CONCLUSION ON PESTICIDES PEER REVIEW

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

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State The Netherlands and co-rapporteur Member State Germany for the pesticide active substance dimethomorph 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 dimethomorph as a fungicide applied via foliar spraying on field strawberry and grapevine crops and permanent greenhouse lettuce crops; via drenching on field and permanent greenhouse strawberry crops and via dripping on permanent greenhouse strawberry crops. The peer review also provided considerations on whether exposure to humans and the environment from the representative uses of dimethomorph can be considered negligible, taking into account the European Commission's draft guidance on this topic. MRLs were assessed in potatoes, other root and tuber vegetables (except radishes), stem vegetables (except celery, leeks, globe artichokes, sugar beet, cereal forage and straw). 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. The concerns are reported where identified.

Keywords: dimethomorph, peer review, risk assessment, pesticide, fungicide, MRL Article 10

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Dimethomorph 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), The Netherlands, and co-rapporteur Member State (co-RMS), Germany, received applications from BASF Agro BV, Arysta LifeScience and Adama Makhteshim Ltd. for the renewal of approval of the active substance dimethomorph. In addition, BASF Agro BV submitted applications for maximum residue levels (MRLs), as referred to in Article 7 of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on dimethomorph 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 the European Food Safety Authority (EFSA) in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659.

It has been concluded that dimethomorph meets the cut-off criteria for non-approval, laid down in Annex II, points 3.6.5 and 3.8.2 of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605 concerning endocrine disrupting potential. As part of the renewal procedure, the applicant provided further information aimed at demonstrating that the exposure of humans and/or the environment to dimethomorph was negligible under realistic conditions of use. Dimethomorph has therefore been assessed under the provisions of negligible exposure to satisfy points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) No 2018/605. Furthermore, the applicant requested a derogation under Article 4(7) of Regulation (EC) No 1107/2009, submitting evidence regarding the necessity of dimethomorph as a fungicide to control a serious danger to plant health. The evaluation of the data regarding this derogation request is presented in Appendices C and D of this conclusion. Overall, it can be concluded that for specific crop-pathogen combinations the derogation is supported: *Phytophthora* disease in red raspberry (Belgium), raspberry (the Netherlands), blackberry (Belgium, the Netherlands), strawberry (Spain), leafy brassicas (Germany), ornamental crops (Belgium), tree nursery crops (only for root rot) (the Netherlands), leek (Austria, Germany, Spain), *Alternaria* disease in potato (Bulgaria), shallot (Italy), ornamental crops (Belgium – only *Alternaria alternata*), garlic (Greece), downy mildew in zucchini (Lithuania, Sweden, Belgium, Denmark), cucumber (Belgium, Sweden, Denmark), squash (Sweden, Belgium), gherkin (Belgium, Denmark, Lithuania), marrow (Lithuania), pattypan squash (Lithuania), onion (Denmark), garlic (Austria, Lithuania, Slovakia, Sweden, Denmark, Spain), shallot (Lithuania and Denmark), chives (Belgium), beans (Germany), fresh herbs (Greece), lamb's lettuce (Belgium), basil (Greece), rosemary (Greece), thyme (Greece), cauliflower (Greece, Germany-only outdoor cauliflower), artichoke (Spain), parsley (Greece), oilseed rape (Germany), poppy seed (Hungary) and *Ascochyta hortorum* in artichoke (Italy).

Following completion of the peer review process, the following conclusions are derived.

The uses of dimethomorph according to the representative uses as a fungicide applied by (i) foliar spraying on field crops, (ii) by drenching on field, permanent greenhouse and non-permanent walk-in tunnels and (iii) by dripping using water as carrier on permanent greenhouse and non-permanent walk-in tunnels; and foliar spray applications on permanent greenhouse lettuce crops. as proposed at EU level result in a sufficient fungicidal efficacy against the target pests.

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 and chemical properties and analytical methods.

In the area of mammalian toxicology, a critical area of concern was identified due to the harmonised classification and labelling of dimethomorph as category 1B for reproductive toxicity and due to endocrine disruption (ED) properties for human health (criteria met for EAS-modalities). At least one of the criteria for negligible exposure were not met for indoor (except dripping) and outdoor uses on strawberries, indoor use on lettuce, and outdoor use on grapes. An issue not being finalised was identified related to the reliability assessment of toxicity studies since a transparent evaluation, according to guidance document European Commission, 2000a, of the analytical methods that were submitted during the first evaluation of the dimethomorph and used to support the renewal risk assessment was not available in the RAR.

The assessment of the data package revealed issues that resulted in consumer risk assessment and risk assessment residue definition for ruminants not being finalised. However, the proposed uses cannot guarantee a negligible exposure of consumers via food intake and drinking water. The MRL requests were partially supported by the available data.

In the area of environmental fate and behaviour, information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water, was missing. This resulted in the consumer risk assessment not being finalised.

In the area of ecotoxicology, high long-term risk to mammals was identified for all representative field uses and high risk to aquatic organisms was concluded for all representative uses in permanent greenhouses structures. The aquatic risk assessment could not be finalised for the walk-in tunnel uses in strawberries via dripping application at 5 kg a.s./ha.

Dimethomorph is an endocrine disruptor for both humans and wild mammals as non-target organism, according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605.

The exposure to the environment might be considered not negligible, as the available predicted environmental concentration (PEC) in soil, surface water and sediment for all the representative uses assessed are above levels that can be routinely measured.

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Background

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

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

In accordance with Article 1 of the Regulation, the RMS The Netherlands and co-RMS Germany received applications from BASF Agro BV, Arysta LifeScience and Adama Makhteshim Ltd. for the renewal of approval of the active substance dimethomorph. In addition, BASF Agro BV submitted applications 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 applicants, the co-RMS (Germany), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on dimethomorph in the RAR, which was received by EFSA on 1 August 2017 (The Netherlands, 2017). 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 applicants, BASF Agro BV, Arysta LifeScience and Adama Makhteshim Ltd., for consultation and comments on 10 April 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 10 June 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 applicants were invited to respond to the comments in column 3 of the reporting table. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS, ECHA and the European Commission on 23 July 2018. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues and ecotoxicology.

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.

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

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

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

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

In addition, in accordance with the provisions of Commission Implementing Regulation (EU) No 2018/1659, following a consultation with Member States in the Pesticides Peer Review Expert meetings 190 and 192 (February 2019), the applicants were given the opportunity to submit, within a period of 3 months, additional information to address the approval criteria set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605[5], and/or documentary evidence demonstrating that dimethomorph may be used such that exposure is negligible, or the conditions for the application of the derogation under Art.4(7) of Regulation (EC) No 1107/2009 are met.

Subsequently, the applicants provided further information aimed at demonstrating that the exposure of humans and/or the environment to dimethomorph was negligible under realistic conditions of use. Dimethomorph has therefore been assessed under the provisions of negligible exposure to satisfy points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009. Furthermore, the applicants requested a derogation under Article 4(7) of Regulation (EC) No 1107/2009, submitting evidence regarding the necessity of dimethomorph as a fungicide to control a serious danger to plant health. The evaluation of the data regarding this derogation request is presented in Appendices C and D of this conclusion. A public consultation on the draft Art 4(7) scientific report and the revised RAR on the ED and negligible exposure assessments made available after the 3-month clock stop was conducted between March and May 2019. All comments received, including the ones from the applicants and the Member States, were collated in the format of a commenting table (on the draft Art 4(7) scientific report) and of a reporting table (on the revised RAR on the assessment of the endocrine-disrupting properties and negligible exposure assessments).

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, on the proposed MRLs, including also the negligible exposure assessment and the evaluation of the data regarding the necessity of dimethomorph as a fungicide to control a serious danger to plant health which cannot be contained by other available means, took place with Member States via a written procedure in April 2023.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulated products, evaluated on the basis of the representative uses of dimethomorph as a fungicide on strawberry, lettuce and grapevine, as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion. MRLs were assessed in potatoes, other root and tuber vegetables (except radishes) and stem vegetables (except celery, leeks, globe artichokes, sugar beet, cereal forage and straw).

In addition, the peer review also provided considerations on whether exposure to humans and the environment from the representative uses of dimethomorph can be considered negligible under realistic conditions of use, taking into account the European Commission's draft guidance on this topic. An evaluation of data concerning the necessity of dimethomorph as a fungicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, is also presented (see Appendices C and D).

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

A key supporting document to this conclusion is the peer review report (EFSA, 2023), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the comments received on the applicant's report submitted for the evaluation of data concerning the necessity of dimethomorph to control a serious danger to plant health (June 2020);

[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, pp. 33–36.

- the reporting tables (24 July 2018 and 1 September 2022[6]);
- the evaluation table (2 May 2023);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft Art 4(7) scientific report;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (The Netherlands, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

The active substance and the formulations for representative uses

Dimethomorph is the ISO common name for (2*EZ*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-(morpholin-4-yl)propanone (IUPAC).

The formulations for the representative uses for the evaluation were 'BAS 550 01 F', a wettable powder (WP) formulation containing 500 g/kg dimethomorph, and 'BAS 550 02 F', a dispersible concentrate (DC) containing 150 g/L dimethomorph.

The representative uses evaluated for 'BAS 550 01 F' were applications against *Phytophthora cactorum* on strawberry crops applied by (i) foliar spraying on field crops, (ii) by drenching on field, permanent greenhouse and non-permanent walk-in tunnels and (iii) by dripping using water as carrier on permanent greenhouse and non-permanent walk-in tunnels; and foliar spray applications against *Bremia lactucae* on permanent greenhouse lettuce crops. The representative use evaluated for 'BAS 550 02 F' was application against *Plasmopara viticola* on grapevine crop applied by foliar spraying on field.

