CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin

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Abstract

The conclusions of the EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Germany, and co-rapporteur Member State, Hungary, for the pesticide active substance beta-cyfluthrin are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of beta-cyfluthrin as an insecticide on beet, potato, wheat and greenhouse tomato. In addition, this conclusion also addresses the request received from the European Commission during the decision-making phase following completion of the peer review with regard to the risk to non-target arthropods. The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: beta-cyfluthrin, peer review, risk assessment, pesticide, insecticide

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') 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. Beta-cyfluthrin is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Germany, and co-rapporteur Member State (co-RMS), Hungary, received an application from the Task Force beta-cyfluthrin (ADAMA Agricultural Solutions Limited and Bayer AG, CropScience Division) for the renewal of approval of the active substance beta-cyfluthrin. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Hungary), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on beta-cyfluthrin in the renewal assessment report (RAR), which was received by EFSA on 8 March 2017. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Task Force beta-cyfluthrin, for comments on 20 March 2017. 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 19 June 2017.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether beta-cyfluthrin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of beta-cyfluthrin as an insecticide on beet, potato, wheat and greenhouse tomato, as proposed by the applicant. This conclusion also addresses the request received from the European Commission during the decision-making phase following completion of the peer review with regard to the risk to non-target arthropods.

Full details of the representative uses can be found in Appendix A of this report.

Data were submitted to conclude that the uses of beta-cyfluthrin according to the representative uses proposed at EU level result in a sufficient insecticidal efficacy against the target organisms.

A data gap was identified for an updated search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites in the mammalian toxicology and ecotoxicology sections.

In the area of identity, physical and chemical properties and analytical methods, data gaps were identified for an analytical method for the determination of beta-cyfluthrin in surface water with a limit of quantification (LOQ) of 0.0002 μg/L and for an analytical method of monitoring of the compounds of the residue definition in body fluids and tissues.

In the area of mammalian toxicology and non-dietary exposure, a data gap was identified to address the phototoxicity potential of beta-cyfluthrin at UVB ranges. For operators and workers during field use of 'Bulldock 25 EC', the use of personal protective equipment is required; whereas during the use of 'Montur Forte FS 230' as seed treatment the operators should use respiratory protective equipment, with the condition that different operators should perform the different tasks of mixing/loading, seed coating and storage logistics. Exposure estimates were exceeding the AOEL for operators, workers and residents (only with EFSA guidance) in greenhouses (even with the use of protective equipment for operators and workers), for workers re-entering fields (according to the EFSA guidance) or handling treated seed, and for residents in the case of field uses according to the EFSA guidance.

In the residues section, data gaps were identified for a rotational crop metabolism study, residue trials on wheat to complete the residue data set in NEU and SEU, two good agricultural practice (GAP)-compliant residue trials on potato, demonstration of stability of beta-cyfluthrin in bovine muscle and fat as well as in sugar beet and determination of the residues in pollen and bee products from human consumption. In view of the data gaps, the consumer risk assessment could not be finalised.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses, with the notable exception that exposure and risk assessment for representative uses on tomato, when using

semi-protected structures, were not finalised. Furthermore, a data gap was identified for information about conversion/preferential degradation of the individual diastereoisomer of beta-cyfluthrin and metabolite DCVA in the environmental compartments. Another data gap was identified for information on the effect of water treatment processes on the nature of residues of both the active substance (semi-protected tomato use) and its identified metabolites potentially present in surface water (all representative uses), when surface water is abstracted for drinking water. This gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses.

In the area of ecotoxicology, a high risk to wild mammals was concluded for the use to tomatoes in semi-protected structures (data gap). The risk assessment for birds and mammals for the use to pelleted beet could not be finalised with the available data; therefore, a data gap was identified. A high risk to aquatic organisms was concluded for the representative uses to wheat, potatoes and tomatoes (data gap). A high risk to honeybees was concluded for the representative use to tomatoes in semi-protected structures (data gap). A data gap for a comprehensive risk assessment for honeybees was concluded for the representative use to beet. A high risk to non-target arthropods was concluded for the representative uses to wheat, potatoes and tomatoes when applications are made in semi-protected structures (data gap).

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (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[2]. 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, Germany, and co-RMS, Hungary, received an application from the Task Force beta-cyfluthrin (ADAMA Agricultural Solutions Limited and Bayer AG, CropScience Division) for the renewal of approval of the active substance beta-cyfluthrin. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Hungary), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on beta-cyfluthrin in the RAR, which was received by EFSA on 8 March 2017 (Germany, 2017).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Task Force beta-cyfluthrin, for consultation and comments on 20 March 2017. 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 19 June 2017. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS and the European Chemicals Agency on 10 October 2017. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in July 2018, leading to the EFSA Conclusion finalised in August 2018 (EFSA, 2018b).

Following further considerations by risk managers during the decision-making process, on 12 December 2019, the European Commission requested EFSA to update the Conclusion on beta-cyfluthrin, in particular the Appendix A: List of end points with regard to the risk to non-target arthropods; more specifically:

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

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

i) to reflect the conclusion of the Pesticides Peer Review 174 expert meeting which was based on the study summaries submitted during the period specified in Article 13(3) of Regulation (EU) No 844/2012;
ii) to include a short summary for Appendix A with the key results of the field studies including the effects and time to recover of the different non-target arthropod species.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of beta-cyfluthrin as an insecticide on beet, potato, wheat and tomato (greenhouse application), as proposed by the applicant.

A list of the relevant end points for the active substance and the formulation, updated following the request received from the European Commission during the decision-making phase, is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2018c), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (10 October 2017);
- the evaluation table (6 August 2018, updated on 26 February 2020);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Germany, 2018, 2020), 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 report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Beta-cyfluthrin is the ISO common name for the reaction mixture comprising the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio 1:2 with the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC). It is noted that the unresolved isomeric mixture of this substance has the ISO common name cyfluthrin.

The representative formulated products for the evaluation were 'Montur Forte FS 230', a flowable concentrate for seed treatment (FS) containing 80 g/L of beta-cyfluthrin and 150 g/L imidacloprid, and 'Bulldock 25 EC (MCW-5976)', an emulsifiable concentrate (EC) containing 25 g/L beta-cyfluthrin.

The representative uses evaluated for 'Montur Forte FS 230' were seed treatment applications on beet against aphids and thrips; the representative uses evaluated for 'Bulldock 25 EC' were field spray applications against sucking and biting insects in potato, wheat and greenhouse tomato in the EU. Full details of the GAPs can be found in the list of end points in Appendix A.

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

A data gap has been identified for an updated scientific peer-reviewed open literature review on the active substance and its relevant metabolites, dealing with side effects on human health and non-target species, published within the 10 years before the date of submission of the dossier and reported in accordance with the EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). In particular for human health to clarify the exclusion process of irrelevant studies based on title and abstract (step 1), to assess relevance rather than reliability at the second step of the selection based on full-text documents and to provide full-text files for articles considered relevant. An updated

literature search using appropriate criteria for selecting studies should also be added to the ecotoxicology dossier (data gap relevant for Sections 2 and 5).

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: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b), SANCO/825/00-rev. 8.1 (European Commission, 2010).

The proposed specification for beta-cyfluthrin is based on batch data from industrial scale production. The proposed minimum purity of the technical material is 965 g/kg with ranges of 300–400 g/kg for diastereoisomer II (AE 1421342; *R*,1*S*,3*S*; *S*,1*R*,3*R*) and 570–670 g/kg for diastereoisomer IV (AE 1421344; *R*,1*S*,3*R*; *S*,1*R*,3*S*). It is proposed to update the reference specification as only the newly proposed specification can be supported from the toxicological point of view. The minimum purity and the content of the diastereoisomers II and IV are identical with the FAO Specification 482/TC (2016).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of beta-cyfluthrin or the representative formulations. For the formulation 'Bulldock 25 EC', a label instruction for protecting from frost is recommended. The main data regarding the identity of beta-cyfluthrin and its physical and chemical properties are given in Appendix A.

Adequate methods of analysis are available for the determination of the active substance in the technical material and in the representative formulations. CIPAC methods are also available for the determination of beta-cyfluthrin in the technical material and representative formulations.

