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Scientific support for preparing an EU position in the 49th Session of the Codex Committee on Pesticide Residues (CCPR)

European Food Safety Authority

Abstract

In accordance with Article 43 of Regulation (EC) 396/2005, EFSA received a request from the European Commission to provide support for the preparation of the EU position for 49th session of the Codex Committee on Pesticide Residues (CCPR). In 2016, JMPR evaluated 12 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (acibenzolar-S-methyl, fenpropimorph, fluazifop-P-butyl, fluensulfone, imazethapyr, isofetamid, oxathiapiprolin, penconazole, pendimethalin, pinoxaden, spiromesifen and teflubenzuron) and 24 active substance regarding the setting of Maximum Residue Limits (MRLs) (acibenzolar-S-methyl, benzovindiflupyr, bixafen, buprofezin, chlorantraniliprole, deltamethrin, dimethomorph, fipronil, fluazifop-P-butyl, fluensulfone, flupyradifurone, imazethapyr, isofetamid, methoprene, metrafenone, oxathiapiprolin, penconazole, pendimethalin, pinoxaden, saflufenacil, spiromesifen, sulfoxaflor, teflubenzuron and tolfenpyrad); EFSA prepared comments on the Codex MRL proposals and the proposed toxicological reference values. In addition, EFSA provided the views on follow-up assessments of JMPR on pesticides where specific concerns were raised in the previous CCPR meetings. The current report should serve as the basis for deriving the EU position for the CCPR meeting are summarised in this report.

Keywords: consumer risk assessment, toxicological evaluation, residue definitions, MRL setting, CCPR meeting 2017

Requestor: European Commission

Question numbers: EFSA-Q-2016-00742, EFSA-Q-2016-00743, EFSA-Q-2016-00744, EFSA-Q-2016-00745, EFSA-Q-2016-00746, EFSA-Q-2016-00747, EFSA-Q-2016-00748, EFSA-Q-2016-00749, EFSA-Q-2016-00750, EFSA-Q-2016-00751, EFSA-Q-2016-00752, EFSA-Q-2016-00753, EFSA-Q-2016-00754, EFSA-Q-2016-00755, EFSA-Q-2016-00756, EFSA-Q-2016-00757, EFSA-Q-2016-00758, EFSA-Q-2016-00759, EFSA-Q-2016-00760, EFSA-Q-2016-00761, EFSA-Q-2016-00762, EFSA-Q-2016-00763, EFSA-Q-2016-00764, EFSA-Q-2016-00765, EFSA-Q-2016-00766, EFSA-Q-2016-00767, EFSA-Q-2016-00768, EFSA-Q-2016-00769, EFSA-Q-2016-00770, EFSA-Q-2016-00771, EFSA-Q-2016-00772, EFSA-Q-2016-00773, EFSA-Q-2016-00774

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Summary

For the preparation of the 49th session of the Codex Committee on Pesticide Residues (CCPR meeting), the European Commission asked the European Food Safety Authority (EFSA) to provide comments on the individual active substances assessed in the 2016 Joint FAO/WHO Meeting on Pesticide Residues (JMPR), in particular on the recommended toxicological reference values and the proposed Maximum Residue Limits (MRLs) at step 3 and 6 of the Codex procedure.

In 2016, JMPR evaluated 12 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (acibenzolar-S-methyl, fenpropimorph, fluazifop-P-butyl, fluensulfone, imazethapyr, isofetamid, oxathiapiprolin, penconazole, pendimethalin, pinoxaden, spiromesifen and teflubenzuron). EFSA compared the acceptable daily intake (ADI) and acute reference dose (ARfD) values derived by JMPR with the values derived at European Union (EU) level and, in case differences were identified, EFSA provided further explanations for the reasons of the differences.

Regarding the setting of MRLs, JMPR assessed 24 substances (acibenzolar-S-methyl, benzovindiflupyr, bixafen, buprofezin, chlorantraniliprole, deltamethrin, dimethomorph, fipronil, fluazifop-P-butyl, fluensulfone, flupyradifurone, imazethapyr, isofetamid, methoprene, metrafenone, oxathiapiprolin, penconazole, pendimethalin, pinoxaden, saflufenacil, spiromesifen, sulfoxaflor, teflubenzuron and tolfenpyrad). EFSA provided comments on the proposed Codex MRLs as well as on active substances that were re-assessed by JMPR following specific concerns raised in the previous years (acetochlor, chlorothalonil, flonicamid and penthiopyrad) and on general issues discussed in the 2016 JMPR meeting.

