CONCLUSION ON PESTICIDES PEER REVIEW

EFSA Journal

APPROVED: 10 August 2017

doi: 10.2903/j.efsa.2017.4976

Updated peer review of the pesticide risk assessment of the active substance flurtamone

European Food Safety Authority (EFSA),
Maria Arena, Domenica Auteri, Stefania Barmaz, Giulia Bellisai, Alba Brancato, Daniela Brocca, Laszlo Bura, Harry Byers, Arianna Chiusolo, Daniele Court Marques, Federica Crivellente, Chloe De Lentdecker, Marcella De Maglie, Mark Egsmose, Zoltan Erdos, Gabriella Fait, Lucien Ferreira, Marina Goumenou, Luna Greco, Alessio Ippolito, Frederique Istace, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Jose Oriol Magrans, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Laura Padovani, Juan Manuel Parra Morte, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Rositsa Serafimova, Rachel Sharp, Alois Stanek, Franz Streissl, Juergen Sturma, Csaba Szentes, Jose Tarazona, Andrea Terron, Anne Theobald, Benedicte Vagenende, Alessia Verani and Laura Villamar-Bouza

Abstract

The conclusions of EFSA following the peer review of the initial risk assessments and the peer review of the revised risk assessments carried out by the competent authorities of the rapporteur Member State, the Czech Republic, and co-rapporteur Member State, Ireland, for the pesticide active substance flurtamone are reported. The context of the peer review and the updated 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 flurtamone as a herbicide on spring cereals (barley, wheat) and winter cereals (barley, oat, rye, triticale, wheat, spelt). 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: flurtamone, peer review, risk assessment, pesticide, herbicide

Requestor: European Commission

Question number: EFSA-Q-2017-00079

Correspondence: pesticides.peerreview@efsa.europa.eu

Update: This scientific output, approved on 10 August 2017, supersedes the previous output published on 6 June 2016 (EFSA, 2016a).

Suggested citation: EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Bellisai G, Brancato A, Brocca D, Bura L, Byers H, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, De Maglie M, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Conclusion on the updated peer review of the pesticide risk assessment of the active substance flurtamone. EFSA Journal 2017;15(8):4976, 25 pp. https://doi.org/10.2903/j.efsa.2017.4976

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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. Flurtamone 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), the Czech Republic, and co-rapporteur Member State (co-RMS), Ireland, received an application from Bayer CropScience AG for the renewal of approval of the active substance flurtamone. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Ireland), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on flurtamone in the renewal assessment report (RAR), which was received by EFSA on 29 May 2015. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Bayer CropScience AG, for comments on 3 July 2015. 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 2 September 2015.

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 flurtamone 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.

Following the peer review of the RAR, EFSA adopted a conclusion on 4 May 2016 (EFSA, 2016a) which was published on 6 June 2016. The European Commission consulted the applicant on the EFSA conclusion. From the comments received during the consultation of the European Commission with the applicant, it became apparent that in some areas a full assessment of the studies and information provided in the dossier had not been presented by the RMS in the RAR, and therefore, it was not possible to conclude on certain key areas, in particular for the mammalian toxicology and the human health risk assessment and for the aquatic risk assessment. The European Commission therefore requested the RMS and co-RMS to complete the assessment and provide an updated RAR to EFSA. The Czech Republic submitted the revised RAR to EFSA on 31 January 2017. EFSA was mandated by the European Commission to organise a further consultation with Member States and the applicant on the updated assessment and to launch a public consultation on the updated sections of the RAR. EFSA distributed the updated RAR for consultation with Member States and the applicant, Bayer CropScience AG, for comments on 20 February 2017. A 'Stop the clock' procedure to request additional information (as foreseen in Article 13(3) of Regulation (EU) No 844/2012) was not considered appropriate by the European Commission since the purpose of the update was to include the missing details identified in the initial peer review to enable conclusions on the risk assessment to be made. Additional information was already requested during the initial peer review and no new data was to be taken into account in this update.

The conclusion of EFSA (2016a) was updated, as appropriate, in the light of the updated peer review. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of flurtamone as a herbicide on spring and winter cereals, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

Sufficient data were supplied to demonstrate the efficacy of the product.

In the area of identity, physical/chemical/technical properties and methods of analysis, data gaps were not identified.

The phototoxicity/photomutagenicity potential of flurtamone was not addressed in a conclusive way, and it is acknowledged that agreed methodological tools are currently missing to address this data gap. 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 are not met. However, since sensitive parameters for endocrine disruption were not all investigated in the studies submitted and thyroid follicular adenomas were observed in male rats without mechanistic investigations, a data gap was identified to investigate the potential endocrine-disrupting properties of flurtamone. The derived

reference values could not be applied for flurtamone due to the genotoxic potential that could not be excluded. As a consequence, the risk assessment for the operators, workers, bystanders and residents exposed to flurtamone cannot be conducted.

In the residue section, the consumer risk assessment cannot be finalised with regard to flurtamone and the major plant metabolite trifluoroacetic acid (TFA) included in the residue definition for risk assessment. A data gap was identified for a complete residue data set analysing TFA residues in cereals in accordance with the representative use and for rotational crop field trials analysing TFA residues and covering the maximum plateau concentration of this compound. The potential exposure of consumers to this compound via drinking water was assessed according to WHO guidelines and resulted in a dietary intake accounting for 6.6% acceptable daily intake (ADI) for the infants, 4.4% ADI for the child and 1.5% ADI for the adults. Information on the relative toxicity of each enantiomer of flurtamone and their potential degradation in plant and animal matrices was not given and provide therefore an additional uncertainty with regard to the consumer exposure assessment. Finally, the data requirement for the determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom could not be addressed considering the outstanding residue field trials on cereals and on rotational crops analysing TFA residues.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the European Union (EU) level for the representative uses, with the notable exception that information was not available regarding the effect of water treatment processes on the nature of residues that may be present in surface water and groundwater at the point of abstraction for drinking water purposes. The potential for groundwater exposure by the metabolite TFA is predicted to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios. Since the concentration of this metabolite was predicted to be above 0.1 μg/L in all the relevant FOCUS groundwater scenarios, this was identified as a critical area of concern. According to the information available in Section 2, metabolite TFA is considered toxicologically relevant due to the proposed classification for parent compound. Additionally, information is missing regarding whether there is any difference in the rate of degradation of the two enantiomers of flurtamone in the aquatic environment. This leads to additional uncertainty in the available aquatic risk assessments than would be the case if flurtamone was not made up of isomers.

In the area of ecotoxicology, data gaps were identified for further information to address the chronic risk to birds for plant metabolites. Data gaps were also identified for valid data on the toxicity of flurtamone to sediment-dweller organisms, for further data to refine the risk of flurtamone to aquatic plants and for further assessments for the outdoor mesocosm studies (analysis of the statistical power of the study). A high risk was identified for aquatic organisms for the representative use of flurtamone leading to a critical area of concern. In addition, suitable data to address the risk of sublethal effects to honeybees due to exposure to flurtamone and to assess the risk to honeybees due to flurtamone metabolites occurring in pollen and nectar are missing.