The residue definition for monitoring for food and feed of plant and animal origin was set to cyfluthrin (including other mixtures of constituent isomers (sum of isomers)). Monitoring the compounds of the residue definition can be done by the multiresidue method DFG S19 using gas chromatography-mass spectroscopy (GC-MS) with LOQs of 0.01 mg/kg in all commodity groups. The components of the residue definition for monitoring for food and feed of animal origin can be determined by using the multi-residue method DFG S19 with gas chromatography-electron capture detector (GC-ECD) with LOQs of 0.01 mg/kg in all matrices.

The residue definition for monitoring in the environmental matrices was defined as constituent isomers of beta-cyfluthrin. Beta-cyfluthrin can be determined in soil by the multi-residue method DFG S19 with GC-ECD with an LOQ of 0.01 mg/kg. Residues of beta-cyfluthrin in surface water and drinking water can be determined by LC-MS/MS with an LOQ of 0.01 μg/L. For surface water, sufficiently validated primary and confirmatory methods allowing the determination of 0.0002 μg/L beta-cyfluthrin are missing; as a consequence, a data gap was identified (see Appendix A, Section 5). Monitoring beta-cyfluthrin residues in air is possible with GC-MS/MS with LOQs of 0.069 $\mu g/m^3$ for each enantiomeric pair.

Residues of beta-cyfluthrin in the body fluids can be determined by LC-MS/MS with an LOQ of 0.05 mg/L and in body tissues by the multi-residue method DFG S19 with GC-ECD with an LOQ = 0.01 mg/kg; however, it was concluded that the residue definition should include the sulfate conjugate of 4-OH-FPB acid, too (see Section 2). As a consequence, a data gap was identified for a method for the monitoring of the compounds of the residue definition in body fluids and tissues.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on Dermal Absorption (EFSA PPR Panel, 2012) and Guidance on the application of the CLP Criteria (ECHA, 2017).

Beta-cyfluthrin has been discussed by the experts in mammalian toxicology during the Pesticides Peer Review Experts' Meeting 172 in February 2018. Considering the similar toxicological profile of beta-cyfluthrin and cyfluthrin in short-term and developmental studies, the experts agreed to read-across from cyfluthrin (e.g. for long-term and reproductive toxicity).

The proposed levels of impurities in the new technical specification are covered by the levels in the batches used for the toxicity studies (with cyfluthrin and beta-cyfluthrin). Impurities are considered non-relevant. The analytical data provided were considered reliable for most of the toxicological studies.

Based on the available data for cyfluthrin and beta-cyfluthrin, the overall oral absorption value for beta-cyfluthrin can be considered as higher than 80%. Widely distributed into the tissues, the compound is extensively metabolised and rapidly excreted, predominantly via urine and faeces. The residue definition for body fluids should include at least the major metabolite, sulfate conjugate of 4-OH-FPB acid, identified in the rat. No unique human metabolite has been detected in an *in vitro* comparative metabolism study.

For the acute toxicity, beta-cyfluthrin has a harmonised classification[3] in category 2 (fatal if swallowed and fatal if inhaled) but does not have irritating or sensitising properties. Beta-cyfluthrin did not show phototoxicity potential in an OECD Test Guideline 3T3 NRU-PT test. However, the test had some limitations. It is also noted that the OECD 3T3 NRU-PT might not allow concluding properly on the phototoxicity potential of beta-cyfluthrin since it is an UVB absorber and the 3T3 NRU-PT test might not be appropriate test for UVB absorbers. It is noted, however, that there is no OECD test for UVB absorber leading to a data gap.

In the short-term toxicity studies, neurotoxic effects were observed in rats and dogs, with a relevant no observed adverse effect level (NOAEL) of 1 mg/kg body weight (bw) per day from the subacute rat study with beta-cyfluthrin. Additionally, taking also into account human medical data, a classification **STOT-SE 3** (May cause respiratory irritation) is proposed[4] for beta-cyfluthrin. A similar toxicological profile was observed in comparable studies with cyfluthrin and beta-cyfluthrin.

Based on the overall weight of evidence from the available studies, beta-cyfluthrin is considered unlikely to be genotoxic *in vivo* or carcinogenic. For the long-term toxicity, the read-across from cyfluthrin to beta-cyfluthrin was considered acceptable. The relevant NOAEL for the rat was 2.6 mg/kg bw per day based on body weight gain reduction, while the relevant lowest observable adverse effect level (LOAEL) for the mouse was 32 mg/kg bw per day based on organ weight changes (ovary and spleen) and skin findings due to scratching (paresthesia).

For the rat multigeneration study, the read-across from cyfluthrin to beta-cyfluthrin was also considered acceptable. In the absence of effects on the reproductive parameters, the parental NOAEL was 3.3 mg/kg bw per day based on body weight reduction. The offspring NOAEL was 3.3 mg/kg bw per day based on clinical signs and lower pup weight, triggering a new proposal for classification as **Lact H362 May cause harm to breast-fed children.**[5]

For the rat developmental studies, the maternal NOAEL was 3 mg/kg bw per day based on decreased body weight gain and food consumption, mortality and clinical signs, and the relevant developmental NOAEL was 10 mg/kg bw per day based on decreased fetal weight and retarded ossification/skeletal variations at 40 mg/kg bw per day. For the rabbit developmental studies, the maternal NOAEL was 20 mg/kg bw per day based on reduced food consumption and body weight loss and the relevant developmental NOAEL was 20 mg/kg bw per day based on increased number of post-implantation resorptions. Based on the increased incidences of microphthalmia in the rat studies by inhalation, the classification **Reproductive toxicant category 2 H361d Suspected of damaging the unborn child**[6] was proposed by the majority of the experts, excluding the RMS (see experts' consultation 2.7[6] in EFSA, 2018c).

Since beta-cyfluthrin is proposed to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and no toxic effects have been observed on the endocrine organs in the available data, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine-disrupting properties would not be met. From the scientific point of view, on the basis of the available data and current knowledge (OECD Conceptual Framework, as analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors; EFSA Scientific Committee, 2013), it is concluded that beta-cyfluthrin is unlikely to have endocrine-disrupting properties.

In neurotoxicity studies, an NOAEL of 2 mg/kg bw was identified in rats based on clinical signs, after acute or repeated exposure. In a developmental neurotoxicity study with beta-cyfluthrin in rats, the maternal and offspring NOAEL was 11 mg/kg bw per day based on lower body weight gain in

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

[4] See experts' consultation 2.3 of the report Pesticides Peer Review 172_03 Beta-cyfluthrin (EFSA, 2018c). It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

[5] See experts' consultation 2.6 of the report Pesticides Peer Review 172_03 Beta-cyfluthrin (EFSA, 2018c).

[6] See experts' consultation 2.7 of the report Pesticides Peer Review 172_03 Beta-cyfluthrin (EFSA, 2018c).

dams and offspring, together with clinical signs in the offspring. On the basis of the available data, beta-cyfluthrin is considered unlikely to have immunotoxic properties.

Being major rat metabolites (or plausible precursor), DCVA, FPB acid (and its precursor FBP aldehyde) and 4-OH-FPB acid were considered covered by the toxicological profile (and the reference values) of beta-cyfluthrin. For the other metabolites, the limited data available (acute studies or Ames test) and poorly reported quantitative structure–activity relationship (QSAR) analysis did not allow to conclude about their toxicological profile. These metabolites included FPB alcohol, FPB amide, Me-FPB acid, FPB, cyfluthrin acid (COOH-cyfluthrin) and Me-cyfluthrin (no data gap considering the representative uses, see also Section 3).

For beta-cyfluthrin, the same value of 0.01 mg/kg bw (per day) was derived for the **Acceptable Daily Intake** (ADI), the **Acute Reference Dose** (ARfD) and the **Acute Acceptable Operator Exposure Level** (AAOEL), on the basis of the 4-week rat study with the application of an uncertainty factor (UF) of 100; whereas the **Acceptable Operator Exposure Level** (AOEL) was 0.000243 mg/kg bw per day based on the subchronic inhalation study in rats, applying an UF of 100. The RMS disagreed with this decision to derive an AAOEL. For the first approval, the ADI was 0.02 mg/kg bw per day based on chronic rat study, revised to 0.003 mg/kg bw per day based on a pharmacological study in mice. The ARfD was 0.02 mg/kg bw based on the acute oral rat neurotoxicity study and the AOEL was 0.02 mg/kg bw per day based on 90-day and acute oral rat neurotoxicity studies (European Commission, 2002b).