It is highlighted that at the JMPR report summarising the recommendations of the 2016 JMPR meeting was published on 12 January 2017. The full evaluations were published after the deadline for the preparation of the draft EFSA report (21 March 2017). Thus, due to the limited details available and the short timelines for providing the comments, an in depth analysis taking into account the detailed information provided in the JMPR evaluation could not always be performed. Thus, the conclusions reached in this report should be considered as indicative and might have to be reconsidered in a more detailed assessment when needed. The comments presented in this report have to be seen in the context of the currently applicable guidance documents and the MRL legislation applicable at the time of commenting. The comments may not be valid any more or may have to be modified, if the legal or scientific framework changes.

Table of contents

1. Introduction

1.1. Background

Manufacturers of pesticides who are interested in the setting of Codex Maximum Residue Limits (CXLs) submit data to the Joint Meeting on Pesticide Residues (JMPR) for assessment. The most recent JMPR evaluations of the toxicological data and the residue studies are summarised in the JMPR Report 2016 (FAO, 2016). It comprises in total 31 active substances: 12 of them were assessed for both toxicological reference values and residues, 13 active substances were assessed in view of setting new CXLs and 6 active substances were assessed for specific concerns raised by the official delegations.

On 11 November 2016, the European Commission requested the European Food Safety Authority (EFSA) to provide support for the preparation of the EU-coordinated position for the 49th session of the Codex Committee on Pesticide Residues (CCPR) in April 2017 in China. In particular, EFSA was asked to give advice and to provide comments on the recommendations of the 2016 Joint FAO/WHO meeting on pesticide residues (JMPR). Additionally, the European Commission requested EFSA to give its comments on other proposed Codex Maximum Residue Limits (MRLs) that were retained at step 4 or 7, respectively, in previous years and are likely to be discussed in the 49th CCPR meeting, in case that such new advice from EFSA is needed and appropriate.

Furthermore, the European Commission asked for comments on the general chapters of the JMPR 2016 report, where relevant for risk assessment as well as other comments on the proposed crop groupings, the JMPR priority list and documents related to the revision of the International estimated of short-term intake (IESTI) equation.

For reasons of transparency and traceability, EFSA has created separate questions for each of the active substances covered by the mandate in the EFSA Register of Questions with the following reference numbers and subjects:

Question number	Subject
EFSA-Q-2016-00742	Acibenzolar-S-methyl - EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00743	Bentazone – EFSA comments on the toxicological reference values evaluated by JMPR in 2016
EFSA-Q-2016-00744	Benzovindiflupyr – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00745	Bixafen – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00746	Buprofezin – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00747	Chlorantraniliprole – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00748	Deltamethrin – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00749	Dimethomorph – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00750	Fenpropimorph – EFSA comments on the toxicological reference values evaluated by JMPR in 2016
EFSA-Q-2016-00751	Fipronil – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00752	Flonicamid – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00753	Fluazifop-P-butyl – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00754	Fluensulfone – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00755	Flupyradifurone – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00756	Imazethapyr – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00757	Isofetamid – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00758	Methoprene – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00759	Metrafenone – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016

Question number	Subject
EFSA-Q-2016-00760	Oxathiapiprolin – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00761	Penconazole – EFSA on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00762	Pendimethalin – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00763	Pinoxaden – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00764	Saflufenacil – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00765	Spiromesifen – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00766	Sulfoxaflor – EFSA comments on the toxicological reference values evaluated by JMPR in 2016
EFSA-Q-2016-00767	Teflubenzuron – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00768	Tolfenpyrad – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2016
EFSA-Q-2016-00769	Acetochlor – EFSA comments on the specific concerns raised during the CCPR meeting in 2016
EFSA-Q-2016-00770	Chlorothalonil – EFSA comments on the specific concerns raised during the CCPR meeting in 2016
EFSA-Q-2016-00771	Flonicamid – EFSA comments on the specific concerns raised during the CCPR meeting in 2016
EFSA-Q-2016-00772	Penthiopyrad – EFSA comments on the specific concerns raised during the CCPR meeting in 2016
EFSA-Q-2016-00773	Picoxystrobin – EFSA comments on the assessment on the new data provided by JMPR 2016
EFSA-Q-2016-00774	EFSA comments on the general considerations provided by JMPR in 2016

The draft scientific report of EFSA was submitted for commenting to the EU Member State experts and European Commission on 3 March 2017. The comments provided by Member States were uploaded on EFSA Document Management System (DMS). All the comments received were addressed either directly in the final EFSA scientific report or though discussion during the Council Working Party meetings for the preparation of the 49th Session of the Codex Committee on Pesticide Residues.