Table of contents

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 up to 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS the Czech Republic and co-RMS Ireland received an application from Bayer CropScience AG for the renewal of approval of the active substance flurtamone. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Ireland), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on flurtamone in the RAR, which was received by EFSA on 29 May 2015 (Czech Republic, 2015).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Bayer CropScience AG, for consultation and comments on 3 July 2015. 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 2 September 2015. 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 on 12 October 2015. 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 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 April 2016. In addition, a key supporting document to the original conclusion is the peer review report (EFSA, 2016b), which is a compilation of the documentation developed to evaluate and address all issues raised in the original peer review, from the initial commenting phase to the conclusion.

Following the peer review of the RAR (Czech Republic, 2015, 2016), EFSA adopted a conclusion on 4 May 2016 (EFSA, 2016a) which was published on 6 June 2016. The European Commission consulted the applicant on the EFSA conclusion. From the comments received during the consultation of the

[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.

European Commission with the applicant, it became apparent that in some areas a full assessment of the studies and information provided in the dossier had not been presented by the RMS in the RAR, and therefore, it was not possible to conclude on certain key areas, in particular for the mammalian toxicology and the human health risk assessment and for the aquatic risk assessment. The European Commission therefore requested the RMS and co-RMS to complete the assessment and provide an updated RAR to EFSA. The Czech Republic submitted the revised RAR to EFSA on 31 January 2017 (Czech Republic, 2017a). EFSA was mandated by European Commission to organise a further consultation with Member States and the applicant on the updated assessment and to launch a public consultation of the updated sections of the RAR. A 'Stop the clock' procedure to request additional information (as foreseen in Article 13(3) of Regulation 844/2012) was not considered appropriate by European Commission since the purpose of the update was to include the missing details identified in the initial peer review to enable conclusions on the risk assessment to be made. Additional information was already requested during the initial peer review and no new data was to be taken into account in this update.

In accordance with Article 12 of the Regulation, EFSA distributed the revised RAR to the Member States and the applicant, Bayer CropScience AG, for consultation and comments on 20 February 2017. EFSA also provided comments. In addition, EFSA conducted a public consultation on the revised RAR. EFSA collated and forwarded all comments received to the European Commission on 27 March 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 was considered in a telephone conference between EFSA and the RMS on 10 May 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 EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology. Due to the specific mandate for this revised assessment, a 'Stop the Clock' procedure to request additional information was not foreseen. Additional information was already requested during the initial peer review and no new data was to be taken into account in this update.

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 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, 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 updated risk assessment took place with Member States via a written procedure in July–August 2017.

The conclusion of EFSA (2016a) was updated, as appropriate, in the light of the updated peer review. This conclusion report summarises the outcome of the updated peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of flurtamone as a herbicide on spring cereals (barley, wheat) and winter cereals (barley, oat, rye, triticale, wheat, spelt), as proposed by the applicant. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2017), which is a compilation of the documentation developed to evaluate and address all issues raised in the revised 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 updated peer review, including minority views, where applicable, can be found:

- the comments received on the revised RAR;
- the reporting table (10 May 2017);
- the evaluation table (8 August 2017);
- the reports of the scientific consultation with Member State experts;
- the comments received on the draft updated EFSA conclusion.

Given the importance of the revised RAR, including its subsequent revisions (Czech Republic, 2017b), 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 European Union (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

Flurtamone is the ISO common name for (2*RS*)-5-methylamino-2-phenyl-4-(α,α,α-trifluoro-*m*-tolyl) furan-3(2*H*)-one (IUPAC). The active substance flurtamone as defined by the ISO common name is a racemate.

The representative formulated product for the evaluation was 'Diflufenican + Flurtamone 350 SC (100 + 250 g/L)', (code number: 102000003844) a suspension concentrate (SC) containing 250 g/L of flurtamone and 100 g/L diflufenican.

The representative uses evaluated were applications by spraying against annual broadleaved weeds and annual grass weeds in spring and winter cereals. Full details of the good agricultural practice (GAP) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of flurtamone according to the representative use proposed at EU level results in a sufficient herbicidal efficacy against the target weeds following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

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/10597/2003-rev. 10.1 (European Commission, 2012) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The reference specification for first approval was updated. The proposed specification is based on batch data from industrial scale production. The minimum purity of the active substance as manufactured is 982 g/kg. No FAO specification exists.

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 flurtamone or the representative formulation. The main data regarding the identity of flurtamone and its physical and chemical properties are given in Appendix A.

Methods of analysis are available for the determination of the active substance in the technical material and representative formulation.

Flurtamone residues can be monitored in food and feed of plant origin by the multiresidue method DFG S19 using gas chromatography with tandem mass spectrometry (GC–MS/MS) in all commodity groups, or by the quick, easy, cheap, effective and safe (QuEChERS) method (liquid chromatography with tandem mass spectrometry (LC–MS/MS)) with limit of quantifications (LOQs) of 0.01 mg/kg for both methods. Residues of flurtamone in food and feed of animal origin can be determined by the multiresidue method DFG S19 using gas chromatography–tandem mass spectrometry (GC–MS) and LC–MS/MS in milk, meat, kidney, fat and eggs with LOQs of 0.01 mg/kg in all animal matrices.

Residues of flurtamone in soil, water and air can be monitored by LC–MS/MS with LOQs of 5 μg/kg, 0.05 μg/L and 0.6 μg/m^3, respectively. Residues of flurtamone in body tissues can be analysed using the methods for food and feed of animal origin. In blood plasma, flurtamone can be analysed by LC–MS/MS with an LOQ of 0.05 mg/L.

2. Mammalian toxicity

The toxicological profile of the active substance flurtamone was discussed at the Pesticides Peer Review Experts' Meetings 141 and 159. The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003a), SANCO/10597/2003-rev. 10.1 (European Commission, 2012) and Guidance on dermal absorption (EFSA PPR Panel, 2012).

Flurtamone is a racemic mixture, and the relative toxicity of each enantiomer has not been specifically addressed, but the toxicity studies were performed with the racemate. The new technical specification is acceptable from a toxicological point of view since no impurities are reported. It is

noted that flurtamone has no harmonised classification and labelling for human health effects according to Regulation (EC) No 1272/2008[3].

In toxicokinetic studies, flurtamone was rapidly absorbed after oral administration (oral absorption 92.5% for the low dose), widely distributed in the body without bioaccumulation and extensively metabolised. An in vitro metabolism study showed that the metabolism of flurtamone in rat and human liver microsomes was similar. In acute toxicity studies, flurtamone was demonstrated to be of low toxicity in rats after oral and inhalation exposure and to rabbits after dermal administration. Pending validated methods to test phototoxicity and photomutagenicity at wavelengths covering the range of natural sunlight between 290 and 320 nm (where flurtamone shows absorption), the phototoxic and photomutagenic potential of flurtamone cannot be concluded (data gap).