Considering the acceptable read-across between cyfluthrin and beta-cyfluthrin (e.g. for long-term and reproductive toxicity), and the similar toxicological profile of both compounds in short-term and developmental studies, it can be considered that the critical study (4-week rat, used for the derivation of the ADI and ARfD) identified for beta-cyfluthrin will also cover the toxicological profile of cyfluthrin.

For the plant protection product '**Bulldock 25 EC**', the dermal absorption values are 13% for the concentrate and 37% for the spray dilution. Revised exposure estimates were provided in the revised RAR (Germany, 2018). For the ***greenhouse use***, the operator and worker exposure estimates are above the AOEL even with the use of personal protective equipment (PPE including workwear and protective gloves and respiratory protective equipment during mixing/loading and application for operators and workwear and gloves for workers), while bystanders and residents are below the AOEL (for non-permanent structure and only if located at 10 m, according to the original German approach (Martin et al. 2008)). Based on the EFSA guidance (EFSA, 2014c), the values for residents are above the AOEL. For the ***field use***, based on the models applicable to the dossier submission, operator and worker exposure is below the AOEL with the use of PPE (gloves during mixing, loading and application, coverall and sturdy footwear during application for operators, and workwear and gloves for workers) according to the German Models. Bystander and resident exposure is below the AOEL according to the original German model (Martin et al. 2008; inhalation exposure to vapour is not taken into account). Estimates for bystander and resident according to the UK approach[7] have not been presented. For the field use, based on the EFSA guidance (EFSA, 2014c), the operator exposure values are below the AOEL with the use of PPE (including workwear and protective gloves during mixing/loading and application, and hood and visor during mixing/loading and drift reduction nozzles during application), while the values for residents and workers are above the AOEL (a re-entry restriction period of 66 days would be needed to reduce the worker estimates below the AOEL, which is not in accordance with the GAP, i.e. preharvest interval (PHI), and therefore, this restriction is not proposed). For the bystanders, the exposure estimates are below the AOEL. From the scientific point of view, EFSA supported the assessment for bystander and resident according to the EFSA guidance since exposure according to previous models might be underestimated.

For the plant protection product '**Montur Forte FS 230**', the dermal absorption values are 0.1% for the concentrate, 0.3% and 0.7% for the spray dilutions. The operator exposure estimates for the representative use on ***beet seed*** are below the AOEL if respiratory protective equipment (RPE) is used during the different tasks which are performed by different operators (based on field studies), while the exposure estimates for workers loading and sowing the treated seed are exceeding the AOEL. Bystanders and residents are not expected to be exposed during seed treatment in professional plants.

[7] It is noted that default vapour concentration of 0.001 mg/m^3 is taking into account in the UK approach (similar to the EFSA guidance where exceedance for this route was noted for residents). It is also noted that the UK approach also considered re-entry of general public in the field (similar to the EFSA guidance where exceedance for this route was noted for residents).

3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on maximum residue level (MRL) calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2011) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

Beta-cyfluthrin was discussed at the Pesticides Peer Review Experts' Meeting 173 in February 2018.

Beta-cyfluthrin and cyfluthrin are two active substances differing only in their isomeric composition. It has been demonstrated in experiments that isomerisation of beta-cyfluthrin starts immediately upon application on plants resulting in an equilibrium of isomeric pairs equal to the composition of cyfluthrin. It is noted that some studies were performed with cyfluthrin, others with beta-cyfluthrin as test material. However, considering that the two substances have similar toxicological profiles (see Section 2), studies performed with cyfluthrin have been accepted in the context of this risk assessment.

Metabolism was studied in fruit crops (tomato and apple), root crops (potato and sugar beet), cereals (wheat) and pulses/oilseeds (soybean and cotton) upon foliar application except for sugar beet (seed treatment). For details of the radiolabelling positions of the test item for each crop group, see Appendix A. No crop group had more than two radiolabelling positions investigated. In the studies with foliar application parent was with more than 50% total radioactive residue (TRR) the predominant residue for all plant parts and growth stages investigated, but a number of metabolites (FPB, FPB aldehyde, FPB acid, FPB alcohol, 4-OH-FPB acid, Me-FPB acid, FPB amide, cyfluthrin acid (COOH-cyfluthrin), Me-cyfluthrin and in the cyclopropyl-labelled study also DCVA) were observed at or below 10% TRR. The studies employing foliar/fruit application are all non-Good Laboratory Practice (GLP) and non-guideline compliant studies. Though they have several shortcomings and cannot be regarded fully acceptable as stand-alone studies, altogether they are considered suitable to elucidate the metabolism in plant and can be used for risk assessment. The treatment of sugar beet seeds with cyclopropane-labelled beta-cyfluthrin resulted in extensive metabolism and only conjugates (up to 80% TRR) were detected in root and leaves at maturity; whereas the labelling with fluorophenyl ring resulted in parent as major residue in roots (43% TRR).

The metabolic pathway in rotational crops could not be derived since metabolites' identification was not conducted at any plant back interval (data gap for all uses) using red beet, kale and wheat. Magnitude of beta-cyfluthrin residues was studied in the rotational crops carrots, lettuce and wheat after application to bare soil and primary crop at different plant back intervals in two studies, assuming that the residue definition for plants would also cover rotational plants. Beta-cyfluthrin was not found at levels above the LOQ of 0.01 mg/kg.

A simulated processing study using [fluorophenyl-UL-14C]-beta-cyfluthrin was provided although not required by legislation due to the low water solubility. The substance was stable under pasteurisation (pH 4 and 90°C) and baking, brewing, boiling (pH 5 and 100°C) conditions, but degradation under sterilisation conditions (pH 6 and 120°C) was observed. Given the low solubility of the parent, the identification attempts were deemed to be sufficient.

Processing factors (mean of two trials) were established for canned tomato, tomato raw juice, tomato raw puree and wet pomace.

The general residue definition for risk assessment and monitoring for primary plants and provisionally pending the new rotational crop study is set as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)**.

A sufficient number of critical GAP compliant residue trials supported by storage stability data for greenhouse tomato were provided. The database for critical GAP compliant field trials with wheat is not complete for NEU and SEU (data gap) and storage time in all potato trials was longer than supported by storage stability data (data gap). Stability data for sugar beet are lacking to conclude on the validity of the residue trials (data gap).

Storage stability data were provided for several raw agricultural and processed commodities covering the high water and high starch commodity category. Stability data for sugar beet covered by the commodity groups 'root and tuber vegetables' within the high starch group are not available (see data gap above). The data in the other two commodity groups, cereal grain and starchy root crops, are too diverse (13/25 months (maize/wheat grain) and 1 month (potato), respectively) in order to conclude on the whole group or to extrapolate to roots of root and tuber vegetables. It should be noted that the analytical method used for maize oil and oranges was not fully validated for these

commodities (no data gap identified for the representative uses, however, in the light of future uses, it is recommended to provide the missing data). For the animal matrices bovine muscle and fat, no data for the incurred residues are available at the time of sacrifices (time zero), and therefore, no conclusion can be drawn on the stability in theses matrices. A data gap has been identified to demonstrate stability for the storage period in these matrices in the feeding study.

Metabolism studies for poultry, ruminants and fish were available. In the poultry study, cyfluthrin was predominant in all matrices (12–75% TRR) and to a minor extent FPB acid and 4-OH-FPB acid (up to 26% and 20% TRR, respectively). In a non-GLP and non-guideline compliant cow study using phenyl C^{14}-cyfluthrin, high TRRs (0.022–0.622 mg/kg) were observed with the parent compound being the major residue in all matrices including milk (56–99% TRR) together with FPB aldehyde in liver (14% TRR) and FPB alcohol in kidney (43% TRR). In a new study in goats with cyclopropane C^{14} label, TRR was below 0.01 mg/kg in liver, kidney and muscle and parent was identified as the major compound in milk. The differences observed were attributed to more extensive excretion in the goats. Metabolism was investigated in rainbow trouts by feeding [cyclopropane-1-^{14}C]beta-cyfluthrin and [fluorophenyl-UL-^{14}C]beta-cyfluthrin. Parent was the major residue in liver (16% TRR for cyclopropyl label ad 27% TRR for the fluorophenyl label) and muscle (82% TRR for cyclopropyl label ad 86% TRR for the fluorophenyl label).

The residue definition both for risk assessment and monitoring for animals is set as **cyfluthrin, including other mixtures of constituent isomers (sum of isomers)**.

