.

Compound (name and/or code)	Ecotoxicology
Pyraclostrobin	Low risk to soil organisms
BF 500–6	Low risk to soil organisms
BF 500–7	Low risk to soil organisms
BF 500–3 (anaerobic metabolite, relevant only for the representative use on winter cereals and soil photolysis metabolite)	Low risk to soil organisms

TABLE 4 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
pyraclostrobin	No	Yes	Yes	–	Yes
BF 500–6 (500M01)	No	Not triggered	Not triggered	Not triggered	Not triggered
BF 500–7 (500M02)	No	Not triggered	No Unlikely to be genotoxic TRVs of the parent may apply (ADI 0.03 mg/kg bw per day; ARfD 0.03 mg/kg bw)	Not triggered	Not triggered
BF 500–3 (500M07) (anaerobic metabolite, relevant only for the representative use on winter cereals and soil photolysis metabolite)	No	Not triggered	Not triggered Data gap for genotoxicity and general toxicity	Not triggered	Not triggered

Abbreviations: ARfD, acute reference dose; bw, body weight.

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

[b]FOCUS scenarios or relevant lysimeter.

TABLE 5 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
pyraclostrobin	High acute and chronic risk identified for aquatic invertebrates for all uses except for potatoes
BF 500–6 (from soil and sediment)	Low risk to sediment dwellers/data gap for organisms living in the water column
BF 500–7 (from soil)	Low risk to sediment dwellers/data gap for organisms living in the water column
BF 500–3 (from soil and sediment)	Low risk to sediment dwellers/data gap for organisms living in the water column
BF 500–11 (aqueous photolysis and in the water phase of the irradiated water/sediment system)	Low risk to aquatic organisms

[34]See experts' consultation point 5.8 in the report of Pesticides Peer Review Experts' TC 93 (EFSA, 2025).

TABLE 5 (Continued)

Compound (name and/or code)	Ecotoxicology
BF 500–13 (aqueous photolysis and in the water phase of the irradiated water/sediment system)	Low risk to aquatic organisms
BF 500–14 (aqueous photolysis and in the water phase of the irradiated water/sediment system)	Low risk to aquatic organisms
BF 500–15 (aqueous photolysis)	The risk assessment could not be conducted due to the lack of data
500M58 (aqueous photolysis)	The risk assessment could not be conducted due to the lack of data

TABLE 6 Air.

Compound (name and/or code)	Toxicology
pyraclostrobin	0.58 mg/L air/4 h (nose only)

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

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

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

8.1 | Particular conditions proposed for the representative uses evaluated

TABLE 7 Risk mitigation measures proposed for the representative uses assessed.

	Potatoes (BAS 516 07F)	Maize (BAS 500 06 F)	Cereals (BAS 500 06 F)	Cereals (BAS 500 06 F)	Cereals (BAS 500 06 F)
Representative use	**4 × 17 g/ha**	**1 × 200 g/ha**	**2 × 250 g/ha**	**1 × 250 g/ha**	**2 × 220 g/ha**
Operator		Use of gloves during MLA[a]	Use of gloves during MLA[a]	Use of gloves during MLA[a]	Use of gloves during MLA[a]
Risk to aquatic organisms	10 m buffer strips need to be implemented to reach low chronic risk to aquatic invertebrates	*	*	*	*

[a]MLA: mixing/loading and application.

*For maize and cereals, insufficient mitigation to reach a low risk to aquatic invertebrates (see Table 2).

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Concerns 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[35] 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).

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

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 concluded since the risk assessment residue definition for plants and animals could not be finalised (see Section 3).

   a. the toxicity profile of metabolite 500M07 needs to be addressed (relevant for all representative uses evaluated; see Sections 2, 3.1 and 3.2).

2. The consumer risk assessment is not finalised with regard to the unknown nature of residues that might be present in drinking water (see Section 3):

   a. information to address the effect of water treatments processes on the nature of the residues of both the active substance and its identified metabolites potentially present in surface water, when surface water is abstracted for drinking water is missing (see Section 4).