1.2. Terms of Reference

The requested advice and comments on the recommendations of the 2016 JMPR and, where appropriate, on other proposed Codex MRLs, retained in the step procedure and reviewed by JMPR in previous years, should contain the following information:

- background information on all active substances under discussion regarding the status of the active substance at EU level (approval status of the active substance, availability of EFSA conclusions and availability of EFSA reasoned opinions on MRL applications or MRL review);
- in case new toxicological reference values were proposed by JMPR, a comparison of the proposed reference values with agreed EU reference values and an evaluation of the reasons for possible differences;
- as regard the proposed draft Codex MRLs for discussion in CCPR 2017, EFSA should provide any relevant comments on the proposed MRLs and specifically address the following questions:
  - whether the residue definitions derived by JMPR are comparable with the existing EU residue definitions,
  - whether the proposed draft Codex MRLs are comparable with the existing EU MRLs,
  - whether the proposed draft Codex MRLs are sufficiently supported by data,
  - whether the proposed Codex draft MRLs are appropriate in terms of the data that have been used to establish them and in terms of the method used for their calculation,
  - whether the proposed draft Codex MRLs are safe for European consumers with regard to chronic, and where relevant, acute exposure.

The requested comments to the general chapters of the JMPR 2016 report relevant for risk assessment as well as comments on the JMPR priority list can be provided as contribution to the EU coordinated positions when these are discussed with the Member States and do not need to be covered by the scientific report.

(Terms of reference as provided by the European Commission in the Mandate of 11 November 2015)

EFSA agreed with the European Commission to respond to this request with a scientific report. The first draft report should be shared with the European Commission and Member States on 28 February 2017, inviting Member States to provide comments. After discussion between EFSA and the requestor, the deadline for the first draft report was extended to 3 March 2017 to allow the presentation of a most complete document. The final draft addressing the Member State comments should be completed in time to be discussed in the second Council meeting scheduled for 10 April 2017. The report will be adopted at the latest one week before the CCPR meeting. It was agreed with the requestor to publish the final report before 31 July 2017.

2. Assessment

EFSA provided the requested background information regarding the toxicological reference values (second bullet point of the Terms of Reference) by comparing the assessments performed by JMPR with the assessments performed at EU level in the framework of the peer review under Regulation (EC) No 1107/2009[1]. The sources of information used are the EFSA conclusions available for the active substances under consideration, the Review Reports, Draft Assessment Reports (DARs) prepared by the Rapporteur Member States and other sources of information if available.

For deriving the comments on the third bullet point in the Terms of Reference (comments on the Codex MRL proposals), EFSA compared the levels of the Codex MRL proposals and the enforcement residue definition derived by JMPR with the MRLs and the residue definition established in the EU legislation (Regulation (EC) No 396/2005) or the legislation under preparation. The EU residue definitions for risk assessment were retrieved from the EFSA conclusions, EFSA reasoned opinions on MRL review under Article 12 of Regulation 396/2005[2] or, where these documents are not available, the reports prepared by the European Commission in the framework of the peer review of active substances or Member State evaluations in Draft Assessment Reports. The comparison of the existing EU MRLs and the proposed Codex MRLs are presented in tabular form. Codex MRL proposals that are higher than the existing EU MRLs are printed in bold. In line with the presentation of MRLs in the EU legislation, limit of quantification (LOQ) MRLs are indicated by adding an asterisk ('*') after the value.

For assessing whether the draft Codex MRL proposals are sufficiently supported by data, EFSA took into account the currently valid EU guidance documents for consumer risk assessment and the agreed EU policies (European Commission, 1996, 1997a–g, 2000, 2010, 2011; OECD, 2011, 2013). It is noted that due to the different data requirements and policies in JMPR (FAO, 2009), the assessment of identical residue data sets submitted in support of a EU MRL and Codex MRL request may result in different recommendations at EU level and by JMPR. In this report, EFSA provides background information on the reasons for these differences. For calculating the numerical MRL value, EFSA used the same methodology as JMPR (OECD calculator) (OECD, 2011).