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

Conclusions of the evaluation

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

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

New reference specifications with minimum purity of 965 g/kg were proposed based on industrial scale batches and on quality control (QC) data from the BASF sources. 1,2-dimethoxybenzene (Z12) and (2 *E*,*Z*)-3-(3,4-dimethoxyphenyl)-1-(morpholin-4-yl)-3-phenylprop-2-en-1-one (Z33) were considered as new relevant impurities specified at 2 and 10 g/kg, respectively (see Section 2). The minimum purity of the active substance as manufactured is 965 g/kg for BASF and 975 g/kg for Adama and Arysta. It is noted that the proposed technical specification of the Adama source is provisional until the submission of QC data to verify the representativeness of the 5-batch analysis and to support the proposed specification level of an impurity; and data to confirm the identity of some of the impurities in the technical material (data gap, see confidential evaluation table of ADAMA and Section 10). Pending the missing data, a conclusion cannot be reached on the chemical equivalence of the Adama technical material to the new reference specification proposed. Arysta technical material was found to be chemically equivalent to the new proposed reference specification. Based on the renewal data and the changes in the relevant impurity profile (see Section 2), it is proposed to update the current reference specification based on the data from the BASF sources. A FAO specification is not available. The batches used in the ecotoxicological assessment support the new proposed and current reference specification (see Section 5); both specifications are supported also from the toxicological point of view (see Section 2).

[6] Reporting table following consultation on the revised RAR on the assessment of the endocrine-disrupting properties and negligible exposure assessment made available after the 3-month clock stop.

The main data regarding the identity of dimethomorph and its physical and chemical properties are given in Appendix B. A data gap was identified for UV/visible absorption spectra, IR, NMR and MS spectra data for the relevant impurities Z12 and Z33 and for n-octanol/water partition coefficient data for the metabolite M550F021 (see Section 10).

Adequate methods are available for the generation of data required for the risk assessment, except for the non-acceptable analytical method SOP MR 029 used in the strawberry residue studies DK-713-039, DK-713-040, DK-713-041 and DK-713-042 (see Section 3). In addition, a data gap was identified for a transparent evaluation, according to guidance document European Commission, 2000a, of the analytical methods that were submitted during the first evaluation of the dimethomorph and used to support the renewal risk assessment (see Sections 2 and 9.1.1). Methods of analysis are available for the determination of the active substance and impurities in the technical materials. Appropriate high-performance liquid chromatography with a diode-array detector (HPLC-DAD) detection methods are available for the quantification of the active substance in the formulations for representative uses; HPLC-UV methods are available for the determination of the relevant impurities in the technical material, no methods are available for the determination of the relevant impurities in the representative formulations (data gap, see Section 10).

Dimethomorph residues can be monitored in food and feed of plant origin in all plant commodity groups by high-performance liquid chromatography with tandem mass spectroscopy (HPLC–MS/MS) with limits of quantification (LOQs) of 0.005 mg/kg for *E*- and *Z*-isomer separately. Residues of dimethomorph in food of animal origin can be determined using HPLC–MS/MS with LOQ of 0.01 mg/kg (sum of *E*- and *Z*-isomers).

Dimethomorph can be monitored in soil by HPLC–MS/MS with an LOQ of 0.01 mg/kg for *E*- and *Z*-isomer separately. Appropriate HPLC–MS/MS method exists for monitoring of residues of dimethomorph in water with LOQs of 0.015 μg /L for *E*- and *Z*-isomer separately. Residues of dimethomorph in air can be monitored using HPLC–MS/MS with LOQ of 3 $\mu g/m^3$ (sum of *E*- and *Z*-isomers).

Residue of dimethomorph and its metabolites M550F013 and M550F007, in body fluids can be determined by an HPLC–MS/MS method with LOQ of 0.01 mg/L. A data gap was identified for a method to monitor dimethomorph and its metabolites M550F013 and M550F007 in body tissues (see Section 10).

2. Mammalian toxicity

The toxicological profile of the active substance dimethomorph and its metabolites was discussed at the Pesticides Peer Review Experts' Meeting 190 (session 1 January–February 2019). The assessment is based on the following guidance documents: European Commission, 2003, 2012; EFSA PPR Panel, 2012 and the available draft Technical Guidance Document on assessment of negligible exposure (European Commission, 2015).

Regarding the proposed **reference specification** (RS), the impurities Z12 and Z33 are identified as relevant impurities based on their hazard (acute toxicity), but not of concern at the level proposed in the specification, with maximum acceptable level at 2 and 10 g/kg, respectively. The proposed and current reference specifications for the active substance and associated impurities are supported from the toxicological point of view.

The analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicity studies submitted during the first evaluation were not re-evaluated by the RMS according to the applicable method validation guidance (see Section 1), leading to an issue not finalised since the reliability of the existing studies cannot be concluded upon (see Section 9.1.1).

Dimethomorph consists of a mixture of approximately equal amounts of two geometrical isomers (*E*- and *Z*-isomers) and the *E*/*Z* ratio in the technical material ranges from 40/60 to 50/50. Based on bridging studies, the toxicological reference values, target organs and mode of action derived in the toxicological studies performed with dimethomorph can be applied to both *E*- and *Z*-isomer.

The oral **absorption** of dimethomorph is estimated to account for > 80% of the administered low dose. **Excretion** occurs predominantly through the bile/faecal route, with appreciable amounts excreted in urine. In the rat, dimethomorph is widely distributed throughout the body, with the highest levels being reached in gastrointestinal tract and liver. There was no evidence of accumulation. The main **metabolic** pathway identified is demethylation, hydroxylation, opening and degradation of morpholine ring and subsequent conjugation. Based on comparative *in vitro* metabolism, no major metabolic inter-species (rat, dog) differences have been observed and no unique human metabolites have been identified. The **residue definition** for body fluids and tissues includes dimethomorph (sum of *E*- and *Z*-isomer) plus the metabolites M550F013 and M550F007.

In the acute toxicity studies, dimethomorph has low acute toxicity when administered orally, dermally or by inhalation to rats. It is not a skin or eye irritant or a skin sensitiser. Dimethomorph tested negative in an *in vitro* phototoxicity assay.

Repeated dose toxicity studies after oral **short-term** exposure were provided for rats and dogs. In rats, adverse effects included increased liver weight resulting in a no observed adverse effect level (NOAEL) of 16 mg/kg body weight (bw) per day (90-day, rat). In dogs, adverse effects included increased liver weight (females), increased testes weight (males) resulting in a NOAEL of 5 mg/kg bw per day (1-year, dog). After oral **long-term** exposure, critical effects for toxicity included reduced body weight gain in rats and mice; and increased incidence of liver ground glass foci in female rats. The rat was the most sensitive species, being the NOAEL 11.3 mg/kg bw per day (2-year, rat).

Based on the available **genotoxicity** studies, dimethomorph is unlikely to be genotoxic. Testing for photogenotoxicity is not required for dimethomorph.

Regarding **reproductive toxicity** studies, the reproductive NOAEL in the extended 1-generation rat study is 26 mg/kg bw per day based on decreased duration of pregnancy, delayed puberty in males, decreased prostate and seminal vesicle weight. The parental NOAEL is 26 mg/kg bw per day based on reduced body weight. The offspring NOAEL is 26 mg/kg bw per day based on reduced growth, decrease anogenital distance/index. ECHA RAC (2019) considered delayed puberty onset in combination with pronounced effects on male reproductive organs/systems as adverse and relevant for humans. The RAC opinion led to the harmonised classification as toxic for reproduction category 1B (Repr. Cat. 1B, H360F) according to Regulation (EC) No 1272/2008[7] for adverse effects on sexual function and fertility (see Section 9.1.2). With regard to foetal development, no teratogenic effect was observed in rats and rabbits. In the rat developmental toxicity study, the maternal NOAEL is 60 mg/kg bw per day based on decreased body weight and food consumption, and the developmental NOAEL is 60 mg/kg bw per day based on slight increase in resorption rate. In the rabbit teratogenicity study, the maternal NOAEL is 300 mg/kg bw per day based on decreased body weight and food consumption and increased abortion rate, and the developmental NOAEL is 300 mg/kg bw per day based on increased prenatal lethality.

With respect to **neurotoxicity**, behavioural effects (functional observation battery, motor activity) without neuro-histopathological correlates were observed in the acute neurotoxicity study in rat at the lowest dose level tested of 250 mg/kg bw per day. In the 90-day neurotoxicity study no neurotoxicity was observed up to 177.9 mg/kg bw per day. Dimethomorph did not show potential for **immunotoxic** effects in the available immunotoxicity studies.

With regard to the toxicological reference values, the agreed acceptable daily intake (**ADI**) is 0.05 mg/kg bw per day (same value as previously set), on the basis of the relevant short-term NOAEL of 5 mg/kg bw in the 1-year study in dogs based on increase liver and testes weight at 15 mg/kg bw per day. An uncertainty factor of 100 was applied. The same basis applies to the systemic acceptable operator exposure level (**AOEL**). During the previous peer review an AOEL of 0.15 mg/kg bw per day was set (European Commission, 2006).

The agreed acute reference dose (**ARfD**) is 0.6 mg/kg bw (same value as previously set - European Commission, 2006) based on the NOAEL of 60 mg/kg bw per day for the decreased body weight gain, decreased food consumption and total litter loss observed at 160 mg/kg bw per day in the developmental-term toxicity study in rats. An uncertainty factor of 100 was applied. The same basis applies to the systemic acute acceptable operator exposure level (**AAOEL**).

For the dermal absorption, a value of 3% was agreed for the concentrate of both BAS 550 02 F and BAS 550 01F, based on *in vitro* dermal absorption studies. For the dilutions, the values of 2% and 14% were agreed for BAS 550 02 F, while the values of 4% and 11% were agreed for BAS 550 01 F.