In feeding studies with poultry and cows (non-GLP and non-guideline compliant), quantifiable residues were found in liver, kidney, muscle and milk (cow) and in fat of both animals. The results from these studies are subject to confirmation of storage stability in muscle and fat tissues (data gap).

The consumer risk assessment is indicative due to data gaps for residue trials on wheat, sugar beet and potato and missing information to address the effect of water treatments processes on the nature of the residues and the relevance for exposure via drinking water (see Section 4). For the representative use on tomatoes data allowed to perform a consumer risk assessment. With the provisional residue levels, the chronic exposure (theoretical maximum daily intake (TMDI)) was around 4.6% of the ADI of beta-cyfluthrin (NL, child) and acute exposure was at maximum 17% ARfD of beta-cyfluthrin for the same population from consumption of tomatoes alone. This assessment does not take into account information on the nature and/or magnitude of residues from rotational crops.

Information on residue levels in pollen and in bee products for human consumption was not submitted (data gap).

4. Environmental fate and behaviour

Beta-cyfluthrin was discussed at the Pesticides Peer Review Teleconference 163 in February 2018.

Cyfluthrin and beta-cyfluthrin are two active substances differing only in their isomeric composition. While cyfluthrin consists of four enantiomeric pairs of diastereoisomers, beta-cyfluthrin represents the biologically more active diastereoisomers (isomers II and isomers IV). It should be noted that the exposure assessment presented in the fate and behaviour section considered the sum of diastereoisomers as input for calculation of the degradation rates, and all Predicted Environmental Concentration (PEC) values were calculated based on total constituent isomers of beta-cyfluthrin present in each environmental compartment. The diastereoisomers of beta-cyfluthrin, however, have not been separately reported in the studies performed to investigate the fate and behaviour of beta-cyfluthrin in the environment. No information on the environmental behaviour of each individual isomer was made available (data gap). This is also the situation for metabolite DCVA that contains chiral carbon atoms. Nevertheless, it is considered that the margin of safety in the available risk assessments for beta-cyfluthrin and metabolite DCVA is large enough so that the uncertainty on the relative toxicity and contributions to the total residue levels of the diastereoisomers does not change the risk assessment. Further information on this is considered unnecessary to finalise the environmental risk assessments for the representative uses assessed (see Section 5).

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, beta-cyfluthrin exhibited low to moderate persistence, forming the major (> 10% applied radioactivity (AR)) metabolites FPB acid (max. 12.7% AR) and DCVA (max. 10.1% AR), which exhibited very low to low and low persistence, respectively. Mineralisation of the fluorophenyl and cyclopropyl ring ^{14}C radiolabel to carbon dioxide accounted for 47.3% AR after 94 days and 41.0–44.1% after 91 days, respectively. The formation of unextractable residues (not extracted by acetonitrile/water) for

fluorophenyl ring ^{14}C radiolabel accounted for 33.4% after 94 days and for cyclopropyl ring ^{14}C radiolabel accounted for 29.2–45.7% AR after 91 days. In anaerobic soil incubation, the degradation pathway was similar to that under aerobic conditions. The contribution of photolytic transformation processes is not relevant for the dissipation of beta-cyfluthrin from the soil surface. No additional metabolites were transformed from parent under radiation.

Adsorption studies were conducted with cyfluthrin as test substance. These studies were considered acceptable in order to derive adsorption endpoints to be used in the exposure assessment of beta-cyfluthrin, since adsorption of diastereoisomers is not expected to be significantly different compared to the variability in adsorption between soils with varying properties. Water solubility of cyfluthrin is low (about 6 μg/L) and the sorption to soil is high; therefore, no Freundlich isotherms were determined and the distribution coefficients Kd at one concentration were determined. Cyfluthrin exhibited immobility in soil. Metabolites FPB acid and DCVA exhibited very high to medium soil mobility. It was concluded that the adsorption of beta-cyfluthrin and its metabolites was not pH dependent. For metabolite DCVA, considering that the pKa is 5.1, it was agreed to split the data set at pH > 5 in order to derive adsorption endpoint to be used for modelling.

Metabolite DCVA is common metabolite to beta-cypermethrin and zeta-cypermethrin for which published EFSA conclusions are available (EFSA 2008a, 2014b). Therefore, reliable peer-reviewed agreed endpoints were added to the degradation and adsorption endpoints of the present assessment (see Appendix A).

In satisfactory field dissipation studies carried out at two sites in France, one in Spain and one in Germany (spray application to the soil surface on bare soil plots in late summer/early autumn) beta-cyfluthrin exhibited low to moderate persistence. Sample analyses were only carried out for the constituent isomers of beta-cyfluthrin. Field study DegT50 values were derived only for two soils following normalisation to FOCUS reference conditions (20°C and PF2 soil moisture) following the EFSA (2014a) DegT50 guidance. Therefore, the field data endpoints were not combined with lab values to derive modelling endpoints.

In laboratory incubations in dark aerobic natural sediment water systems, where cyfluthrin was dosed, the relative amounts of diastereoisomers II and IV were summed up and combined with the measured concentration (% AR) of cyfluthrin to account for beta-cyfluthrin. Beta-cyfluthrin exhibited moderate persistence, forming the major metabolites DCVA (max. 36.0% AR in water and 23.7% AR in sediment, exhibiting high persistence based on the available data), FPB aldehyde (max. 1.1% AR in water and 15.7% AR in sediment, exhibiting low persistence), and FPB acid (max. 29.1% AR in water and 24.3% AR in sediment, exhibiting low persistence). The unextractable sediment fraction (not extracted by acetonitrile/water) was the major sink for the cyclopropane ring ^{14}C radiolabel, accounting for 12.2–26.0% AR at study end (100 days). Mineralisation of this radiolabel accounted for 14.2–36.7% AR at the end of the study. The rate of decline of beta-cyfluthrin in a laboratory sterile aqueous photolysis experiment was fast, relative to that occurred in the aerobic sediment water incubations. No chromatographically resolved component (excluding constituent isomers of beta-cyfluthrin) accounted for more than 8% AR.

For the representative uses in winter and spring cereals and potato, the necessary surface water and sediment exposure assessments (PEC calculations) were carried out for the metabolites DCVA, FPB acid and FPB aldehyde, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1-2 in FOCUS calculator). For the active substance beta-cyfluthrin, appropriate step 3 (FOCUS, 2001) simulations were available. Surrogate Step 4 calculations were carried out by the RMS for the uses on winter and spring cereals and potatoes reducing manually the Step 3 concentrations by 95%. These PECs were considered inappropriate.

For the representative protected use on tomato, when using permanent greenhouse structures, the necessary PEC were appropriately carried out using the FOCUS (2001) Step 3 scenarios approach, which was modified by pre-processing the spray drift input generated by SWASH to obtain a 0.1% emission of beta-cyfluthrin from greenhouses being re-deposited on adjacent surface water bodies. Substance daily mass flux calculated by PRZM and MACRO were manually edited to zero in the P2T and M2T files, resulting in there being no input of beta-cyfluthrin via runoff or drainage in the simulations. This approach of assuming 0.1% emission has been accepted for surface water exposure assessments for greenhouse uses as it is in line with FOCUS (2008) guidance as being appropriate, except when applications are made with ultra-low volume application techniques, when 0.2% emission is prescribed. For the representative protected use on tomato, when using semi-protected structures, the necessary PECs were not carried out. This has led to the identification of a data gap (see Section 7) and results in the exposure and risk a/ssessment not being finalised for uses in

semi-protected structures (see Section 9). However, it is anticipated that the level of exposure would be higher than that calculated for the permanent greenhouse use.

For the representative uses in beet, Step 3 calculations performed by the applicant were considered acceptable for beta-cyfluthrin. Some of the input parameters used in this modelling exercise were slightly different to the ones that should have been used. However, it is expected that these small deviations of input parameters have not affected the assessment. The RMS provided Step 3 calculations for uses in beet using the draft guidance (SANCO/10553/2012, European Commission, 2014c). However, this document is a draft and is not noted by the European Commission. Therefore, the RMS calculations have not been considered by EFSA in this conclusion.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3.[8] The potential for groundwater exposure from the representative uses of beta-cyfluthrin above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios for beta-cyfluthrin and its metabolites DCVA and FPB acid. Input parameters used in this modelling were close to those resulting from the peer review. However, considering that the calculated PECgw were < 0.003 μg/L, it is expected that the slight deviations of input parameters do not affect the assessment that concentrations above the parametric drinking water limit would not be expected.