3. The risk assessment to aquatic organisms from the exposure to relevant metabolites in the water and sediment environmental compartments could not be finalised due to the lack of:

   a. PEC surface water and PEC sediment calculations were not provided for the aqueous photolysis metabolites BF 500–15 and 500M58 (see Section 4).
   b. Ecotoxicity data for the metabolites BF 500–6 and BF 500–7 for the organisms living in the water column or a risk assessment considering the metabolites 10 times more toxic than the parent (see Section 5).

4. The exposure and risk assessments for the boscalid active substance in the product for representative uses 'BAS 516 07 F' have not been included in the RAR and list of agreed endpoints and have not been peer reviewed (see Sections 4 and 5).

   a. Predicted environmental concentrations (PEC) in soil, groundwater, surface water and sediment for boscalid and its transformation products were not available (see Section 4).
   b. A mixture risk assessment for the formulation for representative uses which includes the second active boscalid and its transformation products was not available for all groups of non-target organisms (see Section 5).

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:

No critical areas of concern have been identified.

9.1.3 | Overview of the concerns identified for each representative use considered (Table 8)

(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 8).

TABLE 8 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.

		Potatoes	Maize	Cereals	Cereals	Cereals
Representative use		**4×17 g/ha**	**1×200 g/ha**	**2×250 g/ha**	**1×250 g/ha**	**2×220 g/ha**
Operator risk	Risk identified					
	Assessment not finalised					
Worker risk	Risk identified					
	Assessment not finalised					
Resident/bystander risk	Risk identified					
	Assessment not finalised					
Consumer risk	Risk identified					
	Assessment not finalised	X[1,2]	X[1,2]	X[1,2]	X[1,2]	X[1,2]
Risk to wild non-target terrestrial vertebrates	Risk identified		X[c]	X[d]	X[e]	X[f]
	Assessment not finalised	X[4]				
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised	X[4]				
Risk to aquatic organisms	Risk identified		X[h] (8 out of 8 FOCUS scenarios)	X[h] (9 out of 9 FOCUS scenarios for winter cereals and 5 out of 5 FOCUS scenarios for spring cereals)	X[h] (9 out of 9 FOCUS scenarios for winter cereals and 5 out of 5 FOCUS scenarios for spring cereals)	X[h] (9 out of 9 FOCUS scenarios for winter cereals and 5 out of 5 FOCUS scenarios for spring cereals)
	Assessment not finalised	X[3,4]	X[3]	X[3]	X[3]	X[3]
Groundwater exposure to active substance	Legal parametric value breached					
	Assessment not finalised					
Groundwater exposure to metabolites	Legal parametric value breached[a]					
	Parametric value of 10 µg/L[b] breached					
	Assessment not finalised	X[4]				

Note: The superscript numbers relate to the numbered points indicated in Sections 9.1.1 and 9.1.2.

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

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

[c]High chronic risk to small herbivorous mammals is identified for the NEU and SEU use in maize.

[d]High chronic risk to large and small herbivorous mammals for the NEU and SEU uses and for small omnivorous mammals for the NEU uses.

[e]High chronic risk to large and small herbivorous mammals and small omnivorous mammals for the NEU uses.

[f]High chronic risk to small and large herbivorous mammals for the SEU use.

[h]High acute and chronic risk to aquatic invertebrates.