In short-term toxicity studies, the relevant no-observed adverse effect levels (NOAELs) were 5.6 mg/kg body weight (bw) per day in rats (90-day study), 140 mg/kg bw per day in mice (90-day study) and 5 mg/kg bw per day in dogs (1-year study) based on effects in the liver (all species) and blood (mice). Based on the available genotoxicity studies (equivocal Ames test performed with the previous technical specification), the gene mutation potential of flurtamone (new technical specification) could not be excluded (data gap). Indeed, the two other tests provided for point mutations were not considered reliable. The RMS disagreed with this conclusion considering the provided information sufficient to conclude that flurtamone is not genotoxic. The long-term NOAELs were 2.84 mg/kg bw per day in rats based on liver findings and 3.7 mg/kg bw per day in mice based on reduced survival and increased incidence of amyloidosis. Based on tumours observed in both species (thyroid follicular adenomas in male rats, and hepatocellular adenomas and carcinomas in male mice), the experts agreed to propose classification[4] as Carcinogen category 2, H351 'Suspected of causing cancer' for flurtamone. In a rat multigeneration study, reproductive and fertility parameters were not affected; a NOAEL of 25 mg/kg bw per day was set for the offspring's toxicity based on decreased mean body weight. In the developmental toxicity studies, no teratogenic effect was observed and the developmental NOAELs were 50 mg/kg bw per day for the rat (based on increased incidence of cervical ribs) and 200 mg/kg bw per day for the rabbit (based on skeletal findings and embryo–fetal deaths in the presence of maternal toxicity).

Flurtamone is not classified or proposed to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore, 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 are not met. With regard to the screening of endocrine-disrupting properties for flurtamone, since sensitive parameters for endocrine disruption were not all investigated in the studies submitted and thyroid follicular adenomas were observed in male rats without mechanistic clarifications, further investigations are required according to the OECD Conceptual Framework (OECD, 2012) and the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA Scientific Committee, 2013) (data gap and issue not finalised).

For the metabolite TFMBA (RE 54488), found in the rat metabolism at a level $< 10\%$ of the administered dose of flurtamone, a genotoxic potential cannot be concluded on the basis of the available data. For the metabolite trifluoroacetic acid (TFA), the acceptable daily intake (ADI) is 0.05 mg/kg bw per day based on the 90-day rat study (uncertainty factor (UF) 200 for the extrapolation from subchronic to chronic). No acute reference dose (ARfD) is needed on the basis of the available toxicological studies.

During the first peer review of flurtamone (European Commission, 2003b), an ADI of 0.03 mg/kg bw per day was derived, on the basis of the 2-year rat study and applying an uncertainty factor of 100 (European Commission, 2003b). An ARfD was not allocated, and an acceptable operator exposure level (AOEL) of 0.02 mg/kg bw per day was adopted on the basis of the 1-year dog study (UF 100, no correction for oral absorption). The reference values (under the renewal process) were discussed by the experts; however, they are not applicable as long as the mutagenic potential of flurtamone cannot be excluded (critical area of concern).

[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] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

The agreed dermal absorption values for flurtamone are 0.3% for the neat formulation (250 g/L) and 8% for the low dose (0.25 g/L). Considering the lack of reference values, the operator, worker, bystander and resident risk assessment could not be concluded (critical area of concern).

3. Residues

The assessment in the residue section is based on the European Commission guideline document on maximum residue level (MRL) setting (European Commission, 2015), the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007) and the OECD publication on MRL calculations (OECD, 2011).

Flurtamone was discussed at the Pesticides Peer Review Meeting 143 in March 2016.

The metabolism studies in the residue section were conducted with the racemate and no information is available on the potential degradation of the two enantiomers of flurtamone in plant and animal matrices.

Metabolism of flurtamone in primary crops was investigated in the cereals/grass (wheat, barley) and in oilseeds/pulses (sunflower, peanuts) crop groups, using ^{14}C-flurtamone labelled on the trifluoromethylphenyl ring and on the phenyl ring, respectively. The active substance was applied pre- and post-emergence on cereals, at growth stages BBCH 19–31. Only pre-emergence application of flurtamone was investigated on sunflower and peanuts. In mature plants and for the phenyl ring labelling, flurtamone was the main component of the terminal residues accounting for 12–57% total radioactive residue (TRR) in wheat/barley straw, 20–92% TRR in wheat forage and 19–44% TRR in sunflower forage. Flurtamone was never detected in cereal grain and was recovered at a trace level in sunflower seed (< 1% TRR; 0.001 mg eq/kg). In peanuts kernels, the major part of the radioactive residues was incorporated into natural plant constituents (fatty acids). In the studies conducted with the trifluoromethylphenyl ring labelling form, TFA metabolite was identified as the most abundant compound of the total residues in wheat grain (86–93% TRR), in wheat forage (44% TRR) and in wheat straw (49% TRR) while TFMBA metabolite was predominantly identified in sunflower seed (19% TRR). The metabolism of flurtamone in primary crops proceeds mainly by hydroxylation respectively of the phenyl and trifluoromethylphenyl rings followed by conjugation with malonic acid and glucose, N-demethylation, oxidative cleavage of the trifluoromethylphenyl moiety leading to TFA metabolite and oxidative ring opening of the furanone moiety with subsequent cleavage and degradation of the carbon chain.

Confined rotational crop metabolism studies were conducted with bare soil applications of flurtamone labelled respectively on the trifluoromethylphenyl ring (3 N rate) and on the phenyl ring (1–4 N rate). Lettuce, radish and wheat were sown at plant-back intervals (PBIs) of 30, 120 and 365 days. In all plant matrices and given the very high persistence of TFA metabolite in soil (DT_{50} > 1,000 days, see Section 4), a preferential uptake of this compound by the rotational crops was observed with residue levels accounting for 95% TRR in lettuce and 63% TRR in radish root at all PBIs and up to 80% TRR and 34% TRR in cereal grain and straw, respectively, at 30 days PBI. Flurtamone was recovered at trace level (< 0.01 mg eq/kg) in lettuce and radish leaves/roots at all PBIs, except in wheat grain (11.5% TRR; 0.001 mg eq/kg), in wheat straw (53% TRR; 0.041 mg eq/kg) and in wheat forage (49% TRR; 0.008 mg eq/kg) at 30 days PBI. Hence, the metabolic pathway in the rotational crops is deemed to be similar to that depicted in the primary crops. A data gap was also identified to provide rotational crop field trials on cereals, leafy vegetables and root vegetables analysing TFA residues and covering the maximum plateau concentration of TFA.