For the assessment of the safety of the draft Codex MRL proposals, EFSA used the EFSA PRIMo rev. 2 (EFSA, 2007). For assessing the acute consumer risk, EFSA applied the standard EU methodology, including the agreed EU variability factors and the acute reference dose (ARfD) agreed at EU level. For the assessment of the long-term consumer risk, EFSA calculated the exposure resulting from the existing EU MRLs, taking into account the most recent information on supervised trials median residues (STMRs) and including the STMR values derived by JMPR for commodities where the proposed Codex MRLs are higher than the existing EU MRLs. It is noted that this approach is likely to overestimate the actual exposure, because it is not likely that each food item consumed contains residues at the maximum level allowed in the European legislation, but it is a sufficiently conservative risk assessment screening. For active substances where the MRL review has not yet been completed, a

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 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.

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

less refined calculation was performed for the commodities where the EU MRL is higher than the proposed Codex MRL, using the EU MRL as input values for the risk assessment. The contribution of the individual crops under consideration in the CCPR meeting was calculated separately. The exposure assessments are usually based on the EU toxicological reference values, unless it is specifically mentioned that the JMPR values were used. For draft Codex MRL proposals for food of animal origin, EFSA focussed mainly on the consumer risk assessment and the validity of feeding studies and animal metabolism studies. For draft Codex MRL proposals for animal commodities a full assessment of the expected dietary burden at EU level is not possible in the framework of this report because relevant information are not available to EFSA (e.g. use of the active substance on all feed items in the EU and in Third Countries). For pesticides where the EU and JMPR residue definitions for risk assessment are not comparable, EFSA calculated tentative risk assessment scenarios. The assumptions and uncertainties of these scenarios are described individually.

It is highlighted that at the JMPR report summarising the recommendations of the 2016 JMPR meeting was published on 12 January 2017. The full evaluations were published on 21 March 2017. Thus, due to the limited time available for providing the comments, an in depth analysis could not always be performed. Thus, the conclusions reached in this report should be considered as indicative and might have to be reconsidered in a more detailed assessment, when needed. The comments presented in this report have to be seen in the context of the currently applicable guidance documents and the MRL legislation valid at the time of commenting. Thus, the comments may not be valid any more or may have to be modified, if the legal or scientific framework changes.

3. General consideration

3.1. Update on the revision of principles and methods for risk assessment of chemicals in food (EHC 240)

3.1.1. Benchmark dose

The EU would like to inform about ongoing scientific developments in the EU on this issue. On 24 January 2017, EFSA published the updated EFSA guidance on the use of the benchmark dose (BMD) approach in risk assessment (EFSA Scientific Committee, 2017). EFSA reconfirmed that the BMD approach is a scientifically more advanced method compared to the no observed adverse effect level (NOAEL) approach for deriving a Reference Point. The main changes with regard to the previous (2009) EFSA guidance (EFSA Scientific Committee, 2009) refer to the way of applying the BMD. The preferred method for calculation the BMD interval is Model Averaging. The set of default models to be used for BMD analysis has been reviewed and a new criterion has been introduced to characterise the goodness of fit of the models considered. The guidance has been discussed during a Workshop in Brussels in March 2017. This workshop confirmed a broad consensus of the experts on the overarching principles regarding dose–response modelling and a number of issues were discussed where further agreement among modellers is still needed. The approach is currently applied only in specific cases in the EFSA peer review of pesticides.

As explained in the EFSA guidance document, ideally, the relationship between dose and response would be described by a biologically based model that describes the toxicokinetic and toxicodynamic processes related to the specific compound. For most compounds, such models are not available, and therefore, the BMD approach uses mathematical curve fitting models that do not describe the underlying biology, and should be treated as purely statistical models. Any model that fits adequately the data set (in the range of observation) is acceptable.

The issue of biological relevance is important in the following steps:

- The selection of the data set/endpoint to be subject to BMD analysis.
- The choice of the benchmark response (BMR): the effect size selected should be biologically relevant.

3.1.2. Chemical-specific adjustment factors (CSAFs)

It is noted that in 2012, EFSA published a guidance on selected default values to be used by the EFSA Scientific Committee, Scientific panels and Units in the absence of actual measured data (EFSA Scientific Committee, 2012) which also addresses the use of chemical specific adjustment factors: Substance-specific data for one particular aspect of uncertainty should be used when available to replace the relevant part of the overall default uncertainty factor.

3.1.3. Guidance on the use and interpretation of statistical evaluations and historical control data

Such an update is fully supported. The interpretation of statistical evaluations and historical control data often is a reason for discussion leading to divergent views of experts and it would be desirable to find a common approach.