9.2 | Issues related to the maximum residue level applications

No issues have been 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 assessed and are listed in the order of the sections:

- For one of the components contained in the formulation for representative uses 'BAS 500 06 F', in order to allow a final conclusion on the safety assessment of 'BAS 500 06 F', further information on this component in relation to its genotoxicity and repeated-dose toxicity information over the short- and long-term might may be considered for further assessment (to be confirmed by Member States when assessing applications for PPP authorisation (relevant for all representative uses evaluated; see Section 'General aspects').
- For three of the components contained in the formulation for the representative uses'BAS 516 07 F', in order to allow a final conclusion on the safety assessment of 'BAS 516 07 F', further information on one components in relation to its specification/composition and on the three components in relation to their genotoxicity and repeated-dose toxicity information over the short- and long-term might be considered for further assessment (to be confirmed by Member States when assessing applications for PPP authorisation (relevant for all representative uses evaluated; see Section 'General aspects').
- Log P_{OW} for metabolites BF 500–6, BF 500–7, BF 500–11, BF 500–13, BF 500–14, BF 500–15 and 500M58. It is acknowledged that for metabolites BF 500-11, BF 500-13 and BF 500-14 values for logP were reported in ecotoxicity section of the RAR, however the studies were not available for peer review during the procedure for the renewal of the approval and therefore the formal data gap is kept also for these three metabolites (relevant for all representative uses evaluated; see Section 1).
- Matrix effects for method for monitoring of pyraclostrobin in food and feed of plant origin (relevant for all representative uses evaluated; see Section 1).
- Confirmatory method of the monitoring method for metabolite 500M106 in body fluids (relevant for all representative uses evaluated; see Section 1)
- Analytical method for monitoring metabolite 500M104/500M46 in body fluids (relevant for all representative uses evaluated; see Section 1)
- Reliable soil DegT50 for use in modelling from the Spanish trials ALO/01/98 (sandy loam/loamy sand) and ALO/02/98 (sandy loam) and the German trial No. D05/02/97 (loamy sand) were available but they were submitted outside the regulatory deadline and accordingly could not be peer reviewed (relevant for all the representative uses evaluated, see Experts' Consultation point 4.4 in the Evaluation Table of Section 4)
- Groundwater exposure assessment using the FOCUS Châteaudun scenario and the FOCUS MACRO model from the representative uses by pyraclostrobin and its soil metabolites BF 500–6, BF 500–7 and BF 500–3 (relevant for all the representative uses evaluated, see Section 4)
- Risk assessment for aquatic organisms from the exposure to the metabolite BF 500–03 was not conducted although ecotoxicity and exposure data were available (relevant for all the uses, see Section 5)
- Chronic toxicity data for honey bee (larvae and adults) for the formulation 'BAS 516 07 F' were not available (relevant for all uses on potatoes, see Section 5)
- Specific literature studies for bees, relevant for the active substance and for the formulation 'BAS 516 07 F' which were requested from the applicant but were not provided (relevant for all the uses, see Section 5)
- An assessment of the potential risk due to the occurrence of pyraclostrobin metabolites in pollen and nectar and an assessment of sub-lethal effects (relevant for all the uses, see Section 5).

ABBREVIATIONS

AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AF	assessment factor
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
bw	body weight
C&L	classification and labelling
CAS	Chemical Abstracts Service
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EAS	oestrogen, androgen and steroidogenesis modalities
EbC_{50}	effective concentration (biomass)

EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
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
HPG	hypopharygeal glands
HQ	hazard quotient
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC–MS-MS	liquid chromatography with tandem mass spectrometry
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MAF	multiple application factor
MRL	maximum residue level
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
RAC	regulatory acceptable concentration
RAC	Committee for Risk Assessment
RAR	Renewal Assessment Report
SC	suspension concentrate
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
WG	water-dispersible granule
WHO	World Health Organization

ACKNOWLEDGEMENTS

EFSA wishes to thank the rapporteur Member State Germany for the preparatory work on this scientific output.