The applicant did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. This has led to the identification of a data gap (see Section 7) and results in the consumer risk assessment not being finalised (see Section 9). The RMS disagreed that this data gap results in the consumer risk assessment not being finalised.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013). According to Regulation (EU) No 283/2013[9], data should be provided regarding the acute and chronic toxicity to honeybees and data to address the development of honeybee brood and larvae. As the European Commission (2002a) does not provide a risk assessment scheme which is able to use the chronic toxicity data for adult honeybees and the honeybee brood, when performing the risk assessment according to European Commission (2002a), the risk to adult honeybees from chronic toxicity and the risk to bee brood could not be finalised due to the lack of a risk assessment scheme. Therefore, the EFSA (2013) was used for risk assessment in order to reach a conclusion for the representative uses.

Several aspects of the hazard and risk assessment for beta-cyfluthrin were discussed at the Pesticides Peer Review Meeting 174 which took place in February 2018. The experts agreed that an adjustment factor of 0.42 should be applied to data performed with cyfluthrin to account for the content of beta-cyfluthrin (see expert consultation points 5.5 and 5.10 of the expert meeting report (EFSA, 2018c) for further details). As specified in Section 4, there was no information on environmental behaviour of each individual isomers for beta-cyfluthrin and metabolite DCVA. Nevertheless, it was concluded that there was no impact on the risk assessments for non-target organisms given that either initial exposure estimates were used or the margin of safety obtained in the assessment was sufficient.

It should be noted that the representative formulation 'Montur Forte FS 230' contains imidacloprid in addition to beta-cyfluthrin. Where risk assessments for the formulated product are available, EFSA has reflected the outcome of the assessment. Nevertheless, the risk posed by the product and the combined exposure to imidacloprid and beta-cyfluthrin will need to be fully evaluated during the product authorisation.

A number of acute avian toxicity studies were available including some reliable toxicity endpoints from the literature. Of the tested species, it is apparent that the canary, *Serinus canaria*, is the most sensitive to beta-cyfluthrin. The experts noted that taking the geometric mean of the available toxicity endpoints with the standard assessment factor of 10 is not sufficiently protective of canaries.

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

[9] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, pp. 1–84.

Consequently, the experts agreed that the most appropriate acute lethal dose (LD_{50}) value to be used in the risk assessment should be the lowest one, but with a modified assessment factor of 3, given the evidence that canaries are more sensitive than other species. Several avian reproductive toxicity studies were available, but the RMS concluded that only a single study, performed with cyfluthrin, was sufficiently reliable. The RMS concluded a no observed effect concentration (NOEC) value of 269 mg cyfluthrin/kg diet. However, after additional details were added to the study summary presented in the RAR, EFSA noted that there was a potential effect on the hatchability of the chicks in this test group. Therefore, EFSA suggests that the NOEC from this study should be lowered to 53.1 mg cyfluthrin/kg diet (equivalent to 2.6 mg beta-cyfluthrin/kg bw per day after applying the correction factor of 0.42). For a more detailed explanation, please refer to open point 5.5 in the evaluation table (EFSA, 2018c). It should be noted that this endpoint has not been peer reviewed and differs from that proposed by the RMS.

The appropriate acute and reproductive endpoints for use in the risk assessment of wild mammals were also discussed and agreed at the expert meeting.

On the basis of the available risk assessments, a low acute and reproductive risk to **birds** and **wild mammals** was demonstrated for the representative uses to wheat and potatoes as a foliar spray. For the representative use to tomatoes in protected structures, a low risk to birds and mammals was concluded assuming that applications are made in permanent greenhouses. However, in situations where the structures are only semi-protected, the available tier 1 risk assessment indicated a high acute and long-term risk to wild mammals. No refinement was available, and therefore, a data gap was concluded. The available risk assessment indicated a low risk to birds for the representative use to tomatoes.

A risk assessment for the representative use of 'Montur Forte FS 230' as a pelleted seed treatment to beet considered exposure via accidental ingestion of the pelleted seeds as grit. A low risk to birds was indicated assuming that the seeds were precision drilled with an average value of 0.17% remained on the soil surface. The risk assessment did not account for the higher density of pelleted seeds which occurred at the end of rows (approximately 4–6 times higher) which may be relevant for the acute risk assessment scenario. However, given the margin of safety obtained in the available assessment, a low risk was concluded. Member States should ensure that the exposure data are relevant for the type of drilling machinery and other conditions when assessing products for national authorisation. A low risk to mammals was also concluded. The available argumentation for birds and mammals consuming germinating beet seedlings was considered to be insufficiently supported with robust data, and therefore, a data gap was concluded and the assessment could not be finalised.

A low risk to bird and mammals from secondary poisoning, consumption of contaminated water and metabolites (FPB acid and DCVA) was concluded for all representative uses.

Data for assessing the toxicity of beta-cyfluthrin were available for all groups of aquatic organisms.

Low risk to **algae** and **aquatic plants** was concluded for all uses of beta-cyfluthrin. The risk assessment was driven by fish and invertebrates. The tier 1 risk assessment indicated high acute and chronic risk to **fish**, **aquatic invertebrates** and **sediment dwelling organisms** for all uses except for the application on seed treatment of beet, for which a low risk was concluded. As indicated, the representative product 'Montur Forte FS 230', applied as seed treatment to beet, contains imidacloprid in addition to beta-cyfluthrin. No peer-reviewed risk assessment was available for such product; nevertheless, it is anticipated that the risk of the mixture to aquatic organisms will be driven by beta-cyfluthrin.

Several refinements, available for **fish and invertebrates**, were discussed at the Pesticides Peer Review Meeting 174. Despite the use of refined acute and chronic endpoints for both fish (up to tier 2) and invertebrates (up to tier 3), high risk was identified in all scenarios for the uses of beta-cyfluthrin on cereals (winter and spring) and potatoes (data gap). The RMS calculated surrogate Step 4 PECs for the uses on cereals (winter and spring) and potatoes via reducing the Step 3 concentrations by 95%. These PECs were not considered acceptable in the environmental fate and behaviour section. However, it is noted that, even when using this surrogate Step 4 PECs in combination with the Tier 3 RAC for invertebrates, a high risk would still be identified for all relevant scenarios.

For the use to tomatoes in permanent greenhouses, a high risk was identified for invertebrates. A low acute risk to fish was concluded for this use. A high chronic risk to fish could not be ruled out, as the exposure profile in the available refined exposure pulse study was not appropriately compared with the predicted FOCUS exposure profiles, despite the comparison of the maximum concentrations suggested that a low risk could be achieved in two out of four scenarios. No exposure assessment was available for the representative use to tomatoes in semi-protected structures leading to a data gap and

consequently the risk to aquatic organisms could not be finalised. However, as noted in Section 4, the expected exposure is anticipated to be higher than that calculated for the permanent greenhouse for which a high risk to aquatic organisms is concluded.

A low risk to fish and aquatic invertebrates was concluded for metabolites DCVA and FPB acid. Only unreliable studies were available for FPB aldehyde, however, a high risk due to exposure to this metabolite is not anticipated. Testing of metabolites' toxicity to algae was not available. However, a low risk to algae was concluded, considering that a low risk to algae was concluded for the parent beta-cyfluthrin, and that all metabolites showed in general significantly less toxicity than the parent.

Acute contact and oral toxicity data for **honeybees** were available for both the active substance and for the representative products 'Bulldock 25 EC' and 'Montur Forte FS 230'. Furthermore, studies investigating the chronic oral toxicity of 'Bulldock 25' to adult bees and to honeybee larvae were available.

A tier 1 risk assessment for the representative spray uses to wheat, potatoes and tomatoes, performed according to European Commission (2002a), indicated a high acute oral and contact risk to honeybees triggering the need for a higher tier refinement. No tier 1 risk assessment for honeybees using the EFSA (2013) guidance document was presented. Several semi-field and field studies performed with honeybees were available and were discussed in the context of the risk assessment during the experts' meeting. The experts agreed that, for the representative uses as a foliar spray to wheat and potatoes, a low risk to honeybees was indicated as long as risk mitigation measures were implemented. On the basis of the available higher tier studies, it was concluded that, for the application rate of 7.5 g a.s./ha, applications should be made in the evenings after bee flight. For the application rates of 12.5 g a.s./ha, additional mitigation was needed to prevent applications being made in the presence of flowering plants (crop and weeds) and insect honeydew. The experts agreed that the higher tier data did not cover the higher application rate for the representative use to tomatoes in semi-protected structures (17.5 g a.s./ha). The experts discussed whether risk mitigation measures to prevent applications to flowering plants would be sufficient to exclude a risk to honeybees. However, as the representative use includes flowering growth stages of the crop, such mitigation is not consistent with the representative GAP, and therefore, a high risk was concluded. The experts at the meeting agreed that the available data were sufficient to conclude a low risk to honeybees, for the foliar spray uses, from exposure to plants in the field margin and adjacent crop. No assessment considering the succeeding crop scenario was available which is needed in accordance with EFSA (2013).