For the non-dietary exposure, the estimates for **operators** wearing gloves are below the (A)AOEL for the outdoor uses on strawberries with tractor mounted equipment and product in water soluble bags, while they exceed the AOEL (not the AAOEL) for the hand-held applications (even with gloves and respiratory protective equipment). For the drenching and dripping applications on strawberries (with automated application), the exposure estimates during mixing/loading are below the (A)AOEL without personal protective equipment (PPE). For the indoor use on lettuces, operator estimates are below the AOEL with use of gloves. For the outdoor use on grapes, the estimated exposure is below the (A)AOEL without PPE. For **workers** re-entering strawberries or lettuces for reaching/picking, the

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

estimated exposure is below the AOEL when using gloves, while the re-entry in strawberries after drip application (handling treated soil) is below the AOEL without gloves. For grapes, worker exposure estimates are below the (A)AOEL on the basis of a field study. For **bystanders** and **residents**, exposure estimates are below the (A)AOEL for all uses.

Since dimethomorph is classified as Reproductive toxicant category 1B and identified as endocrine disruptor (EAS modality), further considerations have been given to **negligible exposure**. For the operators, outdoor spraying of strawberries and indoor spraying of lettuces do not result in exposure estimates lower than 10% of the AOEL, while drenching/dripping of strawberries and spraying of grapes result in exposure levels below 10% of the (A)AOEL with use of appropriate PPE. For the workers, outdoor spraying of strawberries and indoor spraying of lettuces do not result in exposure estimates lower than 10% of the AOEL, while handling treated soil after drenching/dripping has a predicted exposure below 10% of the AOEL. Based on a field study, the worker exposure during re-entry in grapes is predicted to exceed 10% of the AOEL. For all outdoor uses, exposure estimates for bystanders and residents are exceeding 10% of the (A)AOEL even considering the available risk mitigation measures while for drenching/dripping in greenhouses, a significant exposure is not expected to occur. A MoE (considering the NOAEL for ED effects) above 1000 has been identified for all categories in the case of drenching/dripping of strawberries in greenhouses.

Regarding **metabolites** found as residues in crops and/or livestock (see Section 3), the experts agreed that the genotoxic potential and toxicological profile of metabolites **M550F002** and **M550F007** are considered covered by the parent based on grouping supported by structurally similarities, metabolism and occurrence in the rat metabolism study with the parent. Therefore, reference values of the parent apply to these metabolites if needed for consumer risk assessment.[8] EFSA considered, in line with the RMS's assessment, that this conclusion would also apply to metabolite **M550F006**, a metabolite not discussed during the experts' meeting but considered under the Section 3. The genotoxic potential of **M550F021 (morpholine)** is currently inconclusive and a new genotoxicity test battery *in vitro* would be needed to clarify the genotoxic potential of morpholine leading to issue not finalised (see Sections 3 and 9.1.1). The experts discussed the toxicological profile of morpholine and the setting of reference values in case the genotoxicity potential is further clarified.[8] Given the current data gap for genotoxicity EFSA does not consider appropriate setting of reference values for morpholine.

3. Residues

The assessment in the residue section is based on the following guidance documents: OECD, 2009, 2011; European Commission, 2019 and JMPR, 2004, 2007.

Dimethomorph was discussed at the Pesticides Peer Review Experts' Meeting 191 which was held in January–February 2019.

3.1. Representative use residues

Plant metabolism was investigated in valid studies applying morpholine-^{14}C- and chlorophenyl-^{14}C-labelled dimethomorph to grape (fruit), lettuce (leafy crop) and potato (tuber crop) via foliar treatment and to tomato in a hydrophonic system. One of the grapes studies employed application to individual leaves and fruit via a syringe and it can cover dripping and drenching treatments proposed for strawberries. Metabolism in plants is not extensive with dimethomorph the predominant residue in grapes, potato peel, mature lettuce and tomato green plants parts. The only metabolites, as a result of demethylation of the dimethoxyphenyl ring, were M550F006 (in potato peel), M550F007 and its glucoside, M550F002, (in grapes). Overall, the metabolism upon foliar spraying, drip/drench application and root uptake can be considered similar. Given that dimethomorph is the major residue and M550F006, M550F007 and M550F002 are covered by the parent toxicity (see Section 2), the **residue definitions** for **risk assessment** and for **monitoring** are set as dimethomorph (sum of isomers) and applicable to all categories of crops following foliar or drenching treatments. In studies employing two label positions, the residue behaviour of dimethomorph was investigated in rotated crops following bare soil treatment with application rates covering the maximum seasonal rates. Overall, the metabolic

[8] See experts' consultation 2.8 in the Pesticides Peer Review Experts' Meeting 190 (session 1 January–February 2019) meeting report. It is noted that the toxicological profile of additional metabolites beyond those relevant for the current representative uses, i.e. M550F003, M550F017 and M550F018, were discussed during the experts' consultation 2.8 and summarised too in the list of endpoints.

picture was similar to primary crops with dimethomorph as major residue. M550F002 (wheat straw, radish tops and lettuce) and M550F007 (lettuce) were both at levels below 0.05 mg/kg as well as M550F021 (morpholine), M550F017 and M550F018. Hence the above **residue definitions** can be extended to **rotational crops**. Stability of dimethomorph under standard processing conditions was demonstrated in a valid nature of residue study and though not required as well as for M550F002. The representative use for strawberries foresees treatment either at transplanting or at growth stage BBCH 15–42 and for each of them with three separate applications techniques (spraying, drenching or dripping). For the most critical growth stage BBCH 42, no residue trials were provided (data gap); while for the growth stage at transplanting, residue field trials were presented. However, for some representative uses the number of trials was not sufficient or details were missing to conclude on their validity and therefore, several data gaps have been set leading to the consumer risk assessment not being finalised[9] (see Section 9.1.1). For the representative use on lettuce and on grapes, a sufficient number of valid residue field trials are available. Processing factors were derived from valid studies for processed products of grape, strawberry, orange, hop and lettuce.

None of the crops for the representative uses are considered to be feed items. However, dietary burden calculation, using the EFSA animal model 2017[10] and results from residue field trials in rotated crops (see Section 3.2), resulted in exceedance of the trigger values for all animals (except turkey). It should be noted that the calculation is not finalised as data on the potential transfer from pulses and oilseeds crops to livestock are not available (see data gap in Section 3.2) leading to the consumer risk assessment not being finalised.

Metabolism studies with morpholine-^{14}C- and chlorophenyl-^{14}C-labelled dimethomorph are available for poultry and ruminants.[11] Overall, the studies confirm a similar metabolic pattern within each species. The metabolism in hen is predominantly via demethylation at the dimethoxy ring leading to formation of M550F006 and M550F007; and in ruminants via hydroxylation, oxidative opening of morpholine ring and its step-wise degradation leading to formation of M550F011, M550F008 and M550F021. In contrast to poultry tissues, M550F021 is found in ruminant's kidney, liver and milk cream in relevant amounts. Feeding studies in poultry were neither provided nor required as from the overdosed metabolism studies quantifiable residues in poultry commodities are not expected. In a ruminant feeding study quantifiable residues of dimethomorph were found only in liver and fat of M550F007 in liver and kidney. Residues of M550F008 in milk were below 0.01 mg/kg. Given the overdosing of the study a transfer from feed to animal commodities is not expected for the representative uses. This statement is pending the update of the dietary burden calculation once the residue field trials on rotated oil crops become available (see data gap in Section 3.2). On the basis of the metabolism and feeding studies and given that the metabolic pattern for poultry and ruminant is not similar two different **residue definitions for risk assessment** are proposed: Dimethomorph (sum of isomers) for **poultry** matrices and dimethomorph (sum of isomers) and M550F021 for **ruminant** matrices. The latter is pending the outcome of the genotoxic potential of M550F021 (see data gap in Sections 2 and 9.1.1). It is noted that analysis of M550F021 was not included in the current feeding study and should a feeding study be triggered in the future, the magnitude and genotoxic potential of M550F021 in ruminant commodities will need to be addressed. The **animal residue definition** for **enforcement** is proposed as dimethomorph (sum of isomers), by default.

The possible shift in the *E*- and *Z*-isomer ratio of the parent compound was investigated in several metabolism studies and residue field trials. Depending on the matrix and the investigated label, a shift could be observed but it was not consistently towards one of the isomers. However, it is noted that the toxicological reference values are covering each individual isomer (see Section 2). Given that dimethomorph is systemic and the application on the representative uses on the melliferous crops grapes and strawberries occurs before flowering, residues in honey and bee products cannot be excluded. Therefore, a data gap is set for studies investigating the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom (see Section 10).

The consumer risk assessment takes into account residues from the representative uses as well as residues in rotated crops and residues from water treatment processes (see Section 4). Given the data gaps (see Sections 9.1.1 and 9.2) it cannot be considered as final. A preliminary consumer risk

[9] For details on the data gaps see Section 9.1 and open point 3.16 of the evaluation table Section 3.
[10] https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en
[11] For details on the animal metabolism studies refer to experts' consultation 3.2 in the evaluation table section 3 and experts' consultation point 3.2 at the Pesticides Peer Review Meeting 191 (EFSA, 2023) and Appendix B.

assessment was performed and it is not expected to be considerably impacted by the data gaps. The calculated chronic intake is maximum 6.9% of the ADI for 'FR all population' (PRIMo rev. 2) and maximum 3% of the ADI for 'PT general' (PRIMo rev. 3.1). The IESTI for table grapes is maximally 28% of the ARfD (table grapes) (PRIMo rev. 2) and maximally 32% of the ARfD (table grapes) (PRIMo rev. 3.1).