REQUESTOR

European Commission

QUESTION NUMBERS

EFSA-Q-2014-00825, EFSA-Q-2024-00681

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. https://echa.europa.eu/guidance-documents/guidance-on-clp

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

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

EFSA (European Food Safety Authority). (2011). Review of the existing maximum residue levels (MRLs) for pyraclostrobin according to article 12 of regulation (EC) No 396/2005. *EFSA Journal*, *9*(8), 2344. https://doi.org/10.2903/j.efsa.2011.2344

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

EFSA (European Food Safety Authority). (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*, *12*(5), 3662. https://doi.org/10.2903/j.efsa.2014.3662

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

EFSA (European Food Safety Authority). (2014c). 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*, *12*(7), 3799. https://doi.org/10.2903/j.efsa.2014.3799

EFSA (European Food Safety Authority). (2018). Reasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for pyraclostrobin in various crops. *EFSA Journal*, *16*(11), 5488. https://doi.org/10.2903/j.efsa.2018.5488

EFSA (European Food Safety Authority). (2019). Reasoned Opinion on the modification of the existing maximum residue level for pyraclostrobin in sweet corn. *EFSA Journal*, *17*(10), 5841. https://doi.org/10.2903/j.efsa.2019.5841

EFSA (European Food Safety Authority). (2023). Reasoned Opinion on the setting of import tolerance for pyraclostrobin in papayas. *EFSA Journal*, *21*(6), 8056. https://doi.org/10.2903/j.efsa.2023.8056

EFSA (European Food Safety Authority). (2025). Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance pyraclostrobin.

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues). (2012). Guidance on dermal absorption. *EFSA Journal*, *10*(4), 2665. https://doi.org/10.2903/j.efsa.2012.2665

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

European Commission. (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. (2004). Review report for the active substance pyraclostrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 November 2033 in view of the inclusion of pyraclostrobin in Annex I of Council Directive 91/414/EEC. SANCO/1420/2001-Final, 8 September 2004, 24 pp.

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.

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. 1.1, March 2012.

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.

Germany. (2018). Renewal Assessment Report (RAR) on the active substance pyraclostrobin prepared by the rapporteur Member State Germany, in the framework of Commission Implementing Regulation (EU) No 844/2012, February 2018. https://www.efsa.europa.eu/en/calls/consultations

Germany. (2024). Revised Renewal Assessment Report (RAR) on pyraclostrobin prepared by the rapporteur Member State Germany in the framework of Commission Implementing Regulation (EU) No 844/2012, September 2024, including the Addendum to the RAR assessing the MRL application form, November 2024. https://open.efsa.europa.eu/study-inventory/EFSA-Q-2014-00825

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

SUPPORTING INFORMATION

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

How to cite this article: EFSA (European Food Safety Authority), Álvarez, F., Arena, M., Auteri, D., Leite, S. B., Binaglia, M., Castoldi, A. F., Chiusolo, A., Colagiorgi, A., Colas, M., Crivellente, F., De Lentdecker, C., De Magistris, I., Egsmose, M., Fait, G., Ferilli, F., Broussard, M. F., Santonja, G. G., Gouliarmou, V., … Villamar-Bouza, L. (2025). Peer review of the pesticide risk assessment of the active substance pyraclostrobin. *EFSA Journal*, *23*(3), e9257. https://doi.org/10.2903/j.efsa.2025.9257

APPENDIX A

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

Properties		Conclusion[a]
CMR	Carcinogenicity (C)	Pyraclostrobin is not considered to be a carcinogen according to point 3.6.3 of Annex II of (Regulation (EC) No 1272/2008).[36]
	Mutagenicity (M)	Pyraclostrobin is not considered to be a mutagen according to point 3.6.2 of Annex II of (Regulation (EC) No 1272/2008).
	Toxic for Reproduction (R)	Pyraclostrobin is classified Repr. 2, H361d Suspected of damaging the unborn child (Regulation (EC) No 1272/2008).
Endocrine disrupting properties		Pyraclostrobin is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Pyraclostrobin is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Pyraclostrobin is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
vPvB	**Persistence** **Bioaccumulation**	Pyraclostrobin is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.