For risk assessment purposes, flurtamone (sum of isomers) and metabolite TFA are the relevant components to be included in the plant residue definition. Whether the consumer dietary risk assessment is to be conducted combined or separately is pending a finalised assessment of the toxicological profile of the parent flurtamone (see Section 2). For monitoring, only flurtamone (sum of isomers) should be included in the residue definition. During the peer review, the experts highlighted that based on the metabolic pattern depicted in cereals and in rotational crops that can be established after a cereal crop, TFA metabolite should actually be considered as the relevant residue marker in plants. However, since TFA residues may result from other pesticides that are metabolised to TFA and from environmental contaminations, this compound cannot be used as a valid marker to monitor residues in plants resulting from the use of flurtamone. The proposed residue definitions are restricted to cereals. For the pulses and oilseeds crop group, the residue definitions could not be finalised. Although TFMBA metabolite was shown to be the relevant compound of the residues in the seeds, the residue data that would enable a reliable consumer risk assessment with regard to this compound are

not available as pulses and oilseeds crops are not a representative use. Furthermore, the genotoxic potential of TFMBA could not be concluded on based on the available data (see Section 2). It is noted that based on additional wheat metabolism studies conducted with ^{14}C-flurtamone labelled on the trifluoromethylphenyl ring and submitted for the renewal of the approval of flurtamone the residue definition for risk assessment has been changed compared to the residue definition proposed as flurtamone only in the framework of the review of the existing MRLs for flurtamone (EFSA, 2012). Furthermore, the reference values derived for flurtamone cannot be applied on as long as the mutagenic potential of flurtamone cannot be excluded (see Section 2). EFSA would recommend the revision of the established MRLs under Article 12 of Regulation (EC) No 396/2005 once the reference values are confirmed.

Sufficient residue field trials on barley and wheat and compliant with the critical GAP on spring and winter cereals (barley, wheat, oats, rye, spelt, triticale) were provided, determining residues of flurtamone. The residue data were supported by acceptable storage stability data where flurtamone was shown to be stable up to 18 months in high starch and high oil content commodities. A data gap was set for a complete residue dataset on cereals (forage, grain, straw) analysing TFA residues in accordance with the representative use. Processing studies are not triggered with regard to flurtamone residues in cereal grain (< 0.01 mg/kg). The need for additional processing studies addressing the nature and the magnitude of residues in processed cereal commodities should however be reconsidered pending upon the magnitude of TFA residues in cereal grain.

Assuming that flurtamone is the relevant residue for livestock exposure from the representative use on cereals, the livestock dietary burden does not trigger investigation of residues in animal commodities. Metabolism studies on ruminants and poultry conducted with ^{14}C Phenyl flurtamone are, however, available and transfer of residues in animal commodities is confirmed to be insignificant (< 0.01 mg/kg). With regard to TFA residues, the livestock dietary burden was tentatively estimated using the highest TFA residues in cereal forage, straw and grain from the wheat metabolism study. At the estimated dietary burden, the transfer of TFA residues into animal commodities was found to be significant based on the submitted poultry and ruminant metabolism studies conducted with ^{14}C Na-TFA with residues > 0.01 mg/kg in all matrices. The estimated dietary burden calculation, the transfer of TFA residues in animal matrices and the need for feeding studies analysing the magnitude of TFA residues in animal matrices should be reconsidered upon the outcome of the requested residue field trials analysing TFA residues in cereals and in rotational crops.

The consumer risk assessment cannot be finalised for flurtamone since the toxicological reference values for the parent compound cannot be applied (see Section 2). Although toxicological reference values were derived for TFA, a consumer risk assessment with regard to this compound is also not possible considering the identified data gaps. Since the concentrations of TFA residues in groundwater were estimated to be in the range 3.619–22.13 μg/L in four out of nine scenarios (winter cereals, PEARL model) (see Section 4), the potential exposure of consumers to this compound via drinking water was assessed and resulted in a dietary intake accounting for 6.6% ADI for infants, 4.4% ADI for children and 1.5% ADI for adults according to the WHO guidelines (WHO, 2011). Information on the relative toxicity of each enantiomer of flurtamone and their potential degradation in plant and animal matrices was not given and provide therefore an additional uncertainty with regard to the consumer exposure assessment.

The data requirement for the determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom could not be addressed considering the outstanding residue field trials on cereals and on rotational crops analysing TFA residues.

4. Environmental fate and behaviour

Flurtamone was discussed at the Pesticides Peer Review Meeting 140 in January 2016. Information in the dossier was insufficient to conclude that during transformation in the environmental matrices soil, water and sediment, the isomer ratio of flurtamone did not change (i.e. it remained a racemic mixture) in the dark and under irradiated conditions. However, it is considered that the margin of safety on the soil risk assessments are large enough that the uncertainty on the relative toxicity and contributions to the total residue levels of the isomers of these metabolites does not change this conclusion of a low risk for soil organisms. On the contrary, for the aquatic environment, this leads to additional uncertainty in the available aquatic risk assessments than would be the case if flurtamone was not made up of isomers.

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, flurtamone exhibited low to moderate persistence, forming the major (> 10% applied radioactivity (AR)) metabolite **M04 TFMBA** (max 24.7% AR), which exhibited low to moderate persistence. Metabolite **M05 TFA** (which exhibited very high persistence) was present at levels that trigger a groundwater exposure assessment. No potential pH dependency of laboratory degradation rates was observed for flurtamone and its metabolites. Mineralisation of the trifluoromethylphenyl and phenyl ring ^{14}C radiolabel to carbon dioxide accounted for up to 55% and 64% AR after 120 days, respectively. The formation of unextractable residues for these radiolabels accounted for ca 35–37% AR after 120 days. Degradation of flurtamone by photolysis in soil led to the formation of metabolite **benzoic acid** (max. 7.2% AR), which exhibited very low persistence. Phototransformation on soil can contribute to the rate degradation of flurtamone under outdoor conditions. Under anaerobic conditions flurtamone and M04 TFMBA are stable. Flurtamone can be considered to exhibit medium mobility in soil. Metabolite M04 TFMBA exhibited very high to high and metabolite benzoic acid exhibited very high mobility in soil. No experimental soil adsorption properties could be determined for metabolite M05 TFA and therefore default worst-case values of K_{Foc} and 1/n were used in exposure modelling. There was an indication that the adsorption of M04 TFMBA is pH dependent. For metabolite benzoic acid, there could be a correlation between pH and adsorption for the investigated soils but no alkaline soils have been tested and therefore this correlation could not be clearly concluded. In satisfactory field dissipation studies carried out at four European sites (spray application on cropped soil plots) flurtamone and metabolite M04 TFMBA exhibited moderate to medium persistence. Field DT_{50} estimates are not available for metabolite TFA which when dosed in some laboratory soil incubations, had single first-order DT_{50} greater than 60 days. In this situation, field DT_{50} and DT_{90} estimates are needed according to the data requirements. This is identified as a data gap (see Section 7). Previously submitted column leaching studies and a lysimeter study showed that flurtamone does not present a leaching risk. The column leaching studies indicated that M04 TFMBA was more mobile than flurtamone but it was found in concentrations of < 0.1 μg/L in the lysimeter study. A new column leaching study on M05 TFA showed it was poorly retained, as would be expected from the results of the adsorption/desorption studies that have been conducted.