As for the assessment if the provisions of **negligible exposure** according to Regulation (EC) 1107/2009 are met, considering the draft technical guidance on assessment of negligible exposure (European Commission, 2015), it should be noted that quantifiable residues were found in commodities for all representative uses and in rotational field trials, except in strawberries at transplanting (drenching/dripping application in NEU). However, there were data gaps regarding the validity of these residue trials and regarding the water treatment processes for drinking water (see Section 9.1.1). It is therefore concluded that based on representative uses, dietary exposure cannot be considered negligible via food intake and drinking water. RMS has proposed possible risk mitigation measures regarding the planting of rotational crops after spray treatment on outdoor strawberries at transplanting which could be considered by Member States at the national authorisation level.

3.2. Maximum residue levels

An application to change the existing MRL for grapes from 3 mg/kg to 4 mg/kg due to new OECD MRL calculator and new residue data and to establish MRLs for rotated crops of potatoes, other root and tuber vegetables (except radishes), stem vegetables (except celery, leeks, globe artichokes), sugar beet, cereal forage, cereal straw was submitted.

In support of this application, sufficient valid residue field trials with grapes have been submitted. The resulting MRL for grapes is proposed as 5 mg/kg.

Sufficient valid rotational crop residue field trials covering the two geographical regions and the major crop groups of root and tuber vegetables, small grains and leafy vegetables were submitted. Merging data from NEU and SEU, MRLs are proposed and they can be used to extrapolate to the respective crop groups when grown in rotation (see Appendix B). These proposals are only applicable if the currently in place EU MRL is lower than the here proposed MRL for rotated crops. The existing MRL for wheat grain (also as rotational crop) is confirmed at the LOQ of 0.01 mg/kg. It is noted that for the pulses and oilseeds crop group no extrapolation is possible from the available rotational crops field trials. Accordingly, this results in a consumer risk assessment not finalised because a sufficient number of rotational field residue trials compliant with representative uses on crops belonging to the pulses/oilseeds crop group and covering the two different geographical regions is missing (see Section 9.2).

4. Environmental fate and behaviour

Dimethomorph consists of the *E*- and *Z*-isomer forms. The sum of both isomers was considered for the environmental exposure assessment.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, dimethomorph exhibited moderate to very high persistence, forming no major (> 10% applied radioactivity (AR)) metabolites. Mineralisation to carbon dioxide accounted for 30.9% after 121 days (^{14}C-morpholine-label), 22.6% after 121 days (^{14}C -chlorophenyl-label) and 0.97% after 120 days (^{14}C -dimethoxyphenyl-label). The formation of unextractable residues accounted for 50% after 121 days (^{14}C -morpholine-label), 56% after 121 days (^{14}C -chlorophenyl-label) and 46% after 120 days (^{14}C -dimethoxyphenyl-label). In anaerobic soil incubations dimethomorph was essentially stable. Dimethomorph exhibited low to medium mobility in soil. In satisfactory field dissipation studies carried out at five sites in Germany, one site in France, one in the UK and one in Spain, dimethomorph exhibited moderate to medium persistence. Field study DegT50 values were derived following normalisation to FOCUS reference conditions (20° C and pF2 soil moisture) following the EFSA (2014b) DegT50 guidance. The field data endpoints were not combined with laboratory values to derive modelling endpoints.

In laboratory incubations in dark aerobic natural sediment water systems, dimethomorph exhibited low to moderate persistence, forming no major (> 10% AR) metabolites. The unextractable sediment fraction was the major sink for the chlorophenyl ring ^{14}C radiolabel, accounting for 46.6–75% AR at study end (100 days) and for the morpholine ring ^{14}C radiolabel, accounting for 62–68% AR at study

end (100 days). Mineralisation of these radiolabels accounted for 3.2–21.9% AR and 1–8.6% AR at the end of the study, respectively. The rate of decline of dimethomorph in a laboratory sterile aqueous photolysis experiment was slow relative to that occurred in the aerobic sediment water incubations. No chromatographically resolved component (excluding dimethomorph) accounted for > 10% AR.

The necessary surface water and sediment exposure assessments (predicted environmental concentration (PEC) calculations) were carried out for dimethomorph, using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). For the active substance dimethomorph, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available.[12] The step 4 calculations appropriately followed the FOCUS (2007) guidance, with no-spray drift buffer zones of up to 20 m 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. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that, for substances with K_{Foc} < 2000 mL/g (i.e. dimethomorph), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

For the representative uses on strawberries in walk-in tunnels, step 3 (FOCUS, 2001) calculations were available[12] for dimethomorph, for the drainage scenarios as recommended by the EFSA guidance (EFSA, 2014a), except for the uses via dripping application at 5 kg a.s./ha (data gap and issue not finalised; see also Sections 5 and 9.1.1).

For the representative uses in permanent greenhouses, calculations were available for dimethomorph using the GEM model (Greenhouse Emission Model – version 3.3.2) (Step 3, EFSA, 2014a). It should be noted that the GEM model and the used scenario definition were an EU guidance agreed example scenario reflecting the Dutch conditions for high technology (permanent) greenhouses. However, it also needs to be noted that it may not be representative for the range of these structure types present in all EU territories.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 for dimethomorph. The potential for groundwater exposure from the representative uses by dimethomorph above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all seven FOCUS groundwater scenarios.

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. This has led to the identification of a data gap 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. A key to the persistence and mobility class wording used, relating these words to numerical DT and K_{oc} endpoint values can be found in Appendix E.

5. Ecotoxicology

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

Several aspects pertaining to the risk assessment of dimethomorph were discussed at the Pesticide Peer Review meeting 192 held in February 2019.

The batches used in the ecotoxicity studies were considered sufficiently representative of the proposed (and current) technical specification.

The greenhouse uses in lettuce are intended for application in permanent structures only, while the greenhouse uses in strawberries include applications both in permanent structures and in walk-in tunnels. For the uses in permanent structures, low risk to birds and mammals, non-target arthropods (including bees) and non-target terrestrial plants was concluded based on the limited exposure.

Acute and long-term toxicity studies with **birds** and **mammals** were available with the active substance. A long-term study with the formulation for representative uses 'BAS 550 01 F' was also

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

submitted. The long-term endpoint for mammals was discussed and agreed at the experts' meeting.[13] Based on the available data and risk assessment, low acute risk to birds was indicated at the screening step for all field uses while low long-term risk to birds was concluded either at the screening step (representative uses in grapes) or at tier 1 (uses in strawberries).

Low acute risk to mammals was indicated at the screening step or at tier 1, respectively, when considering the endpoint derived from the study with the active substance or with the formulation 'BAS 550 01 F' (only relevant for the uses in strawberries). High long-term risk to mammals was indicated at tier 1 for all representative field and walk-in tunnel uses.[14] Several options to refine the long-term risk to mammals were discussed at the experts' meeting.[15] The experts agreed to (i) refine the DT_{50} values for monocotyledonous and dicotyledonous plant food items based on the available residue decline trials in wheat and peas; (ii) use an updated deposition factor of 0.4 for strawberries at BBCH $\geq$ 40 based on EFSA (2014a); (iii) consider the common vole as relevant focal species for herbivorous mammals; (iv) refine the proportion of the diet of the common vole based on 50:50 monocotyledonous:dicotyledonous plants. After considering all these options in the refined assessment, high long-term risk to mammals was still indicated for all representative field and walk-in tunnel uses.

A low risk to birds and mammals from exposure to dimethomorph via drinking water was concluded for all representative uses. Considering that the octanol/water partition coefficient (log K_{ow}) of dimethomorph is < 3, a risk assessment for exposure via secondary poisoning was not triggered. Low risk to the relevant plant metabolites M550F002 and M550F006 was concluded for birds and mammals.

To evaluate the risk of dimethomorph to **aquatic organisms**, acute and chronic studies with several fish and aquatic invertebrate species were available with the active substance and the two formulations for the representative uses. A study with dimethomorph on the sediment-dwelling species *Chironomus riparius* was submitted. Toxicity studies with algae were available for the active substance and 'BAS 550 02 F'. Finally, two studies with macrophytes were available with 'BAS 550 01 F'. The outcome of the aquatic risk assessment is presented below:

- For the intended uses in grapes (both early and late applications), low risk to aquatic organisms was concluded at FOCUS Step 3 PEC_{sw};
- For the field uses in strawberries, high chronic risk to fish and aquatic invertebrates was indicated at FOCUS Step 3 PEC_{sw} (two out of four scenarios). However, low risk to aquatic organisms could be concluded at FOCUS Step 4 PEC_{sw} when considering mitigation measures consisting in 20 m no-spray buffer zone in combination with 20 m vegetative buffer strip;
- For the representative uses in strawberries in walk-in tunnels via drenching and dripping application at 1.5 kg a.s./ha, FOCUS Step 3 PEC_{sw} calculations were available for the drainage scenarios, as recommended by the EFSA guidance (EFSA, 2014a). Low risk to aquatic organisms could be concluded for such uses. For the uses via dripping application at 5 kg a.s./ha, FOCUS Step 3 PEC_{sw} calculations were not available for the drainage scenarios (data gap and issue not finalised; see Sections 4 and 9.1.1).
- For the uses in strawberries (dripping and drenching applications) and lettuce in permanent structures, low risk was concluded for strawberries and lettuces rooted in growing media at GEM PEC_{sw} whereas high risk to aquatic organisms was indicated for hydroponic strawberries and lettuces. No mitigation measures were available to refine the risk for any of those uses of dimethomorph.

Relevant aquatic metabolites were not identified; therefore, exposure to aquatic metabolites has not been considered further.

Acute (oral and contact) toxicity studies with **honeybees** were available with the active substance and both formulations for the representative uses. An acute oral larval study (single exposure) with 'BAS 550 01 F' was also submitted. A chronic adult study was available with 'BAS 550 01 F'. The endpoint from this study was used to assess the risk for the representative uses in grapes with 'BAS 550 02 F'. Further evidence is needed to conclude on the equivalence between both formulations (data gap, see Section 10). Acute toxicity studies were also available for the active substance on bumble bees. A semi-field (tunnel) study on *Phacelia tanacetifolia* was also submitted for 'BAS 550 01 F'. A risk assessment following the SANCO guidance on terrestrial ecotoxicology (European Commission, 2002a)

[13] Geometric mean DT_{50}'s were calculated from the available residue decline trials in wheat and peas. For further details, see experts' consultation point 5.1 at the Pesticide Peer Review Experts' meeting 192 (EFSA, 2023).