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

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

APPENDIX B

List of end points for the active substance and the representative formulation

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2025.9257

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

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

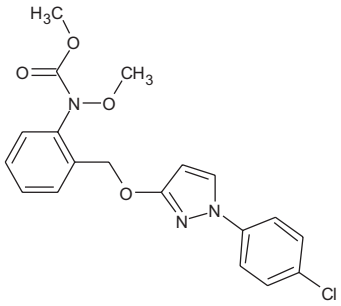
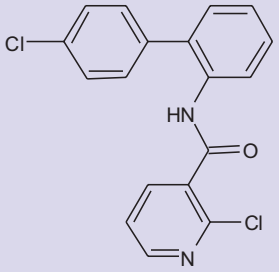
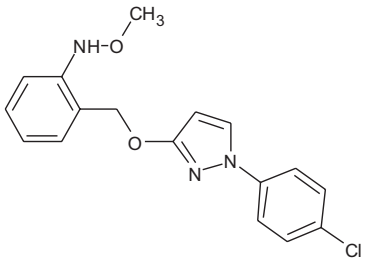
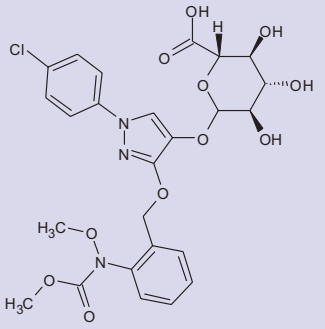
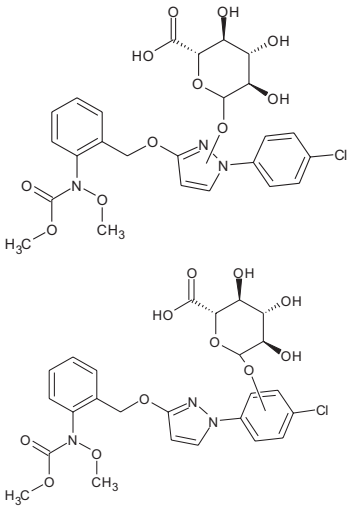
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2000
Slight mobility	2001–5000
Immobile	> 5000

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

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

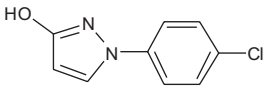
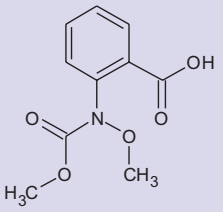
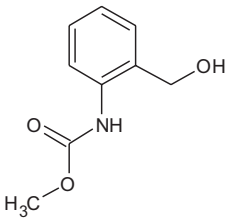
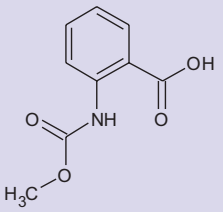
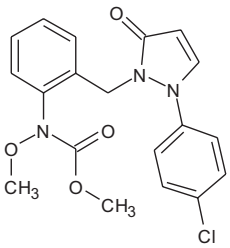
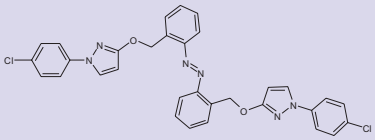
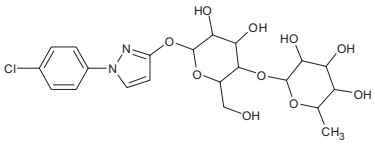
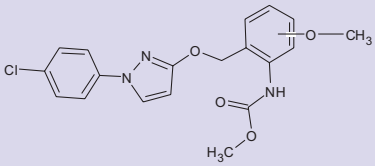
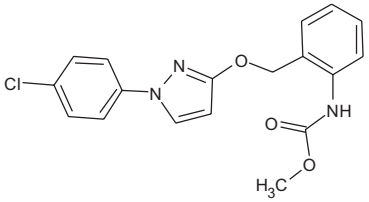
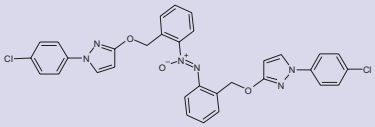
APPENDIX D