Toxicity data investigating sublethal effects (hypopharygeal glands (HPG)) on honeybees, accumulative effects or effects of metabolites were not available. However, as the risk assessment for the representative foliar spray uses was based on higher tier studies; these data are not required.

No toxicity data were available for bumblebees and solitary bees. A screening assessment for the field foliar spray uses, where it was assumed that bumblebees and solitary bees are 10 times more sensitive than honeybees, was available and indicated that a high risk could not be excluded.

For the representative use to tomatoes in permanent greenhouses, a low risk to honeybees, wild bumblebees and solitary bees was concluded. A high risk to pollinators introduced to greenhouses cannot be excluded with the available information; this should be considered at Member State level.

The representative product 'Montur Forte FS 230' contains imidacloprid in addition to beta-cyfluthrin. It may be noted that EFSA (2018a) presents a risk assessment of the use of imidacloprid as a seed treatment to pelleted sugar beet. No tier 1 risk assessment for honeybees was presented for the representative use as a seed treatment to beet. However, in situations where the beet is harvested before flowering, a low risk to bees can be concluded for the treated crop scenario. A data gap is concluded for a risk assessment for when the treated crop is allowed to flower, to consider other routes of exposure and for relevant metabolites.

A risk assessment for honeybees exposed to residues in contaminated water was not available for any of the representative uses. Therefore, a data gap was concluded.

Suitable toxicity data and risk assessments for **non-target arthropods** were available for the representative uses to wheat, potatoes and tomatoes. A high in-field and off-field risk was indicated using the available tier 1 toxicity data. Several field studies considering the effects to non-target arthropods were available (see Appendix A). The data were discussed in detail at the peer review meeting. On the basis of the available data, performed at in-field application rates, the experts agreed that recovery within 1 year was not demonstrated. Furthermore, the available higher tier study was not considered to demonstrate a low risk to off-field populations of non-target arthropods. Consequently, a high risk to non-target arthropods was concluded for the representative uses to

wheat, potatoes and for tomatoes (assuming applications are made in semi-protected structures). A low risk to non-target arthropods was concluded for the use to tomatoes in permanent greenhouses.

Toxicity data for **soil dwelling arthropods** were available for the representative product 'Montur Forte 230 FS' and, when used in a risk assessment, demonstrated a low in-field risk to non-target arthropods for the representative seed treatment use to sugar beet. The experts noted that exposure, via dust drift during the drilling of sugar beet, to off-field populations of non-target arthropods could not be excluded. No risk assessment for this route of exposure could be performed as suitable toxicity data were not available. Furthermore, the experts noted that no agreed guidance is available for performing such as risk assessment. Therefore, it was agreed that this should be reflected in the Conclusion.

No data giving the chronic toxicity of beta-cyfluthrin to **earthworms** was available. Instead, toxicity data and risk assessments for each of the representative products were available. A low risk to earthworms was concluded for the representative uses to wheat, potatoes and tomatoes. The available first tier risk assessment for the representative use of 'Montur Forte FS 230' (containing imidacloprid in addition to beta-cyfluthrin) indicated a high chronic risk to earthworms from the formulated product. An additional chronic earthworm study using sugar beet seeds treated with 'Montur Forte FS 230' was available but not considered in the context of the risk assessment. However, a risk assessment was performed in terms of beta-cyfluthrin which showed a low chronic risk to earthworms from the active substance under consideration. A low risk to earthworms from metabolites FPB acid and DCVA was concluded for all representative uses.

A low risk to **earthworms**, other **soil macroorganisms** and **soil microorganism** was concluded for the active substance and the pertinent metabolites FPB acid and DCVA for all representative uses. For some soil organisms, the formulated products indicated higher toxicity than beta-cyfluthrin, and therefore, risk assessments for soil organisms for the representative formulations were also presented. A high risk to *Folsomia candida,* from the formulated product, was indicated for 'Bulldock 25 EC' for all representative uses other than those in permanent greenhouses where exposure to soil is not anticipated.

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

With regard to the **endocrine disruption** potential, as discussed in Section 2, it is unlikely that beta-cyfluthrin is an endocrine disruptor in mammals; however, no firm conclusion can be drawn regarding non-target organisms other than mammals.

6. 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)	Persistence	Ecotoxicology
Constituent isomers of beta-cyfluthrin	Low to moderate persistence Bi-phasic kinetics DT_{50} 5.9–15.8 days (DT_{90} 66–194 days; laboratory conditions at 20°C, 11–31% MWHC soil moisture) European field dissipation studies bi-phasic kinetics DT_{50} 3.3–45 days	Low risk to soil organisms
FPB acid	Very low to low persistence Single first-order DT_{50} 0.9–2.9 days (DT_{90} 2.9–9.8 days; laboratory conditions at 20°C, 13–47% MWHC soil moisture)	Low risk to soil organisms
Constituent isomers of DCVA	Low persistence Single first-order DT_{50} 1.7–8.5 days (DT_{90} 5.5–28 days; laboratory conditions at 20°C, 11–31% MWHC soil moisture)	Low risk to soil organisms

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
Constituent isomers of beta-cyfluthrin	Immobile Kdoc 64,286–180,290 mL/g	No	Yes	Yes
FPB acid	Very high to medium mobility KFoc 39–424 mL/g	No	No	Yes
Constituent isomers of DCVA	Very high to medium mobility KFoc 9.0–362 mL/g	No	No	Yes

(a): FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Constituent isomers of beta-cyfluthrin	High risk to aquatic organisms
FPB acid (soil, water/sediment)	Low risk to aquatic organisms
Constituent isomers of DCVA (soil, water/sediment)	Low risk to aquatic organisms
FPB aldehyde (water/sediment)	Low risk to aquatic organisms

Table 4: Air

Compound (name and/or code)	Toxicology
Beta-cyfluthrin	Fatal if inhaled (Acute Tox 2)

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- A data gap has been identified for an updated scientific peer-reviewed open literature review on the active substance and its relevant metabolites, dealing with side effects on human health and non-target species published within the 10 years before the date of submission of the dossier, and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). In particular for human health to clarify the exclusion process of irrelevant studies based on title and abstract (step 1), to assess relevance rather than reliability at the second step of the selection based on full-text documents, and to provide full-text files for articles considered relevant. An updated literature search using appropriate criteria for selecting studies should also be added to the ecotoxicology dossier (relevant for all representative uses; submission date proposed by the applicant: unknown; relevant for Sections 2 and 5).
- Analytical method for the determination of beta-cyfluthrin in surface water with an LOQ of 0.0002 μg/L (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 5).
- Analytical method of monitoring of the compounds of the residue definition in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 2).
- The phototoxic potential of beta-cyfluthrin at UVB ranges should be addressed once an appropriate OECD test for UVB absorbers is available (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- A new rotational crop metabolism study conducted in compliance with the OECD recommendations is required (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- A sufficient number of critical GAP-compliant residue trials on wheat to complete the residue data set in NEU and SEU are required (relevant for the representative use in wheat; submission date proposed by the applicant: unknown; see Section 3).
- Two GAP-compliant residue trials on potato with analysis of the beta-cyfluthrin residues in a short time interval where acceptable storage stability is demonstrated (max. within 1 month after sampling) are requested (relevant for the representative use in potato; submission date proposed by the applicant: unknown; see Section 3).
- Storage stability data for sugar beet in order to support the field residue trials (relevant for the use in beet; submission date proposed by the applicant: unknown; see Section 3).
- Demonstration of stability of beta-cyfluthrin in bovine muscle and fat (relevant for the representative uses in beet, potato and wheat; submission date proposed by the applicant: unknown; see Section 3).
- Determination of the residues in pollen and bee products from human consumption resulting from residues taken up by honeybees from crops at blossom (relevant for all representative uses; submission date proposed by the applicant: unknown; see Section 3).
- Information about conversion/preferential degradation of the individual diastereoisomers of beta-cyfluthrin and metabolite DCVA in the environmental compartments (not needed to finalise the risk assessment for the representative uses; submission date proposed by the applicant: unknown; see Section 4).
- An aerobic mineralisation in surface water study or information to demonstrate that contamination of open water (freshwater, estuarine and marine) will not occur (although this information is not needed for any of the representative uses evaluated when following the agreed EU level environmental exposure assessment guidance; submission date proposed by the applicant: unknown; see Section 4 of the evaluation table contained in the peer review report (EFSA, 2018c)).
- The effect of water treatment processes on the nature of residues present in surface, when surface water is abstracted for drinking water (Article 4 (approval criteria for active

substances) 3. (b) of Regulation (EC) No 1107/2009). In the first instance, a consideration of the processes of ozonation and chlorination may be considered appropriate. If an argumentation is made that concentrations at the point of abstraction for drinking water purposes will be low, this argumentation should cover metabolites predicted to be in surface water, as well as the active substance (relevant for all representative uses evaluated with respect of metabolites and the semi-protected use on tomatoes for the active substance; submission date proposed by the applicant: unknown; see Section 4).