[14] For the uses in strawberries high risk was indicated for: small herbivorous mammals at BBCH > 40, small omnivorous mammals at BBCH 10–39, and large herbivorous mammals at BBCH 10–39. For the uses in grapes, high risk was indicated for small herbivorous mammals at BBCH $\geq$ 10–19.

[15] See experts' consultation points 5.2 and 5.3 at the Pesticide Peer Review Experts' meeting 192 (EFSA, 2023).

was not available. The risk assessment was conducted according to the EFSA (2013) bee guidance document. For honeybees, low acute risk from oral and contact exposure and low chronic risk to adults was concluded at the screening step for honeybees for all representative field uses. A repeated-exposure study on honeybee larvae covering the full life cycle was not available. However, low risk- to honeybee larvae could be concluded for the field uses in strawberries considering the single exposure study and the semi-field study where no effects on brood development were observed. Conversely, for the uses in grapes, the risk assessment to honeybee larvae could not be finalised due to the lack of sufficient evidence (issue not finalised and data gap, see Section 9.1.1).[16] Low risk due to exposure to contaminated water and guttation was concluded for all uses. A suitable assessment for accumulative and sublethal effects was not available (data gap, see Section 10). For bumble bees, high acute risk from contact exposure was indicated at tier 1 for the 'treated crop' scenario for the field uses in strawberries whereas low acute risk was concluded from oral exposure for such uses as well as from oral and contact exposure for the uses in grapes. No risk assessment was available for solitary bees.

Tier 1 laboratory studies on **non-target arthropods** (NTAs) other than bees were provided with the standard species, the predatory mite *Typhlodromus pyri* and the parasitic wasp *Aphidius rhopalosiphi* for 'BAS 550 01 F' and 'BAS 550 02 F', and with several other species (*Aleochara bilineata*, *Chrysoperla carnea*, *Episyrphus balteatus*, *Pardosa* sp., *Poecilus cupreus*) for one or both formulations for the representative uses. In addition, tier 2 extended laboratory studies were available for the standard species as well as for several other NTAs (*A. bilineata*, *Pardosa* sp., *Phytoseiulus persimilis*, *Trichogramma cacoeciae*). Several field studies with *T. pyri* and 'BAS 550 02 F' were also submitted as additional information. Based on the available data and risk assessment, low in-field and off-field risk was concluded for all representative uses.

Reproductive studies with **earthworms** were available with dimethomorph and both formulations for representative uses. Based on the available data and risk assessment, low risk was indicated for all representative uses, except for the drenching applications on strawberries in the field. To address the risk to **other soil macroorganisms**, reproductive studies were submitted with the collembolan *Folsomia candida* with both formulations and with the predatory mite *Hypoaspis aculeifer* with a formulation ('BAS 651 02 F')[17] different from any of the ones for representative uses. Low risk for soil macroorganisms other than earthworms was concluded for all uses. Also, low risk to **soil microorganisms** was indicated for all representative uses.

Seedling emergence and vegetative vigour studies with both representative formulations were submitted for several **non-target terrestrial plant** species. Based on the available data and risk assessment, a low risk was concluded for all representative uses of dimethomorph.

A study was available with the active substance to address the impact of dimethomorph on the **biological methods for sewage treatment**, and based on these data, a low risk was concluded.

6. Endocrine disruption properties

With regard to the assessment of the ED potential of dimethomorph for **humans** according to the ECHA/EFSA guidance (2018), in determining whether dimethomorph 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 dimethomorph with the EAS and T signalling pathways using the available evidence in the data set.

The **T-modality** has been considered sufficiently investigated and T-mediated adversity was not identified. Therefore, based on the available and sufficient data set, it was concluded that the ED criteria are not met for the T-modality (Scenario 1a of the EFSA/ECHA (2018) guidance).

A pattern of EAS mediated adversity has been observed for dimethomorph in a sufficiently investigated data set (i.e. histopathological changes in the prostate and testis in dog, decreased prostate weight in dog and rat, delayed preputial separation and decreased AGD in rat, decreased seminal vesicles weight in rat). The observed pattern of EAS-mediated adversity suggests an anti-androgenic mode of action (MoA). Although the endocrine nature of the observed effects is such that

[16] EFSA disagrees with the RMS who concluded low risk to honeybee larvae for the uses in grapes considering that (i) the larval toxicity study did not indicate any increased toxicity to larvae as opposed to adults and that (ii) exposure is expected to be lower.

[17] BAS 651 02 F contains dimethomorph (100 g/L) and a second active substance, ametoctradin (120 g/L).

biological plausibility can be reached without generating further data, the data set includes supporting evidence of endocrine activity from QSAR prediction (anti-androgen) and from the MDA-kb2 assay (IC20 = 0.263 μM). In addition, though the AR Tox-cast model prediction value is 0.06 (inconclusive), some limitations (low sensitivity) are recognised, and effects observed in the area under the curve above 0 should be considered in the overall weight of evidence. The two YAS assays were also indicative of anti-androgenic activity; though the effect was only noted at high concentrations (10–4 M, IC20 = 38.8 μM).

It was concluded that the ED criteria were met for the **EAS-modalities** (Scenario 1b of the EFSA/ECHA (2018) guidance).[18]

Adverse effects (changes in prostate and seminal vesicle weight and delayed preputial separation) were observed at the average dose of 63 mg/kg/day (44.3–100.3) with a NOAEL set at the average dose of 23.4 mg/kg bw per day (16.5–37.7) in the extended one generation study conducted in the rat. In the 90-day and in the 1-year dog studies, a decreased prostate weight and an increase in prostatic interstitial fibrosis were found at 43 and 47 mg/kg bw per day. The NOAEL for these effects was set at 15 mg/kg bw per day.

The outcome of the assessment for humans also applies to **wild mammals as non-target organism for oestrogen, androgen, steroidogenesis and thyroid (EATS) modalities.** Dimethomorph is not considered to be an endocrine disruptor for wild mammals through the **T-modality**, in line with the assessment for humans. Conversely, as also indicated for humans, dimethomorph meets the ED criteria for wild mammals for **EAS-modalities.** For instance, effects on reproductive organs (see above) linked to anti-androgenic MoA were observed in two species (rat and dog), and the MoA is considered also relevant for wild mammals.

For **non-target organisms other than mammals**, no data were available for the assessment of the ED properties through the T-modality. Regarding EAS-modalities, a fish short-term reproduction assay (FSTRA) was available. In such study, no treatment-related effects on apical endpoints (fecundity and growth) nor on diagnostic endpoints (secondary sexual characteristics in males and VTG) were observed over the 21-day exposure period. However, since the available *in vitro* evidence indicated that dimethomorph may be an androgen receptor antagonist, the FSTRA may not be sufficiently sensitive to detect anti-androgenic activity, as reported in the ECHA/EFSA ED Guidance (2018), and as also discussed during the Expert Meeting.[19] At the same meeting, it was concluded that since dimethomorph meets the ED criteria for humans and wild mammals as NTOs, no further data on fish were considered needed.

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605, it can be concluded that dimethomorph is an endocrine disruptor (critical area of concern in Section 9.1.2).

Regarding human health, considerations on the **negligible exposure** are reported in Section 2 (mammalian toxicology) and Section 3 (residues). Regarding the environment, it might be considered that exposure was not negligible, as the available PEC in soil, surface water and sediment for all the representative uses assessed are above levels that can be routinely measured.[20] There will be exposure of dimethomorph via food items of non-target organisms for the representative field uses, as these organisms will enter fields on the same day an application is made.

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
Dimethomorph	Low risk[(a)]

(a): Low risk to soil organisms was concluded for all representative uses of dimethomorph, except for the field uses in strawberries (drenching applications).

[18] See experts' consultation point 2.7 at the Pesticide Peer Review Meeting 190 (EFSA, 2023).
[19] See experts' consultation point 5.4 at the Pesticide Peer Review Meeting 192 (EFSA, 2023).
[20] In line with the ethos of FAO/WHO (2009) further discussed in EFSA Scientific Committee (2012) and limits of analytical quantification needed for monitoring methods set out in European Commission (2021).

Table 2: 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
Dimethomorph	No	Yes	–	–	Yes

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or a relevant lysimeter. Ranges indicated for FOCUS scenarios include the result from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014a) guidance.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Dimethomorph	High risk[(a)]

(a): High risk to aquatic organisms was indicated for uses in permanent structures in strawberries (dripping and drenching applications) and lettuce (hydroponic production only). The risk to the walk-in tunnel uses via dripping applications at 5.0 g a.s./ha could not be finalised. Low risk was concluded for all the other representative uses.

Table 4: Air

Compound (name and/or code)	Toxicology
Dimethomorph	Low acute oral toxicity by inhalation to rats.
	Rat LC_{50} inhalation > 5.2 g/L air/4 h (nose only)

LC_{50}: lethal concentration, median.