Used compound codes

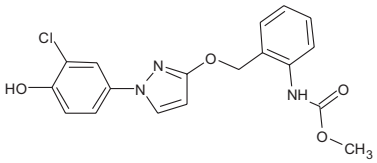
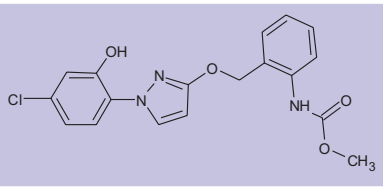
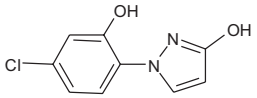
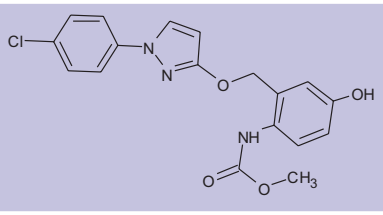
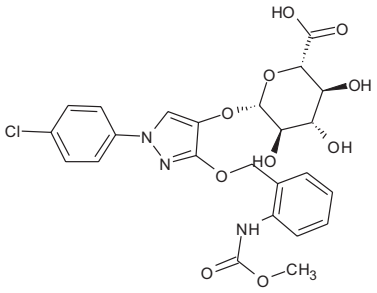
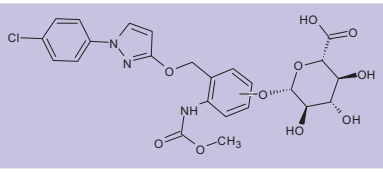
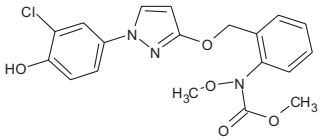
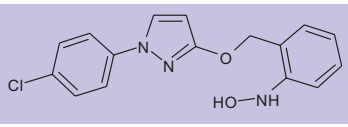
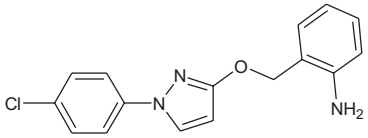
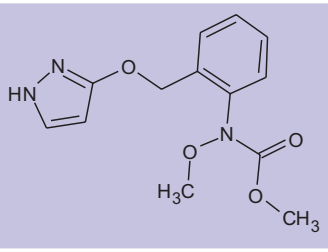
Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Pyraclostrobin	methyl 2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy} methyl)-*N*-methoxycarbanilate O=C(OC)N(OC)c1ccccc1COc1ccn(n1)c1ccc(Cl)cc1 HZRSNVGNWUDEFX-UHFFFAOYSA-N	
Boscalid	2-chloro-*N*-(4′-chlorobiphenyl-2-yl)pyridine-3-carboxamide O=C(Nc1ccccc1c1ccc(Cl)cc1)c1cccnc1Cl WYEMLYFITZORAB-UHFFFAOYSA-N	
500M106	2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy} methyl)-N-methoxyaniline CONc1ccccc1COc1ccn(n1)c1ccc(Cl)cc1 FJGSGWMPNPVBHT-UHFFFAOYSA-N	
500M46	1-(4-chlorophenyl)-3-({2-[methoxy(methoxycarbonyl)amino]phenyl} methoxy)-1*H*-pyrazol-4-yl D-glucopyranosiduronic acid O=C(OC)N(OC)c1ccccc1COc1nn(cc1OC1O[C@@H]([C@@H](O)[C@H](O)[C@H]1O)C(=O)O)c1ccc(Cl)cc1 LKIXKKLCZJUBSO-MAKRBESHSA-N	
500M104	Structure undefined, a unique name/SMILES/InChiKey cannot be allocated	

(Continues)

(Continued)