- Exposure and aquatic risk assessments when using semi-protected structures (relevant for the representative use to tomatoes when used in semi-protected structures; submission date proposed by the applicant: unknown; see Sections 4 and 5).
- Further information is required to refine the risk to wild mammals for the representative use to tomatoes when used in semi-protected structures (relevant for the representative use to tomatoes; submission date proposed by the applicant: unknown; see Section 5).
- A risk assessment for herbivorous birds and mammals consuming germinating seedlings is needed (relevant for the representative use as a seed treatment to beet; submission date proposed by the applicant: unknown; see Section 5).
- Further information to refine the risk to aquatic invertebrates and fish (relevant for all uses evaluated except the use as seed treatment on beet; submission date proposed by the applicant: unknown; see section 5).
- Further information is required to refine the risk to honeybees for the representative use to tomatoes when used in semi-protected structures (relevant for the representative use to tomatoes in semi-protected structures; submission date proposed by the applicant: unknown; see Section 5).
- A comprehensive risk assessment for honeybees is needed for the representative use as a seed treatment to beet. This should be performed in accordance with the EFSA (2013) guidance document and should also consider the risk from relevant metabolites (relevant for the representative use to beet; submission date proposed by the applicant: unknown; see Section 5).
- A risk assessment for honeybees exposed to residues in contaminated water is needed (relevant for all representative uses; submission date proposed by the applicant: unknown; see Section 5).
- Further information is needed to refine the risk to non-target arthropods for the representative foliar spray uses (relevant for the representative uses to wheat, potatoes and tomatoes in semi-protected structures; submission date proposed by the applicant: unknown; see Section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- For the formulation 'Bulldock 25 EC', a label instruction for protecting from frost is recommended (see Section 1).
- Use of personal protective equipment is required for operators and workers during field use of 'Bulldock 25 EC' (see Section 2).
- Bystander and residents should be located at least at 10 metres distance to reduce exposure below the AOEL during the greenhouse (non-permanent structure) use (see Section 2).
- Use of respiratory protective equipment is required for operators during the use as seed treatment of 'Montur Forte FS 230', with the condition that different operators should perform the different tasks of mixing/loading, seed coating and storage logistics (see Section 2).
- Risk mitigation measures are needed to ensure that applications are made after bee flight are needed for the representative uses to wheat and potato at 7.5 g a.s./ha. Further risk mitigation measures are needed to prevent applications being made in the presence of flowering plants (crop and weeds) and insect honeydew for the representative uses to wheat and potato at 12.5 g a.s./ha (see Section 5).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for 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[10] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

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

1) The consumer risk assessment could not be finalised as residue trials with wheat, sugar beet and potato compliant with cGAP and/or supported by storage stability data are missing as well as stability data for muscle and fat and a rotational crop metabolism study (see Section 3).
2) The consumer risk assessment is not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface water that might contain beta-cyfluthrin and its metabolites (see Section 4).
3) The risk assessment for birds and mammals consuming germinating beet seedlings was not finalised (see Section 5).
4) The exposure and risk assessments for aquatic organisms were not finalised with regard to the representative greenhouse use in tomato, when using semi-protected structures (see Sections 4 and 5).

9.2. Critical areas of concern

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

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

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

Critical areas of concerns have not been identified.

9.3. Overview of the concerns identified for each representative use considered

(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 5.)

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

Table 5: Overview of concerns

Representative use		Beet (harvested before flowering)	Beet (allowed to flower)	Potato 0.0075 kg a.s./ha	Potato 0.0125 kg a.s./ha	Wheat 0.0075 kg a.s./ha	Wheat 0.0125 kg a.s./ha	Tomato semi-protected	Tomato permanent greenhouse
Operator risk	Risk identified							X	X
	Assessment not finalised								
Worker risk	Risk identified	X	X					X	X
	Assessment not finalised								
Bystander risk	Risk identified								
	Assessment not finalised								
Resident risk	Risk identified			X*	X*	X*	X*	X*	
	Assessment not finalised								
Consumer risk	Risk identified								
	Assessment not finalised	X[1,2]	X[1,2]	X[1,2]	X[1,2]	X[1,2]	X[1,2]	X[2]	X[2]
Risk to wild non-target terrestrial vertebrates	Risk identified							X	
	Assessment not finalised	X[3]	X[3]						
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified			X	X	X	X	X	
	Assessment not finalised								
Risk to aquatic organisms	Risk identified			X	X	X	X	X	X
	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[(a)]								
	Parametric value of 10 µg/L[(b)] breached								
	Assessment not finalised								

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.

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

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

*: A risk is identified based on the EFSA guidance. Based on the original German approach (inhalation exposure is not taken into account), a risk is not identified.

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Abbreviations

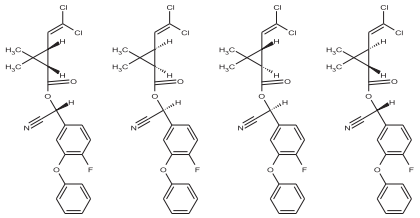
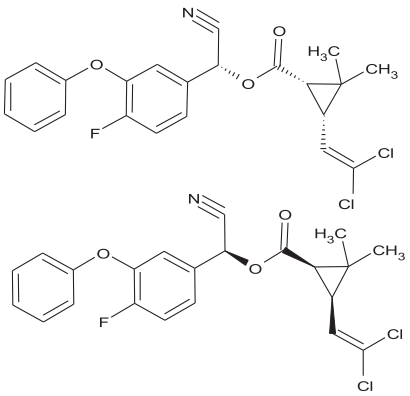
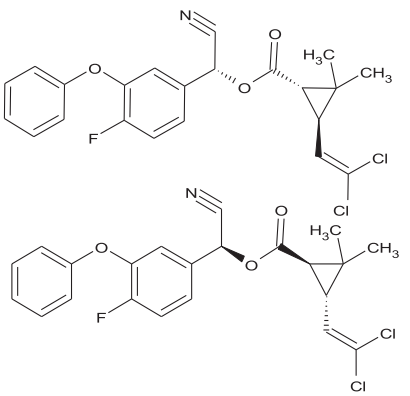
a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
ECHA	European Chemicals Agency

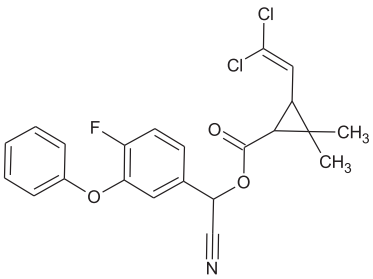
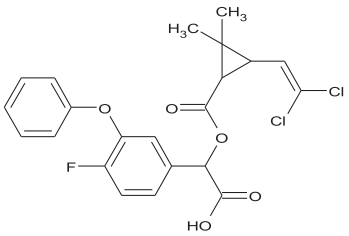
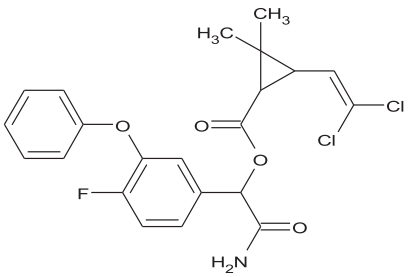
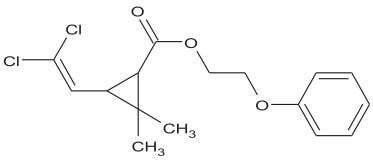
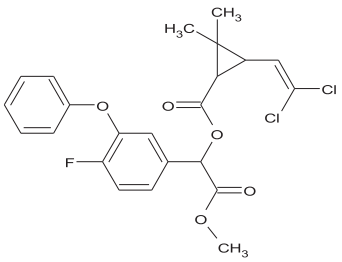
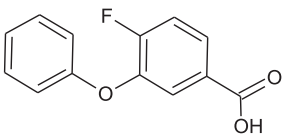
EEC	European Economic Community
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
HPG	hypopharygeal glands
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LD_{50}	lethal dose, medianaaa dosis letalis media
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-Newton
MRL	maximum residue level
MS	mass spectrometry
MWHC	maximum water-holding capacity
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	preharvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure–activity relationship
RAR	Renewal Assessment Report
RMS	rapporteur Member State
RPE	respiratory protective equipment
SMILES	simplified molecular-input line-entry system
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UF	uncertainty factor
UV	ultraviolet
WHO	World Health Organization