8. Particular conditions proposed to be taken into account by risk managers

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

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

Table 5: Risk mitigation measures (RMMs) proposed for the representative uses assessed

Representative use	Strawberries	Strawberries		Strawberries	Lettuce	Grapes
	F	F/G	G	G	G	F
	Spray (1.5 kg as/ha)	Drenching (1.5 kg as/ ha)	Dripping (5 kg as/ ha)	Dripping (1.5 kg as/ ha)	Spray (0.18 kg as/ ha)	Foliar spray
Operator standard exposure	Use of PPE is required[(a)]	No RMM needed	No RMM needed	No RMM needed	Use of PPE is required[(b)]	No RMM needed
Operator negligible* exposure	RMM insufficient	Use of gloves	Use of gloves	Use of gloves	RMM insufficient	Use of PPE is required[(c)]
Worker standard exposure	Use of gloves	No RMM needed	No RMM needed	No RMM needed	Use of gloves	No RMM needed[(d)]

Representative use	Strawberries	Strawberries		Strawberries	Lettuce	Grapes
	F	F/G	G	G	G	F
	Spray (1.5 kg as/ha)	Drenching (1.5 kg as/ ha)	Dripping (5 kg as/ ha)	Dripping (1.5 kg as/ ha)	Spray (0.18 kg as/ ha)	Foliar spray
Worker Negligible* exposure	RMM insufficient	No RMM needed	No RMM needed	No RMM needed	RMM insufficient	RMM insufficient(e)
Bystander/ resident standard exposure	No RMM needed	No RMM needed	No RMM needed	No RMM needed	No RMM needed	No RMM needed
Bystander/ resident negligible* exposure	RMM insufficient	No RMM needed	No RMM needed	No RMM needed	RMM insufficient	RMM insufficient
Risk to aquatic organisms	RMM equivalent to 20-m no-spray buffer zone combined with a 20-m vegetative strip(f)	RMM equivalent to 20-m no-spray buffer zone combined with a 20-m vegetative strip(g)	RMM not available(h)	RMM equivalent to 20-m no-spray buffer zone combined with a 20-m vegetative strip(f)	RMM not available(i)	RMM not needed

*: For negligible exposure, RMMs are reflected in the table in case they would lead to exposure below or equal to 10% of the AOEL and MoE > 1000. In order to give a clear overview, it is also mentioned when RMM are not needed or are insufficient to lead to an exposure level meeting the criteria for standard or negligible exposure. For further details and considerations as regards negligible exposure assessment please refer to Section 2 and Appendix B.

(a): For tractor-mounted applications: gloves (G) during mixing/loading (M/L); for hand-held applications: G and respiratory protective equipment (RPE) during M/L and G during application (A) (EFSA, 2014c).

(b): For hand-held application in greenhouse: use of gloves (Dutch greenhouse model).

(c): For tractor-mounted application: gloves during M/L and A, and closed cab; for hand-held application: gloves during M/L and A (EFSA, 2014c).

(d): Based on a field study.

(e): Based on a field study: use of gloves is not sufficient to reduce chronic exposure below 10% of the AOEL.

(f): Based on FOCUS Step 4 PECsw values.

(g): Only for field uses, based FOCUS Step 4 PECsw values. For greenhouse uses in permanent structures, FOCUS Step 4 PECsw values were not available. For uses walk-in tunnels, RMM were not needed.

(h): For the uses in permanent structures: RMM were not available for hydroponic strawberries while RMM were not needed for strawberries rooted in growing media. For the uses in walk-in tunnels, the risk assessment could not be finalised.

(i): Only for hydroponic lettuces. For lettuces rooted in growing media, RMM were not needed.

9. Concerns and related data gaps

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

9.1.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[22] 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).

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

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 assessment of the reliability of toxicity studies is not finalised (see Section 2).
   a) A transparent evaluation, according to guidance document European Commission, 2000a, of the analytical methods that were submitted during the first evaluation of the dimethomorph and used to support the renewal risk assessment was not available in the RAR (see Sections 1 and 2).
2) The risk assessment residue definition for ruminants is not finalised (see Section 3).
   a) New genotoxicity test battery on metabolite M550F021 (morpholine) following current OECD TG and GLP-compliant is not available (see Section 2).
3) The consumer risk assessment could not be finalised as several data gaps have been identified:
   a) A sufficient number of residue field trials (both greenhouse and NEU) on strawberries and compliant with the GAP on drenching/dipping at the latest BBCH GS 42 and compliant with the agreed residue definitions with analysis performed in a timeframe covered by storage stability data is required (relevant for the representative use on strawberries for both greenhouse and NEU with drenching/dipping application, see Section 3.1).
   b) A sufficient number of residue field trials in NEU on strawberries and compliant with the GAP on foliar spray application at the latest BBCH GS 42 and compliant with the agreed residue definitions with analysis performed in a timeframe covered by storage stability data is required (relevant for the representative use on strawberries in NEU and with foliar spray application, see Section 3.1).
   c) One additional drenching/dripping trial in NEU with strawberries at transplanting only is required (relevant for the representative use on strawberries in NEU with drenching/ dipping application, see Section 3.1).
   d) Proof of independency of the residue field trials with foliar spray application at transplanting (CA 6.3.1/3, study 1, spray application) as well as the validation reports of the analytical method is required. Alternatively, four residue trials with strawberry in the NEU with foliar spray application at transplanting are required (relevant for the representative use on strawberries in NEU with foliar spray application, see Section 3.1).
   e) Proof of independency of the four residue field trials with strawberries using drench application at transplanting in NEU (CA 6.3.1/3, study 2, drench application) is required. Alternatively, the same number of residue field trials is required (relevant for the representative use on strawberries in NEU with drenching/dipping application, see Section 3.1).
   f) Information of the exact application rate used in the four greenhouse residue field trials with strawberries using drench application at transplanting (CA 6.3.1/5, study 4), in order to perform a scaling calculation to the target GAP application rate, is required (relevant for the representative use on strawberries in greenhouse with drenching/dripping application, see Section 3.1).
   g) Appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water, is required (see Section 4).
4) The aquatic risk assessment for the walk-in tunnel uses in strawberries via dripping application at 5 kg a.s./ha could not be finalised.
   a) FOCUS Step 3 PEC_{sw} calculations were not available for the drainage scenarios (see Section 4).

5) The chronic risk to honeybee larvae could not be finalised based on EFSA (2013) for the representative uses in grapes.

   a) A toxicity study (repeated exposure covering the full life-cycle) was not available for the uses in grapes (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:

6) Dimethomorph has a harmonised classification as Reproductive toxicant category 1B (H360F 'may damage fertility'). According to the Annex II of Regulation (EC) No 1107/2009 point 3.6.4, an active substance shall only be approved if it is not classified as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use is negligible; or in accordance with the Art 4(7) where on the basis of documented evidence included in the application it is necessary to control serious danger to plant health which cannot be contained by other available means including non-chemical methods.
7) Dimethomorph is an endocrine disruptor for both humans and wild mammals as non-target organism, according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605.

9.1.3. Overview of the concerns identified for each representative use considered (Table **6**)

(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 6).

In addition to the issues indicated below, dimethomorph is considered to meet the criteria for ED for humans and wild mammals as non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605. For the considerations as regards negligible exposure assessment, please refer to Sections 2, 3 and 6, Table 5 and Appendix B. Moreover, dimethomorph is classified as Reproductive toxicant category 1B (H360F 'may damage fertility') and thus does not meet the criteria set in point 3.6.4 of the Annex II of Regulation (EC) No 1107/2009.

Table 6: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

Representative use		Strawberries	Strawberries		Strawberries		Strawberries	
		Spray and drenching (1.5 kg as/ha)	Drenching (1.5 kg a.s./ha)		Dripping (5 kg a.s./ha)		Dripping (1.5 kg a.s./ha)	
		Field	Green-houses	Walk-in tunnels	Green-houses	Walk-in tunnels	Green-houses	Walk-in tunnels
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[2,3]	X[2,3]	X[2,3]	X[2,3]	X[2,3]	X[2,3]	
Risk to wild non-target terrestrial vertebrates	Risk identified	X		X		X		X
	Assessment not finalised							
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X[(b)]						
	Assessment not finalised							
Risk to aquatic organisms	Risk identified		X[(c)]		X[(c)]		X[(c)]	
	Assessment not finalised					X[4]		
Groundwater exposure to active substance	Legal parametric value breached							
	Assessment not finalised							
Groundwater exposure to metabolites	Legal parametric value breached							
	Parametric value of 10 µg/L[(a)] breached							
	Assessment not finalised							

The superscript numbers relate to the numbered points indicated in Sections 9.1.1. Where there is no superscript number, see Sections 2–7 for further information.

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

(b): High risk to earthworms was concluded for the drenching applications.

(c): High risk to aquatic organisms was concluded for the greenhouse uses (permanent structures) in hydroponic strawberries and lettuce productions.

Representative use		Lettuce Spray Greenhouses	Grapes Spray Field
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non-target terrestrial vertebrates	Risk identified		X
	Assessment not finalised		
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		X[5]
Risk to aquatic organisms	Risk identified	X[(c)]	
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure to metabolites	Legal parametric value breached		
	Parametric value of 10 µg/L[(a)] breached		
	Assessment not finalised		

The superscript numbers relate to the numbered points indicated in Sections 9.1.1. Where there is no superscript number, see Sections 2–7 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.
(b): High risk to earthworms was concluded for the drenching applications.
(c): High risk to aquatic organisms was concluded for the greenhouse uses (permanent structures) in hydroponic strawberries and lettuce productions.

9.2. Issues not finalised under the maximum residue level applications

1. The consumer risk assessment could not be finalised.
    a) Sufficient number of rotational field residue trials compliant with representative uses on crops and representative of the pulses and oilseeds crop group and covering two different geographical regions (see OECD TG 504) are required (see Section 3.2).

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:

- Quality control data to support the proposed specification level of a significant impurity and data to confirm the identity of some of the impurities in the technical material were not available (data gaps, see confidential evaluation table of ADAMA and Section 1).
- Analytical methods for the determination of the relevant impurities Z12 and Z33 in the formulations for representative uses 'BAS 550 01 F' and 'BAS 550 02 F' were not available (see Section 1).
- A validated method for monitoring dimethomorph (as sum of *E*- and *Z*-isomer), and its metabolites M550F013 and M550F007 in body tissues was not available (see Section 1).
- UV/visible absorption spectra, IR, NMR and MS spectra data for the relevant impurities Z12 and Z33 were not provided (see Section 1).