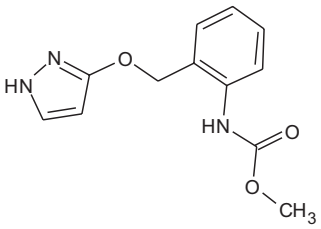
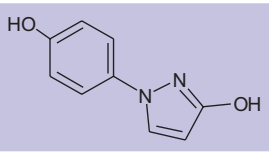
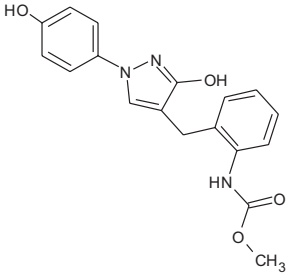
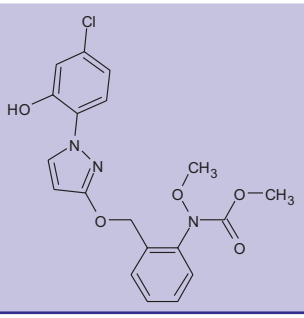
Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
500M04, BF 500-5	1-(4-chlorophenyl)-1*H*-pyrazol-3-ol Clc1ccc(cc1)n1ccc(O)n1 DRENHOMDLNJDOG-UHFFFAOYSA-N	
500M24	2-[methoxy(methoxycarbonyl)amino]benzoic acid CON(C(=O)OC)c1ccccc1C(=O)O AUTLSJHPWGFEJN-UHFFFAOYSA-N	
500M49	methyl [2-(hydroxymethyl)phenyl]carbamate O=C(OC)Nc1ccccc1CO QNCPWLXCDKFGEK-UHFFFAOYSA-N	
500M51	2-[(methoxycarbonyl)amino]benzoic acid O=C(O)c1ccccc1NC(=O)OC VRBXNTUDJOJJDK-UHFFFAOYSA-N	
500M76, BF 500–14	methyl (2-{[2-(4-chlorophenyl)-5-oxo-2,5-dihydro-1*H*-pyrazol-1-yl] methyl}phenyl)methoxycarbamate O=C(OC)N(OC)c1ccccc1CN1C(=O)C=CN1c1ccc(Cl)cc1 VZMUDBQOGBTGKF-UHFFFAOYSA-N	
500M02, BF 500–7	3,3′-[(*E*)-diazenediylbis(2,1-phenylenemethyleneoxy)] bis[1-(4-chlorophenyl)-1*H*-pyrazole] Clc1ccc(cc1)n1ccc(n1)OCc1ccccc1/N=N/c1ccccc1COc1ccn(n1)c1ccc(Cl) cc1 JKLNCXIYXHLUGY-ULDVOPSXSA-N	
glycoside 500M55	1-(4-chlorophenyl)-1*H*-pyrazol-3-yl 4-*O*-(6-deoxyhexopyranosyl) hexopyranoside Clc1ccc(cc1)n1nc(OC2OC(CO)C(OC3OC(C)C(O)C(O)C3O)C(O)C2O)cc1 QKWWXVHKPYLVDN-UHFFFAOYSA-N	
500M54	Structure undefined, a unique name/SMILES/InChiKey cannot be allocated	
500M07, BF 500-3	methyl [2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)phenyl] carbamate O=C(OC)Nc1ccccc1COc1ccn(n1)c1ccc(Cl)cc1 SEUOYURJKYLAPC-UHFFFAOYSA-N	
500M01, BF 500-6	1-(4-chlorophenyl)-3-[(2-{(Z)-[2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl] oxy}methyl)phenyl]-*ONN*-azoxy}phenyl)methoxy]-1*H*-pyrazole Clc1ccc(cc1)n1ccc(n1)OCc1ccccc1[N+](/[O-])=N/c1ccccc1COc1ccn(n1) c1ccc(Cl)cc1 SMHCYRVROCXXNI-IHFXRMRWSA-N	