Hydrolysis is considered not to be a route of dissipation in the aquatic environment. Flurtamone is susceptible to aqueous photolysis, forming the major photodegradate **M07 flurtamone-carboxylic acid** (max. 33.5% AR). In laboratory incubations in dark aerobic natural sediment water systems, flurtamone exhibited moderate to high persistence, forming the major (> 10% AR) metabolites **M08 flurtamone-desphenyl** (max. 7.8% AR in water and 3.6% in sediment). The unextractable sediment fraction was a limited sink, accounting for ca 23–41% AR at study end (100–161 days). Mineralisation accounted for 4.3–47.9% AR at the end of the study. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were appropriately carried out for flurtamone and its metabolites M04 TFMBA, M05 TFA, benzoic acid, M07 flurtamone-carboxylic acid (major photolysis degradates) and M08 flurtamone-desphenyl (major water-sediment metabolite) using the FOCUS (2001) step 1 and step 2 approach (version 2.1 of the steps 1-2 in FOCUS calculator). For the active substance flurtamone, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available.[5] The step 4 calculations appropriately followed the FOCUS (2007) guidance, with for the representative use on winter cereals (autumn or spring application) and on spring cereals no-spray drift buffer zones of up to 30 m being implemented for the drainage scenarios, and combined no-spray buffer zones with vegetative buffer strips of up to 20 m being implemented for the run-off scenarios. The SWAN tool (version 3.0.0) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that while run-off mitigation is included in the step 4 calculations available, the FOCUS (2007) report acknowledges that for substances with K_{Foc} < 2,000 mL/g (i.e. flurtamone), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds. New PEC_{sw} and PEC_{sed} values have been recalculated by the RMS using DT_{50}soil for flurtamone of 10.7 days agreed at the expert meeting. All other input data and the approaches taken remained the same as in the previous calculation: in the first approach, DT_{50}water of 82.4 days and DT_{50}sed of 1,000 days was used; in the second approach, the interchanged DT_{50} values were used (DT_{50}water of 1,000 days and DT_{50}sed of 82.4 days). The second approach resulted in higher PEC_{sw} values, which were used to perform the aquatic risk assessment.

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

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2009) scenarios and the models PELMO 5.5.3 and PEARL 4.4.4 for the active substance flurtamone and metabolites M04 TFMBA, M05 TFA and benzoic acid that reached levels triggering assessment. Following the Pesticides Peer Review Meeting 140, revised PEC_{gw} calculations with new agreed endpoints (i.e. geometric mean DT_{50}soil for the active substance and metabolites TFMBA and TFA; kinetic formation fractions for metabolites TFMBA and TFA; soil pH dependency for adsorption properties of metabolite TFMBA; plant uptake factor of 0 for metabolite TFMBA) were provided. The potential for groundwater exposure from the representative uses by flurtamone and metabolite TFMBA 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 metabolite TFA, the 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 10 μg/L at four out of nine scenarios (winter cereals, PEARL model), with these concentrations estimated to be in the range 3.619–22.13 μg/L. Based on the information available in the Section 2, metabolite TFA is considered a ground water toxicologically relevant metabolite as the parent is proposed for classification as carcinogenic category 2.

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are 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 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,b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013). According to Regulation (EU) No 283/2013[6], 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.

Flurtamone was discussed at the Pesticide Peer Review Experts' meeting 142 and 160.

It is noted that the flurtamone representative formulation contains two active substances (flurtamone and diflufenican). The combined toxicity of flurtamone in mixture with diflufenican was not addressed in this conclusion and, if relevant, should be considered at Member State level within the authorisation of the formulated product(s).

A low acute and chronic risk to **birds and wild mammals** was concluded for flurtamone for all relevant routes of exposure.

The risk assessment for birds and mammals with respect to flurtamone metabolites was discussed at the Pesticide Peer Review Experts' meeting 142. The experts identified six major metabolites occurring at levels higher than 10% in plants. It is noted that only two of the identified metabolites occur in crops relevant for the representative used assessed (cereals) at levels higher than 10% (TFA and flurtamone-trifluoromethyl-hydroxy). Only the latter were, therefore, considered further in the risk assessment. At the screening level, assuming a 10 times higher toxicity than the parent, a high chronic risk via dietary exposure cannot be excluded for the plant metabolite TFA for small granivorous and omnivorous birds and for the plant metabolite flurtamone-trifluoromethyl-hydroxy for small omnivorous birds, leading to a data gap. A low risk to small herbivorous and granivorous mammals via dietary exposure was concluded for the plant metabolites TFA and flurtamone-trifluoromethyl-hydroxy.

Regarding the **aquatic organisms**, based on the available data, a low risk to fish, aquatic invertebrates and algae was concluded by using FOCUS step 1 and 4 values. Low risk to algae was identified when risk mitigation measures up to 10 m no-spray buffer zone and 10 m vegetative buffer strip for the FOCUS scenarios R1 and R3 are implemented. A data gap has been identified for further

[6] 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, p. 1–84.

data on sediment-dweller organisms as the available study was not considered valid. A pulse exposure laboratory study was available in the RAR aiming at refining the exposure representing a more realistically exposure in the study compared to the field exposure conditions. The study, however, lacked of a control and therefore the experts at the Peer Review Experts' meeting 142 did not agree on its use for refining the risk to algae. The lower tier data used in the risk assessment for aquatic plants were not sufficient to conclude low risk.