- *n*-Octanol/water partition coefficient data for the metabolite M550F021 were not provided (see Section 1).
- Studies investigating the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom were not available (relevant for the representative use on strawberries in NEU with foliar spray application and with drench/ drenching application and for and grapes, see Section 3).
- Additional data were not available to conclude on the equivalence between the formulations for representative uses (relevant for the uses in grapes, see Section 5).
- Relevant data were not available to address the risk to honeybees from sublethal effects (relevant for all representative field uses, see Section 5).

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Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
DAD	diode-array detector
DAR	draft assessment report
DAT	days after treatment
DC	dispersible concentrate
DT_{50}	period required for 50% dissipation (define method of estimation)
EAS	oestrogen, androgen and steroidogenesis modalities
ECHA	European Chemicals Agency
ED	endocrine disruption
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
IESTI	international estimated short-term intake
IR	infrared
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_{50}	lethal concentration, median
LOQ	limit of quantification
MoA	mode of action
MRL	maximum residue level
NMR	Nuclear magnetic resonance
NOAEL	no observed adverse effect level
NTA	non-target arthropod
OECD	Organisation for Economic Co-operation and Development
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
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure–activity relationship
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation

RPE	respiratory protective equipment
SFO	single first-order
SMILES	simplified molecular-input line-entry system
T	thyroid
UV	ultraviolet
WHO	World Health Organization
WP	wettable powder

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

Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Dimethomorph does not have a harmonised classification as carcinogenic (any category) (ECHA RAC, 2019).
	Mutagenicity (M)	Dimethomorph does not have a harmonised classification as germ cell mutagenicity (any category) (ECHA RAC, 2019).
	Toxic for Reproduction (R)	Dimethomorph has a harmonised classification as Reproductive toxicant category 1B (H360F 'may damage fertility') (ECHA RAC, 2019).
Endocrine disrupting properties		The endocrine disruption properties of dimethomorph according to points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605. Dimethomorph is considered to meet the criteria for endocrine disruption for human health (EAS modalities) and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605.
POP	**Persistence**	Dimethomorph is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) No 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Dimethomorph is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) No 1107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Dimethomorph is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) No 1107/2009.
	Bioaccumulation	

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

Appendix B – List of end points for the active substance and the formulations for representative uses

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2023.8032

Appendix C – Evaluation of data concerning the necessity of dimethomorph as a fungicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

Appendix C can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2023.8032

Appendix D – Data collection set

Validated Excel files submitted by MS and evaluated by EFSA in the context of the assessment of the evaluation of data under Art 4(7) of Regulation (EC) No 1107/2009 concerning the necessity of dimethomorph as a fungicide to control a serious danger to plant health which cannot be contained by other available means.

Appendix D can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2023.8032

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

Wording	DT_{50} normalised to 20°C for laboratory[23] incubations 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

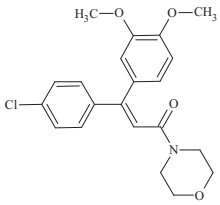
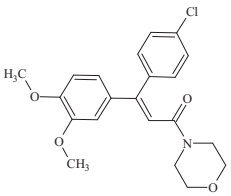
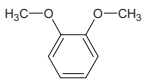
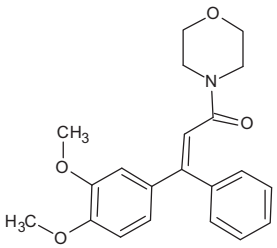
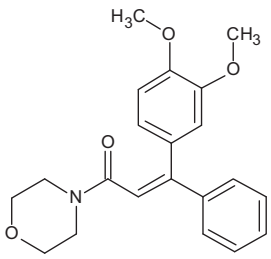
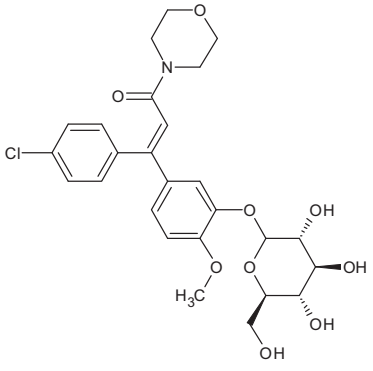
Note: These classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

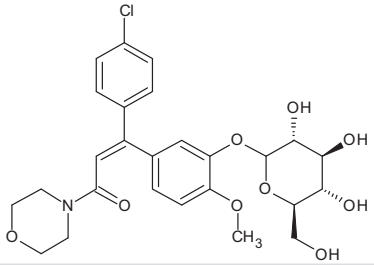
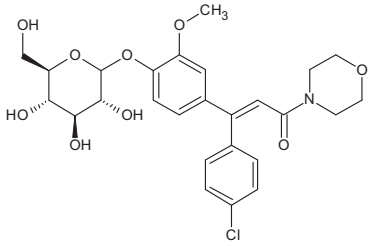
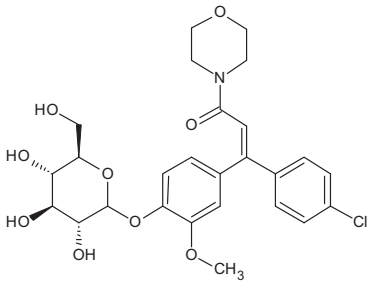
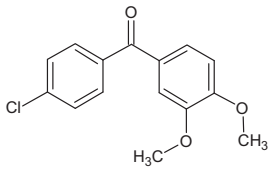
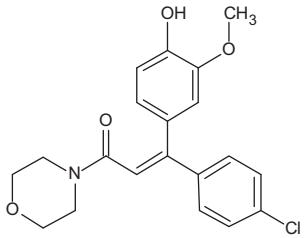
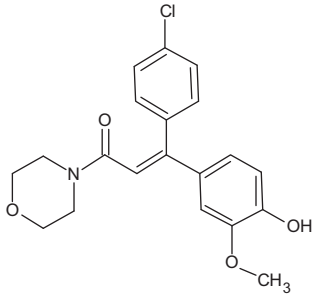
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0 to 50
High mobility	51 to 150
Medium mobility	151 to 500
Low mobility	501 to 2000
Slight mobility	2001 to 5000
Immobile	> 5000

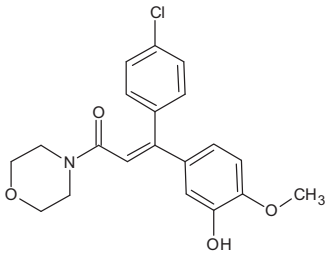
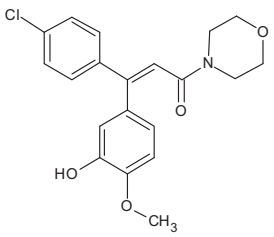
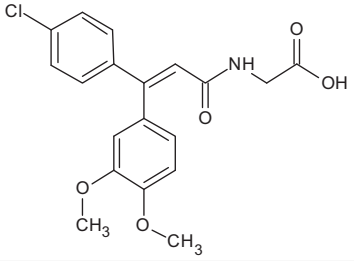
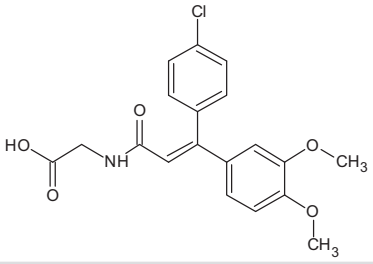
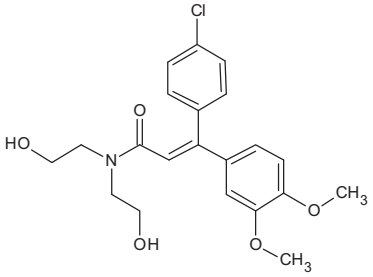
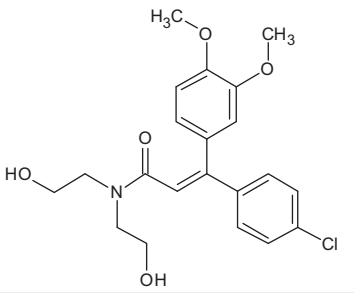
Based on McCall et al. (1980).

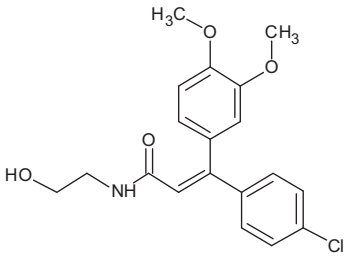
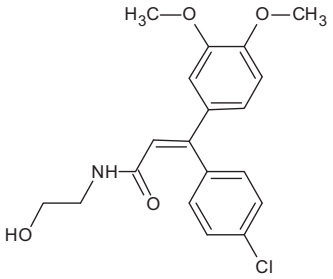
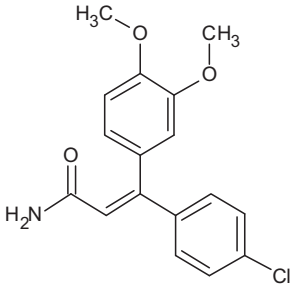
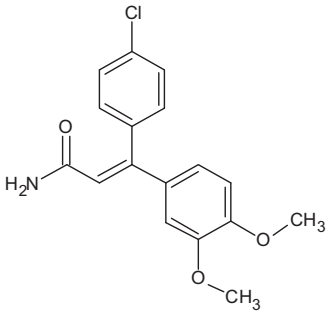
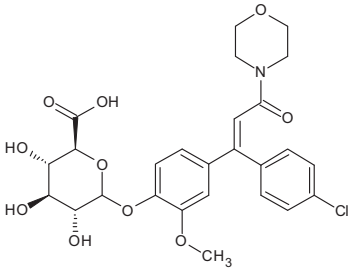
[23] For laboratory soil incubations normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