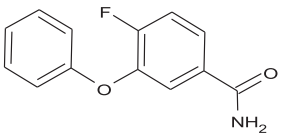
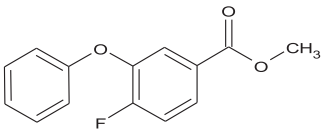
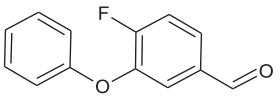
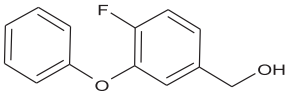
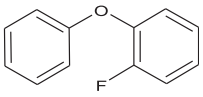
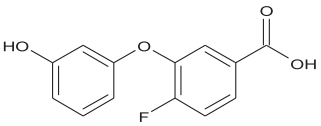
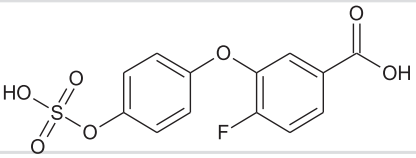
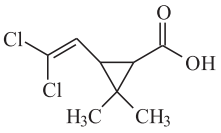
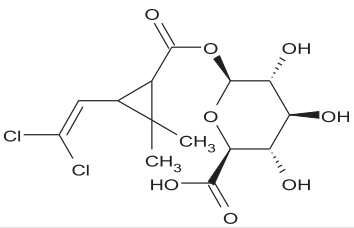
Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.6058

Appendix B – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
beta-cyfluthrin	reaction mixture comprising the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio 1:2 with the enantiomeric pair (*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl\C(Cl)=C/[C@@H]1[C@@H](C(=O)O[C@H](C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C.Fc1ccc(cc1Oc1ccccc1)[C@H](C#N)OC(=O)[C@H]1[C@H](/C=C(/Cl)Cl)C1(C)C.Cl\C(Cl)=C/[C@H]1[C@@H](C(=O)O[C@H](C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C.Fc1ccc(cc1Oc1ccccc1)[C@H](C#N)OC(=O)[C@H]1[C@H](/C=C(/Cl)Cl)C1(C)C MUAQRFLDMBWWOD-XWJCWIGJSA-N	
diastereoisomer II (AE 1421342) isomer II	(*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl/C(Cl)=C/[C@@H]1[C@H](C(=O)O[C@@H](C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C.Fc1ccc(cc1Oc1ccccc1)[C@@H](C#N)OC(=O)[C@@H]1[C@H](/C=C(\Cl)Cl)C1(C)C OFHFONYRMVKULH-WNYJFNBPSA-N	
diastereoisomer IV (AE 1421344) isomer IV	(*R*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl/C(Cl)=C/[C@H]1[C@H](C(=O)O[C@@H](C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C.Fc1ccc(cc1Oc1ccccc1)[C@@H](C#N)OC(=O)[C@@H]1[C@@H](/C=C(\Cl)Cl)C1(C)C OFHFONYRMVKULH-NIGOVZMWSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
cyfluthrin	(*RS*)-α-cyano-4-fluoro-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl\C(Cl)=C/C1C(C(=O)OC(C#N)c2ccc(F)c(Oc3ccccc3)c2)C1(C)C QQODLKZGRKWIFG-UHFFFAOYSA-N	
COOH-cyfluthrin (cyfluthrin acid) (FCR 2728)	(2*RS*)-(@[(1*RS*,3*RS:RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropyl] carbonyl@oxy)(4-fluoro-3-phenoxyphenyl) acetic acid Cl\C(Cl)=C/C1C(C(=O)OC(c2ccc(F)c(Oc3ccccc3)c2)C(=O)O)C1(C)C ZHILWBKCVCRPAU-UHFFFAOYSA-N	
CONH2-cyfluthrin (FCR 2978)	(1*RS*)-2-amino-1-(4-fluoro-3-phenoxyphenyl)-2-oxoethyl (1*RS*,3*RS:*1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl\C(Cl)=C/C1C(C(=O)OC(c2ccc(F)c(Oc3ccccc3)c2)C(N)=O)C1(C)C XGUKHWABHDWDDL-UHFFFAOYSA-N	
FCR 1272-Phenoxyethylester	2-phenoxyethyl (1*RS*,3*RS:*1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-1-carboxylate Cl\C(Cl)=C/C1C(C(=O)OCCOc2ccccc2)C1(C)C RRDMFDGPYAZXKU-UHFFFAOYSA-N	
Me-cyfluthrin	(1*RS*)-1-(4-fluoro-3-phenoxyphenyl)-2-methoxy-2-oxoethyl (1*RS*,3*RS:RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl\C(Cl)=C/C1C(C(=O)OC(c2ccc(F)c(Oc3ccccc3)c2)C(=O)OC)C1(C)C WHGBPPSHDPQMSF-UHFFFAOYSA-N	
FPB acid	4-fluoro-3-phenoxybenzoic acid O=C(O)c1cc(Oc2ccccc2)c(F)cc1 VLXNXMTVRWIUJZ-UHFFFAOYSA-N	

Code/trivial name[(a)]	IUPAC name/SMILES notation/ InChiKey[(b)]	Structural formula[(c)]
FPB amide	4-fluoro-3-phenoxybenzamide NC(=O)c1cc(Oc2ccccc2)c(F)cc1 GLHKJRYVFRAGNU-UHFFFAOYSA-N	
Me-FPB acid	methyl 4-fluoro-3-phenoxybenzoate O=C(OC)c1cc(Oc2ccccc2)c(F)cc1 JYKULQBXNKHHEF-UHFFFAOYSA-N	
FPB aldehyde	4-fluoro-3-phenoxybenzaldehyde O=Cc1cc(Oc2ccccc2)c(F)cc1 JDICMOLUAHZVDS-UHFFFAOYSA-N	
FPB alcohol	(4-fluoro-3-phenoxyphenyl)methanol OCc1cc(Oc2ccccc2)c(F)cc1 UFXDRIJUGWOQTP-UHFFFAOYSA-N	
FPB	1-fluoro-2-phenoxybenzene Fc1ccccc1Oc1ccccc1 PVFAQWWQJZQMBN-UHFFFAOYSA-N	
4-OH-FPB acid	4-fluoro-3-(3-hydroxyphenoxy)benzoic acid O=C(O)c1cc(Oc2cc(O)ccc2)c(F)cc1 LFHXTRYARIOMGR-UHFFFAOYSA-N	
sulfate conjugate of 4-OH-FPB acid	4-fluoro-3-[4-(sulfooxy)phenoxy]benzoic acid O=S(=O)(O)Oc1ccc(cc1)Oc1cc(ccc1F)C(=O)O JXEIRFQVKGCGLD-UHFFFAOYSA-N	
DCVA	(1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylic acid Cl\C(Cl)=C/C1C(C(=O)O)C1(C)C LLMLSUSAKZVFOA-UHFFFAOYSA-N	
DCVA acyl glucuronide	1-*O*-@[(1*RS*,3*RS; 1RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropyl] carbonyl@-β-D-glucopyranuronic acid O=C(O[C@@H]1O[C@@H]([C@@H](O)[C@H](O)[C@H]1O)C(=O)O)C1C(/C=C(/Cl)Cl)C1(C)C SCDVRNUOLGVBJK-UUADDGCPSA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 06 Sep 2017).
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 Feb 2018).