Approaches for refinements of the risk to aquatic plants were available in the RAR and were discussed by the experts at the Pesticide Peer Review Experts' meeting 142, i.e. (i) the use of the PEC_{TWA}, (ii) the use of a lower assessment factor considering the studies with additional species of macrophytes than the standard ones, (iii) a pulse exposure study, (iv) a semifield peak exposure study and (v) two mesocosm studies. The experts did not agree with the use of the PEC_{TWA} as latency of effects could not be excluded from the available information and the reciprocity was not appropriately demonstrated. The use of a lower assessment factor was also not considered appropriate since the endpoints available for the additional species of macrophytes were not all derived from laboratory studies. The experts agreed that the pulse exposure study with *Lemna gibba* could be used in the risk assessment for aquatic plants pending on the calculation of an endpoint after the 2-day-exposure and the comparison of the exposure in the study with the FOCUS profiles. The comparison of the exposure in the study with the FOCUS profiles was provided in the revised RAR and discussed at the Peer Review experts' meeting 160. The experts agreed that the exposure in the study can be considered comparable for the R1 and R3 FOCUS exposure profiles but not for D1 and D6. The available semi-field peak exposure study with *Elodea canadensis* and *Myriophyllum spicatum* was not considered reliable for risk assessment because biological measurements were only carried out after 14 days exposure and therefore it is not clear whether recovery occurred after the peak exposure. In addition, an analysis of the statistical power of the study (i.e. minimum detectable difference (MDD)) was not considered reliable. The outdoor mesocosm studies with nine aquatic macrophytes species could not be used either to derive a no observed effect concentration (NOEC) or a no observed ecologically adverse effect concentration (NOEAEC) because of the effects observed at the lowest tested concentration on *E. canadensis* and the lack of recovery over the study duration for that species. Analysis of the statistical power of the study (e.g. MDD calculation) was not provided (data gap). The outdoor mesocosm study with *E. canadensis* and *Potamogeton crispus* was considered reliable even if some uncertainties were identified as the first biological measurements were only performed after 28 days from the first application. Moreover, the mesocosm showed a potential higher sensitivity of macrophytes than the first tier studies and therefore the experts agreed that this result cannot be neglected. The experts agreed that assuming that recovery occurred for *E. canadensis* and using all the other available information as supportive, the NOEAEC of 1 μg/L from this study can be used for risk assessment in association with an assessment factor (AF) of 3. However, the MDD calculations were not provided either for this study (data gap). In addition, the experts agreed that the endpoint derived from this study does not fully cover the representative uses as presented in the GAP (the study was conducted in May–July).

By using this endpoint with the AF of 3, overall, a high risk was identified for five out of nine FOCUS scenarios. It is noted that the endpoint used in the refined risk assessment (NOEAEC) is more adverse than the one used in the Tier I assessment and the one derived from the pulse exposure study with *Lemna*. The RMS disagrees with the use of the endpoint derived from the higher tier study in the refined risk assessment when this is more adverse than the one derived from the Tier I data.

It is noted that flurtamone is a racemic mixture of two enantiomers. From the available information in the dossier, it is not possible to conclude on whether the isomer ratio of flurtamone would change during the transformation in water and sediment (see Section 4). This leads to additional uncertainty in the available aquatic risk assessments.

A low risk was identified to aquatic organisms for all the pertinent metabolites by using FOCUS Step 1 values.

Acute contact and acute oral toxicity studies for honey**bees**, performed with the active substance and the representative formulation, were available. A honeybee chronic toxicity study performed with the formulated product 'Flurtamone SC 350 G' was available. The risk assessment for honeybees was performed using these data in accordance with EFSA (2013). A low acute risk for contact and oral exposure to flurtamone was concluded. At first tier a high chronic risk was identified for the weed scenario. However, considering the mode of action of flurtamone and the representative uses assessed (pre- and post-emergence uses up to BBCH 29), a low risk could be concluded. An assessment of the effects on hypopharyngeal glands (HPG) was not available (data gap). No assessment for accumulative effects was available.

Regarding the honeybee brood development, a semifield study performed according to OECD 75 was available. In this study, effects on honeybee brood development were not observed. The use of this study in the risk assessment was discussed at the Pesticide Peer Review meeting 142 and the experts concluded that this study could be considered as representative of a worst case exposure since in this study *Phacelia tanacetifolia* was applied with the maximum application rate (according to the representative uses assessed) of 125 g a.s./ha. A study performed according to the Oomen method (Oomen et al., 1992) was available as well. In this study, a higher mean eggs' termination rate compared to the control was observed in the treated group. This difference was considered as not statistically significant by the study author. This study presented various shortcomings with respect to EFSA (2013) and it was therefore concluded by the experts that a firm conclusion cannot be reached on its basis. Overall, on a weight of evidence basis, the risk to honey**bee brood and larvae** is considered as low.

A low risk to adult (acute and chronic) honeybees was concluded on the basis of the screening assessment for exposure to residues in surface and in guttation fluids. No assessments were available for exposure via residues in puddle water. However, considering all the available data and assessments including the assessments on guttation fluid and on surface water, a low acute and chronic risk was concluded also for the puddle scenario. Due to the lack of toxicological endpoints, similar quantitative assessments for exposure via water consumptions were not performed for larvae and for the development of HPG. However, a low risk was concluded using a weight of evidence approach. For these qualitative assessments, the following aspects were taken into consideration: the water solubility of flurtamone, the bee brood feeding test and available toxicological data on adults.

Information was not available to perform a risk assessment to honeybees for relevant metabolites in pollen and nectar. Therefore, a data gap is identified.

Data to perform a risk assessment for solitary bees were not available. Acute contact toxicity data on flurtamone on bumble bees (*Bombus terrestris*) were available. With these data a low acute risk for contact exposure can be concluded.

With the available information, a low risk to **non-target arthropods** was concluded.

A low risk to **non-target soil macro-** and **microorganisms** was concluded for flurtamone and the pertinent soil metabolites. It is noted that, from the available information in the dossier, it is not possible to conclude on whether the isomer ratio of flurtamone would change during the transformation in soil (see Section 4). However, the margin of safety of the soil risk assessments is large enough to exclude that the uncertainty related to the isomer ratio of flurtamone in soil could change this conclusion.

A low risk to **sewage treatment organisms** and to **terrestrial non-target higher plants** was concluded.

With regard to the assessment of endocrine disruption potential, as discussed in Section 2, a data gap was concluded for further information to assess the potential for endocrine disruption in mammals. No firm conclusion can be drawn regarding birds, fish and amphibians.

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
Flurtamone	Low to moderate persistence Single first-order DT_{50} 9.1–12.0 days (20°C 24.1–44.9% MWHC) Moderate to medium persistence European field dissipation studies single first-order and biphasic DT_{50} 15.3–91.6 days (DT_{90} 155–304 days)	Low risk
M04 TFMBA	Low to moderate persistence Single first-order DT_{50} 2.8–13.6 days (20°C 45–55% MWHC) Moderate to medium persistence European field dissipation studies single first-order DT_{50} 13.3–64.5 days	Low risk
M05 TFA	Very high persistence Single first-order DT_{50} > 1,000 days (20°C 55% MWHC) Data gap for field dissipation rates	Low risk
Benzoic acid (soil photolysis)	Very low persistence Single first-order DT_{50} < 0.1 day (20°C 13–39% MWHC)	Low risk

DT_{50}: period required for 50% dissipation; DT_{90}: period required for 90% dissipation; MWHC: maximum water-holding capacity.