The recommendation to update the document 'Principles and Methods for the Risk Assessment of Chemical in Food' (EHC 240) is welcome (WHO, 2009).

3.2. JMPR guidance document for WHO monographers and reviewers

JMPR recommended updating the guidance document for WHO monographers and reviewers in accordance with the recommendations derived for benchmark dose, CSAFs and use and interpretation of statistical evaluations and historical control data. JMPR recommended harmonising the approaches, in particular regarding the BMD approach that EFSA revised with the collaboration of the US EPA and RIVM. For reasons of transparency and clarity of the assessment methodology, an update on the use and interpretation of statistical evaluations and historical control data is fully supported.

3.3. Evaluations of genotoxicity data

In 2011, EFSA published a Scientific Opinion on genotoxicity strategies applicable to food and feed safety assessment (EFSA Scientific Committee, 2011).

The Scientific Committee of EFSA was mandated by the European Commission to review some aspects of the genotoxicity assessment. Following this assessment, the Scientific Opinion of EFSA may be revised.

The update of the EHC 240 guidance on genotoxicity proposed by JMPR is appreciated insofar it intends to clarify how to balance data from regulatory dossiers and published studies.

3.4. Update of the OECD livestock Animal Burden feed table

The use of the updated dietary burden feed table published in the OECD guidance document on residues in livestock (OECD, 2013) is appreciated. It is noted that the same source of information is used at EU level for the calculation of the EU dietary burden of livestock. Thus, the use of the same data is an important step for harmonisation of the risk assessment methodologies.

4. EFSA Comments on JMPR report chapter 3.1 (Concerns raised by the Codex Committee on Pesticide Residues)

4.1. Acetochlor (280)

In 2015, JMPR assessed the Good Agricultural Practice (GAP) reported for soya beans (US GAP). It was concluded that no suitable residue trials matching the critical GAPs (cGAPs) were provided. The USA submitted a concern form requesting JMPR to reconsider the conclusion derived in 2015. According to the USA, the metabolism study and other studies and information (e.g. confined rotational crop study) could be used to derive a MRL after scaling the match the cGAP.

JMPR confirmed its previous conclusion that the data are not suitable for the application of the proportionality approach.

EFSA shares the view of JMRP.

4.2. Chlorothalonil (081)

In 2015, JMPR assessed residue trials in cranberries. Since the stability of residues for both parent compound and SDS-3701 was not sufficient, JMPR did not derive a MRL proposal. USA submitted a concern form asking JMPR to reconsider the conclusion.

JMPR confirmed its previous conclusion on the invalidity of the studies.

EFSA shares the view of JMPR.

4.3. Flonicamid (282)

The USA has submitted a concern form requesting a review of the JMPR decision on MRLs for cucurbits based on greenhouse cucumber data. In 2015, JMPR derived a Codes MRL proposal for

fruiting vegetables, cucurbits based on residue trials matching the Australian GAP (0.2 mg/kg). For the more critical US GAP, the number of trials were considered insufficient (greenhouse use, only 4 trials were matching the US GAP). JMPR confirms its previous conclusion. EFSA agrees with the position of JMPR.

In 2015, JMPR also recalculated the dietary burden for livestock, including kale. The results of the revised dietary burden calculations are significantly higher (slightly exceeding the highest feeding level for of the feeding study in ruminants), triggering new proposals for food of animal origin.

EFSA updated the risk assessment performed in 2016, including the new STMR values for mammalian fats, meat, milks, edible offal and for poultry products in the long-term risk assessment. For the short-term risk assessment, the MRL proposals were used (JMPR did not derive HR values since according to JMPR no ARfD was considered necessary).

The overall long-term exposure including the higher input values for animal commodities accounted for ca 34% of the ADI.

In the short-term exposure assessment, the higher MRL proposals did not exceed the ARfD (among the animal products, the highest short-term exposure was calculated for milk (25% of the ARfD).

For more details, see Section 6.17.