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
500M66	methyl [2-({[1-(3-chloro-4-hydroxyphenyl)-1*H*-pyrazol-3-yl]oxy} methyl)phenyl]carbamate O=C(OC)Nc1ccccc1COc1ccn(n1)c1cc(Cl)c(O)cc1 FAZFZMXSCXVCMR-UHFFFAOYSA-N	
500M67	methyl [2-({[1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazol-3-yl]oxy} methyl)phenyl]carbamate O=C(OC)Nc1ccccc1COc1ccn(n1)c1ccc(Cl)cc1O UHTYIEFVLYPPJW-UHFFFAOYSA-N	
500M85, BF 500-8	1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazol-3-ol Clc1cc(O)c(cc1)n1ccc(O)n1 AVNZJTYXIWEOTQ-UHFFFAOYSA-N	
500M64	methyl [2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy}methyl)-4-hydroxyphenyl]carbamate O=C(OC)Nc1ccc(O)cc1COc1ccn(n1)c1ccc(Cl)cc1 BJQDKRVJBJZFNZ-UHFFFAOYSA-N	
500M06	1-(4-chlorophenyl)-3-({2-[(methoxycarbonyl)amino]phenyl} methoxy)-1*H*-pyrazol-4-yl β-D-glucopyranosiduronic acid O=C(OC)Nc1ccccc1COc1nn(cc1O[C@@H]1O[C@@H]([C@@H](O)[C@H](O)[C@H]1O)C(=O)O)c1ccc(Cl)cc1 AKGNRMSNGBEIHM-BPDSMXLESA-N	
500M32	Structure undefined, a unique name/SMILES/InChiKey cannot be allocated	
M500M77, BF 500-16	methyl [2-({[1-(3-chloro-4-hydroxyphenyl)-1*H*-pyrazol-3-yl]oxy} methyl)phenyl]methoxycarbamate O=C(OC)N(OC)c1ccccc1COc1ccn(n1)c1cc(Cl)c(O)cc1 FUPHCBVVVPLOQH-UHFFFAOYSA-N	
500M89	2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy} methyl)-*N*-hydroxyaniline ONc1ccccc1COc1ccn(n1)c1ccc(Cl)cc1 KERBJEXQLCHSQI-UHFFFAOYSA-N	
BF 500-4	2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)aniline Nc1ccccc1COc1ccn(n1)c1ccc(Cl)cc1 LIUOORDMFAVVFQ-UHFFFAOYSA-N	
500M60, BF 500-11	methyl methoxy(2-{[(1*H*-pyrazol-3-yl)oxy]methyl}phenyl)carbamate O=C(OC)N(OC)c1ccccc1COc1cc[NH]n1 TVUWJLCTZNPJBQ-UHFFFAOYSA-N	

(Continues)

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
500M62, BF 500-13	methyl (2-{[(1*H*-pyrazol-3-yl)oxy]methyl}phenyl)carbamate O=C(OC)Nc1ccccc1COc1cc[NH]n1 PSWMOBUAZJZQSN-UHFFFAOYSA-N	
BF 500-15	1-(4-hydroxyphenyl)-1*H*-pyrazol-3-ol Oc1ccc(cc1)n1ccc(O)n1 QIGKXZHYPZVYGM-UHFFFAOYSA-N	
500M58	methyl (2-{[3-hydroxy-1-(4-hydroxyphenyl)-1*H*-pyrazol-4-yl]methyl}phenyl)carbamate O=C(OC)Nc1ccccc1Cc1cn(nc1O)c1ccc(O)cc1 OYQRTNNENHUYDE-UHFFFAOYSA-N	
BF 500-10	methyl [2-({[1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazol-3-yl]oxy}methyl)phenyl]methoxycarbamate O=C(OC)N(OC)c1ccccc1COc1ccn(n1)c1ccc(Cl)cc1O HJAONZSBWBUIFU-UHFFFAOYSA-N	

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

[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).