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	Ecotoxicology
Flurtamone	Medium mobility K_{Foc} 225–288 mL/g	No	Yes	Yes	High risk to organisms living in surface water was identified for 5/9 FOCUS scenarios
M04 TFMBA	Very high to high mobility K_{Foc} 15–52 mL/g	No	No	Yes based on the proposed classification Carc cat 2 for flurtamone	Low risk identified for organisms living in surface water
M05 TFA	Not determined Worst case default values used in FOCUS modelling	Yes 9/9 FOCUS scenarios > 0.1 µg/L (range 3.62–22.13 µg/L)	No	Yes based on the proposed classification Carc cat 2 for flurtamone ADI 0.05 mg/kg bw per day	Low risk identified for organisms living in surface water

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	Ecotoxicology
Benzoic acid (soil photolysis)	Very high mobility K_{Foc} 0.9–19 mL/g	No	Yes	No	Low risk identified for organisms living in surface water

K_{Foc}: Freundlich organic carbon adsorption coefficient; FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use; ADI: acceptable daily intake; bw: body weight.
(a): At least one FOCUS scenario or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Flurtamone	Data gap for sediment organisms High risk to organisms living in surface water was identified for 5/9 FOCUS scenarios
M04 TFMBA	Low risk
M05 TFA	Low risk
Benzoic acid (soil photolysis)	Low risk
M07 flurtamone-carboxylic acid	Low risk
M08 flurtamone-desphenyl	Low risk

FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use.

Table 4: Air

Compound (name and/or code)	Toxicology
Flurtamone	Rat LC_{50} > 2.2 mg/L air/4 h (whole body exposure) – no classification required

LC_{50}: lethal concentration, median.

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).

- Pending the availability of validated methods to test phototoxicity and photomutagenicity at wavelengths covering the range of natural sunlight between 290 and 320 nm (where flurtamone shows a maximal absorption), the phototoxic and photomutagenic potential of flurtamone needs to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see Section 2).
- An Ames test with the new technical specification of flurtamone has to be performed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Since sensitive parameters for endocrine disruption were not all investigated in the studies submitted and thyroid follicular adenomas were observed in male rats without mechanistic clarifications, further investigations of the potential endocrine-disrupting properties of flurtamone, according to the OECD Conceptual Framework (OECD, 2012) and the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA Scientific Committee, 2013) are needed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 2 and 5).
- A complete residue data set on cereals (forage, grain, straw) analysing TFA residues in accordance with the representative use (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Rotational crop field trials on cereals, leafy vegetables and root vegetables analysing TFA residues and covering the maximum plateau concentration of this compound (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- The estimated dietary burden calculation, the transfer of TFA residues in animal matrices and the need for feeding studies analysing the magnitude of TFA residues in animal matrices should be reconsidered upon the outcome of the requested residue field trials analysing TFA residues in cereals and in rotational crops (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Determination of the residues in pollen and bee products for human consumption resulting from TFA residues taken up by honeybees from crops at blossom considering the outstanding residue field trials on cereals and on rotational crops analysing TFA residues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Reliable field DT_{50} and DT_{90} estimates from three different field trial sites were not available for metabolite M05 TFA. These are needed according to the results of laboratory incubations and the data requirements (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Flurtamone consists of two enantiomers. This needs to be taken into account in the environmental risk assessment. Information on the toxicity and/or on the degradation of the two enantiomers in the environment is needed. For the aquatic environment, this lack of information leads to additional uncertainty in the available aquatic risk assessments (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 4 and 5).
- Information to address the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water was not available. Probably in the first instance, a consideration of the processes of ozonation and chlorination would be appropriate. If an argumentation is made that concentrations at the point of extraction for drinking water processes will be low, this argumentation should cover metabolites predicted to be in groundwater and surface water, as well as the active substance. Should this consideration indicate novel compounds might be expected, the risk to human or animal health through the consumption of drinking water containing would need to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).

- Further information to address the chronic risk to birds for the plants metabolites TFA and flurtamone-trifluoromethyl-hydroxy (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5)
- Valid data on the toxicity of flurtamone to sediment-dweller organisms (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5)
- Analysis of the statistical power of the study (e.g. MDD calculations) for the outdoor mesocosm study with *E. canadensis* and *P. crispus* and for the outdoor mesocosm study with nine aquatic macrophytes species (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5)
- Further data to refine the risk identified for flurtamone to aquatic plants (relevant for the representative use, i.e. cereals five out of nine FOCUS scenarios; submission date proposed by the applicant: unknown; see Section 5)
- Based on EFSA (2013), suitable data to address the risk of sublethal effects (i.e. HPG development effects) to honeybees due to exposure to flurtamone (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Information to assess the risk to honeybees due to plant metabolites occurring in pollen and nectar (relevant for all representative uses evaluated; 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

- Mitigation measures up to 10 m no-spray buffer zone and 10 m vegetative buffer strip for the FOCUS scenarios R1 and R3 are needed to conclude low risk to algae; for the FOCUS scenarios D3, D4 and D5 mitigation measures up to 30 m no-spray buffer zone are needed to conclude low risk to plants while for the FOCUS scenario R4, mitigation measures of 20 m no-spray buffer zone and 20 m vegetative strip need to be implemented (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[7] 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) Flurtamone is not classified or proposed to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008[3] and therefore, 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 are not met. With regard to the screening of endocrine-disrupting properties for flurtamone, since sensitive parameters for endocrine disruption were not all investigated in the studies submitted and thyroid follicular adenomas were observed in male rats without mechanistic clarifications, further investigations are requested according to the OECD Conceptual Framework (OECD, 2012) and the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA Scientific Committee, 2013) (see Sections 2 and 5).

[7] 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.

2) The consumer risk assessment with regard to the residues that might be present in drinking water consequent to water treatment following abstraction for drinking water cannot be finalised (see Sections 3 and 4).

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 a 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.

3) The derivation of the health-based reference values could not be concluded for flurtamone as long as its mutagenic potential cannot be excluded (see Section 2).
4) The operator, worker, bystander and resident exposure risk assessment cannot be conducted since non-dietary reference values could not be derived for flurtamone (see Section 2).
5) The consumer risk assessment cannot be conducted with regard to flurtamone and the major plant metabolite TFA included in the residue definition for risk assessment considering that toxicological reference values could not be derived for flurtamone and the identified data gaps in regards to TFA (see Sections 2 and 3).
6) The relevant metabolite TFA is predicted to be present in groundwater at concentrations exceeding 0.1 μg/L in all the relevant FOCUS groundwater scenarios (see Section 4).
7) A high risk (5 out of 9 FOCUS scenarios) was identified for aquatic organisms for the representative use of flurtamone (see Section 5).

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.)

Table 5: Overview of concerns

Representative use		**Cereals (Winter, Spring)**
Operator risk	Risk identified	
	Assessment not finalised	X[3,4]
Worker risk	Risk identified	
	Assessment not finalised	X[3,4]
Resident/bystander risk	Risk identified	
	Assessment not finalised	X[3,4]
Consumer risk	Risk identified	
	Assessment not finalised	X[2,5]
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	

Representative use		Cereals (Winter, Spring)
Risk to aquatic organisms	Risk identified	X[7]
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	X[6]
	Parametric value of 10 μg/L[(b)] breached	
	Assessment not finalised	

Columns are grey if no safe use can be identified. 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, 2003a.