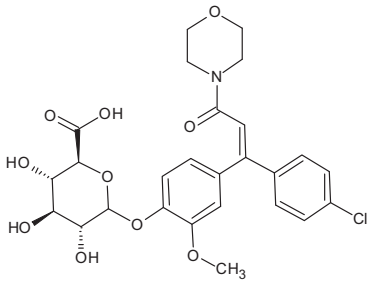
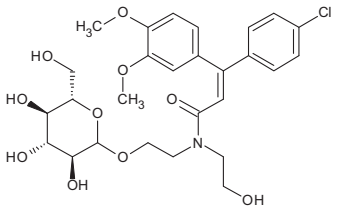
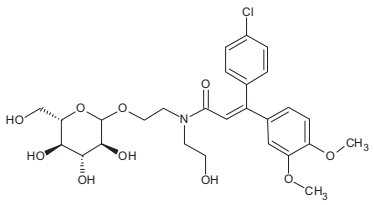
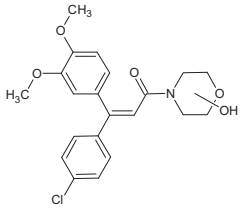
Appendix F – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
Dimethomorph	(2*EZ*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-(morpholin-4-yl)propanone Z- isomer: O=C(\C=C(\c1ccc(Cl)cc1)c1ccc(OC)c(OC)c1)N1CCOCC1 QNBTYORWCCMPQP-JXAWBTAJSA-N	
	E-isomer: O=C(\C=C(/c1ccc(Cl)cc1)c1ccc(OC)c(OC)c1)N1CCOCC1 QNBTYORWCCMPQP-NBVRZTHBSA-N	
Z12	1,2-dimethoxybenzene COc1ccccc1OC ABDKAPXRBAPSQN-UHFFFAOYSA-N	
Z33	(2E)-3-(3,4-dimethoxyphenyl)-1-(morpholin-4-yl)-3-phenylprop-2-en-1-one O=C(\C=C(/c1ccccc1)c1ccc(OC)c(OC)c1)N1CCOCC1 LYPNHHLQBJDNKX-OBGWFSINSA-N	
	(2Z)-3-(3,4-dimethoxyphenyl)-1-(morpholin-4-yl)-3-phenylprop-2-en-1-one O=C(\C=C(\c1ccccc1)c1ccc(OC)c(OC)c1)N1CCOCC1 LYPNHHLQBJDNKX-SDXDJHTJSA-N	
M550F001	5-[(1*E*)-1-(4-chlorophenyl)-3-(morpholin-4-yl)-3-oxoprop-1-en-1-yl]-2-methoxyphenyl D-glucopyranoside Clc1ccc(cc1)/C(=C\C(=O)N1CCOCC1)c1cc(OC2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)c(OC)cc1 CRQHSKGOMLZYOF-SUHHPTDKSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
	5-[(1*Z*)-1-(4-chlorophenyl)-3-(morpholin-4-yl)-3-oxoprop-1-en-1-yl]-2-methoxyphenyl D-glucopyranoside Clc1ccc(cc1)\C(=C\C(=O)N1CCOCC1)c1cc(OC2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)c(OC)cc1 CRQHSKGOMLZYOF-PRPWQQQDSA-N	
M550F002	4-[(1*E*)-1-(4-chlorophenyl)-3-(morpholin-4-yl)-3-oxoprop-1-en-1-yl]-2-methoxyphenyl D-glucopyranoside Clc1ccc(cc1)/C(=C\C(=O)N1CCOCC1)c1ccc(OC2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)c(OC)c1 UBNREEHHXZTZBU-SUHHPTDKSA-N	
	4-[(1*Z*)-1-(4-chlorophenyl)-3-(morpholin-4-yl)-3-oxoprop-1-en-1-yl]-2-methoxyphenyl D-glucopyranoside Clc1ccc(cc1)\C(=C\C(=O)N1CCOCC1)c1ccc(OC2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)c(OC)c1 UBNREEHHXZTZBU-PRPWQQQDSA-N	
M550F003	(4-chlorophenyl)(3,4-dimethoxyphenyl) methanone O=C(c1ccc(Cl)cc1)c1ccc(OC)c(OC)c1 MLLIIHAKTPXMFF-UHFFFAOYSA-N	
M550F007	(2*Z*)-3-(4-chlorophenyl)-3-(4-hydroxy-3-methoxyphenyl)-1-(morpholin-4-yl)prop-2-en-1-one O=C(\C=C(\c1ccc(Cl)cc1)c1ccc(O)c(OC)c1)N1CCOCC1 DZHMQVGPRFIRMK-LGMDPLHJSA-N	
	(2*E*)-3-(4-chlorophenyl)-3-(4-hydroxy-3-methoxyphenyl)-1-(morpholin-4-yl)prop-2-en-1-one O=C(\C=C(/c1ccc(Cl)cc1)c1ccc(O)c(OC)c1)N1CCOCC1 DZHMQVGPRFIRMK-GHRIWEEISA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
M550F006	(2*E*)-3-(4-chlorophenyl)-3-(3-hydroxy-4-methoxyphenyl)-1-(morpholin-4-yl)prop-2-en-1-one O=C(\C=C(/c1ccc(Cl)cc1)c1ccc(OC)c(O)c1)N1CCOCC1 VYDGFSXOLQSWOD-GHRIWEEISA-N	
	(2*Z*)-3-(4-chlorophenyl)-3-(3-hydroxy-4-methoxyphenyl)-1-(morpholin-4-yl)prop-2-en-1-one O=C(\C=C(\c1ccc(Cl)cc1)c1ccc(OC)c(O)c1)N1CCOCC1 VYDGFSXOLQSWOD-LGMDPLHJSA-N	
M550F008	N-[(2*Z*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)prop-2-enoyl]glycine Clc1ccc(cc1)/C(=C/C(=O)NCC(=O)O)c1ccc(OC)c(OC)c1 DYTWFTODJURDHV-GDNBJRDFSA-N	
	N-[(2*E*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)prop-2-enoyl]glycine Clc1ccc(cc1)\C(=C/C(=O)NCC(=O)O)c1ccc(OC)c(OC)c1 DYTWFTODJURDHV-XNTDXEJSSA-N	
M550F009	(2*E*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-N,N-bis(2-hydroxyethyl) prop-2-enamide Clc1ccc(cc1)\C(=C/C(=O)N(CCO)CCO)c1ccc(OC)c(OC)c1 CCVCCEKTQGPYLS-NBVRZTHBSA-N	
	(2*Z*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-N,N-bis(2-hydroxyethyl) prop-2-enamide Clc1ccc(cc1)/C(=C/C(=O)N(CCO)CCO)c1ccc(OC)c(OC)c1 CCVCCEKTQGPYLS-JXAWBTAJSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
M550F011	(2*Z*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-N-(2-hydroxyethyl)prop-2-enamide Clc1ccc(cc1)/C(=C/C(=O)NCCO)c1ccc(OC)c(OC)c1 LMXFCIQOJZGTAN-VBKFSLOCSA-N	
	(2*E*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-N-(2-hydroxyethyl)prop-2-enamide Clc1ccc(cc1)\C(=C/C(=O)NCCO)c1ccc(OC)c(OC)c1 LMXFCIQOJZGTAN-FOWTUZBSSA-N	
M550F012	(2*Z*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)prop-2-enamide Clc1ccc(cc1)/C(=C/C(N) = O)c1ccc(OC)c(OC)c1 MTDKZEXSIJZKKZ-UVTDQMKNSA-N	
	(2*E*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)prop-2-enamide Clc1ccc(cc1)\C(=C/C(N) = O)c1ccc(OC)c(OC)c1 MTDKZEXSIJZKKZ-GXDHUFHOSA-N	
M550F013	4-[(1*E*)-1-(4-chlorophenyl)-3-(morpholin-4-yl)-3-oxoprop-1-en-1-yl]-2-methoxyphenyl D-glucopyranosiduronic acid Clc1ccc(cc1)/C(=C\C(=O)N1CCOCC1)c1ccc(OC2O[C@@H]([C@@H](O)[C@H](O)[C@H]2O)C(=O)O)c(OC)c1 CRLFGPVOILZOMG-QSMZBRNKSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
	4-[(1*Z*)-1-(4-chlorophenyl)-3-(morpholin-4-yl)-3-oxoprop-1-en-1-yl]-2-methoxyphenyl D-glucopyranosiduronic acid Clc1ccc(cc1)\C(=C\C(=O)N1CCOCC1)c1ccc(OC2O[C@@H]([C@@H](O)[C@H](O)[C@H]2O)C(=O)O)c(OC)c1 CRLFGPVOILZOMG-XKSAQPKMSA-N	
M550F017	(2*Z*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-N-[2-(L-glucopyranosyloxy)ethyl]-N-(2-hydroxyethyl)prop-2-enamide Clc1ccc(cc1)/C(=C/C(=O)N(CCOC1O[C@@H](CO)[C@H](O)[C@@H](O)[C@@H]1O)CCO)c1ccc(OC)c(OC)c1 KYDLXEOGHYTKGK-MBCDTOAVSA-N	
	(2*E*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-N-[2-(L-glucopyranosyloxy)ethyl]-N-(2-hydroxyethyl)prop-2-enamide Clc1ccc(cc1)\C(=C/C(=O)N(CCOC1O[C@@H](CO)[C@H](O)[C@@H](O)[C@@H]1O)CCO)c1ccc(OC)c(OC)c1 KYDLXEOGHYTKGK-SFAYTMTGSA-N	
M550F018	Structure undefined, a unique name/SMILES/ InChiKey cannot be allocated	
M550F021, morpholine	Morpholine C1CNCCO1 YNAVUWVOSKDBBP-UHFFFAOYSA-N	

(a): The compound/ metabolite 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, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).