References

Czech Republic, 2015. Renewal Assessment Report (RAR) on the active substance flurtamone prepared by the rapporteur Member State Czech Republic in the framework of Regulation (EC) No 844/2012, May 2015. Available online: www.efsa.europa.eu

Czech Republic, 2016. Revised Renewal Assessment Report (RAR) on flurtamone prepared by the rapporteur Member State Czech Republic in the framework of Regulation (EC) No 844/2012, March 2016. Available online: www.efsa.europa.eu

Czech Republic, 2017a. Revised Renewal Assessment Report (RAR) on flurtamone prepared by the rapporteur Member State Czech Republic in the framework of Regulation (EC) No 844/2012 following the request for an updated peer review, January 2017. Available online: www.efsa.europa.eu

Czech Republic, 2017b. Revised Renewal Assessment Report (RAR) on flurtamone prepared by the rapporteur Member State Czech Republic in the framework of Regulation (EC) No 844/2012 following the request for an updated peer review, June 2017. Available online: www.efsa.europa.eu

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

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

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flurtamone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(12):3009, 27 pp. https://doi.org/10.2903/j.efsa.2012.3009

EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp. https://doi.org/10.2903/j.efsa.2013.3295

EFSA (European Food Safety Authority), 2016a. Conclusion on the peer review of the pesticide risk assessment of the active substance flurtamone. EFSA Journal 2016;14(6):4498, 24 pp. https://doi.org/10.2903/j.efsa.2016.4498

EFSA (European Food Safety Authority), 2016b. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance flurtamone. EFSA Journal 2016;14(6):4498, 24 pp. https://doi.org/10.2903/j.efsa.2016.4498

EFSA (European Food Safety Authority), 2017. Peer review report to the conclusion regarding the updated peer review of the pesticide risk assessment of the active substance flurtamone. EFSA Journal 2017. Available online: www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Guidance on dermal absorption. EFSA Journal 2012;10(4):2665, 30 pp. https://doi.org/10.2903/j.efsa.2012.2665

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. https://doi.org/10.2903/j.efsa.2013.3290

EFSA Scientific Committee, 2013. Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132, 84 pp. https://doi.org/10.2903/j.efsa.2013.3132

European Commission, 2000a. Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission, 2000b. Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000.
European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002
European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001-rev. 4 final, 17 October 2002.
European Commission, 2003a. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.
European Commission, 2003b. Review report for the active substance flurtamone. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 4 July 2003 in view of the inclusion of flurtamone in Annex I of Council Directive 91/414/EEC. SANCO/10162/2003-Final, 3 July 2003, 24 pp.
European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.
European Commission, 2014. Guidance document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012. SANCO/2012/11251-rev. 4, 12 December 2014.
European Commission, 2015. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95-rev. 10.1. December 2015. pp. 1–56.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2001. FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev. 2, 245 pp., as updated by Generic guidance for FOCUS surface water scenarios, v. 1.1, March 2012.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2007. Landscape and mitigation factors in aquatic risk assessment. Volume 1. Extended summary and recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. EC Document Reference SANCO/10422/2005 v. 2.0, 169 pp.
FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2009. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 1, 604 pp., as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.0, January 2011.
JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004, 383 pp.
JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 18–27 September 2007, 164 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2012. Series on Testing and Assessment: No 150: Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption. ENV/JM/MONO(2012)22, 524 pp.
Oomen PA, De Ruliter A and dervan Steen J, 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bulletin OEPP/EPPO Bulletin, 22, 613–616 (1992).
SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT 2.
WHO (World Health Organization), 2011. *Guidelines for Drinking-water Quality*. 4th edition. WHO, Geneva, ISBN 978 92 4 154815 1.

Abbreviations

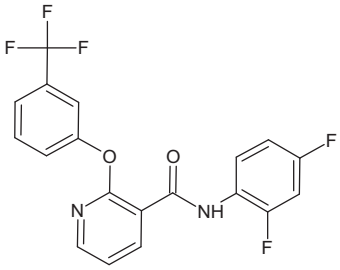
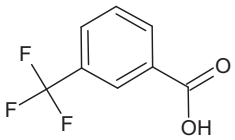
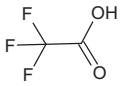
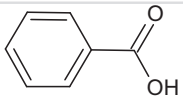
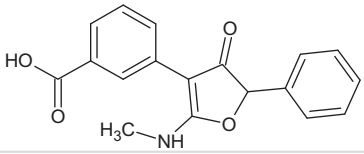
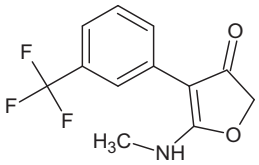
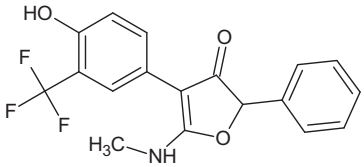
ε	decadic molar extinction coefficient
a.s.	active substance
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level

AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
DFG	Deutsche Forschungsgemeinschaft method
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GC	gas chromatography
GC–MS	gas chromatography – mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
HPG	hypopharyngeal gland
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC_{50}	lethal concentration, median
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MDD	minimum detectable difference
MRL	maximum residue level
MWHC	maximum water-holding capacity
NOAEL	no observed adverse effect level
NOEAEC	no observed ecologically adverse effect concentration
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{sw}	predicted environmental concentration in surface water
QuEChERS	quick, easy, cheap, effective and safe method
SC	suspension concentrate
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TFA	trifluoroacetic acid
TRR	total radioactive residue
UF	uncertainty factor
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.2017.4976.

Appendix B – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation	Structural formula
Diflufenican	2′,4′-difluoro-2-(α,α,α-trifluoro-*m*-tolyloxy) nicotinanilide Fc3ccc(NC(=O)c2cccnc2Oc1cccc(c1)C(F)(F)F)c(F)c3	
TFMBA **M04** **RE 54488**	3-(trifluoromethyl)benzoic acid FC(F)(F)c1cccc(c1)C(=O)O	
TFA **M05**	Trifluoroacetic acid FC(F)(F)C(=O)O	
Benzoic acid	Benzoic acid O=C(O)c1ccccc1	
flurtamone-carboxylic acid **M07**	3-[2-(methylamino)-4-oxo-5-phenyl-4, 5-dihydrofuran-3-yl]benzoic acid O=C(O)c1cccc(c1)C3=C(NC)OC(c2ccccc2)C3=O	
Flurtamone-desphenyl **M08**	5-(methylamino)-4-[3-(trifluoromethyl)phenyl] furan-3(2*H*)-one O=C2COC(NC)=C2c1cc(ccc1)C(F)(F)F	
Flurtamone-trifluoromethyl-hydroxy	4-[4-hydroxy-3-(trifluoromethyl)phenyl]-5-(methylamino)-2-phenylfuran-3(2*H*)-one FC(F)(F)c1cc(ccc1O)C3=C(NC)OC(c2ccccc2)C3=O	

SMILES: simplified molecular-input line-entry system.
(a): The compound name in bold is the name used in the conclusion.