4.4. Penthiopyrad (253)

A number of MRL proposals relevant for feed (e.g. cabbage head, cotton seed, eggs, maize, millet, oats, peanut, pome fruits, poultry meat, poultry edible offal, rape seed, rye, sorghum, soya bean, sugar beet, sunflower seed, triticale, wheat and related by products relevant for feed) derived by JMPR in 2012 were retained at step 4 awaiting the JMPR assessment of an animal dietary burden that excludes the Australian dietary burden estimates (as penthiopyrad was not registered for use on soy beans in Australia) and consideration of an alternative GAP for mustard greens (for which an exceedance of the ARfD was identified by JMPR). In 2012, no CXL proposals could be derived for mammalian animal products and milk as the calculated DB (Australian livestock diet) was higher than the highest feeding level. For JMPR 2013, Australia confirmed that no fodder crops are imported. Thus, the new Codex MRL proposals were derived by JMPR in 2013 based on the DB calculated for US/CAN livestock. The residue data in animal feed are from JMPR 2012 and reflect total residues (penthiopyrad +PAM).

In 2014 CCPR, the EU delegation expressed a reservation on the advancement of the proposed draft MRLs for animal commodities because of the different residue definitions for enforcement established by JMPR and in the EU. The CXL proposals were found to be not compatible with the EU residue definition and can therefore not be taken over in EU legislation (JMPR residue definition for enforcement (animal products): penthiopyrad+PAM; EU residue definition for animal products: penthiopyrad.

For the 2015 JMPR meeting, no new information for mustard greens was provided.

Australia also provided a confirmation of the GAP information submitted already in 2013 to JMPR. JMPR did not see the need to update the dietary burden calculation performed in 2013. The proposed Codex MRLs are now confirmed by JMPR.

At EU level, the position did not change since 2014. Thus, the reservation on the advancement of the proposed draft MRLs for animal commodities should be maintained because of the different residue definitions for enforcement established by JMPR and in the EU.

5. EFSA Comments on JMPR report chapter 3.2 (Other matters of interest)

5.1. Bentazone (172)

In 2015, JMPR recommended to re-evaluate bentazone with view to the toxicological properties. In particular, it should be assessed whether there is a need to establish an ARfD. New toxicological studies were provided which were used to derive an ARfD of 0.5 mg/kg body weight (bw). More detailed background information and a comparison of the ARfD values derived by EFSA and JMPR, as well as an outline of the risk assessment are presented below.

5.1.1. Background information

Bentazone was assessed by JMPR in 2016 following comments from the EU and CAN on the previous conclusion of JMPR that an ARfD for bentazone was not necessary. Thus, JMPR re-evaluated the active substance (a.s.) specifically to determine whether there is a need to establish an ARfD. In the Table 1, some background information on bentazone is presented.

Table 1: Background information on bentazone

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Decision 2000/68/EC[(a)]	NL	EFSA conclusion	Yes	EFSA (2015g)
			MRL review	Yes	EFSA (2012h)
			MRL applications	Yes	In legume vegetables and fresh herbs (EFSA, 2011c) In sweet corn (EFSA, 2010c)

(a): 2000/68/EC: Commission Directive 2000/68/EC of 23 October 2000 including an active substance (bentazone) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ L 276, 28.10.2000, p. 41–43.

5.1.2. Toxicological reference values – bentazone

The following toxicological reference values derived at EU level and by JMPR are presented in Table 2.

Table 2: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.09 mg/kg bw per day	JMPR (2012) 2-year rat study, 100 UF	0.09 mg/kg bw per day	EFSA (2015g) Rat, 2-year study with an UF of 100
ARfD	0.5 mg/kg bw	JMPR (2016) Rat, acute neurotoxicity study, 100 UF	1 mg/kg bw	EFSA (2015g) Rat developmental toxicity study, 100 UF

Conclusion:
Both the JMPR and EU evaluations agree that the ADI of bentazone should be based on the NOAEL of 9 mg/kg bw per day for blood (prolonged blood coagulation), liver and kidney toxicity observed in the 2-year study in rats and applying the standard uncertainty factor (UF) of 100.
With regard to the ARfD, the JMPR based its assessment on a NOAEL of 50 mg/kg bw for decreased motor activity in an acute neurotoxicity study in rats, using an uncertainty factor of 100.
The EU evaluation concluded on an ARfD of 1 mg/kg bw, based on the NOAEL of 100 mg/kg bw per day for increased post-implantation loss, reduced number of live foetuses and retarded foetal development observed in a developmental toxicity study in rats, 100 UF applied. The developmental effects were observed in the absence of maternal toxicity and may trigger classification regarding developmental toxicity.
EFSA notes that the acute neurotoxicity study used by the JMPR to set the ARfD was not available to the peer review; the study is highly relevant and should be assessed at the EU level. The ARfD set by the JMPR may be supported.
The metabolite 8-hydroxy-bentazone was found to be less toxic than the parent bentazone from the acute, short-term and developmental toxicity point of view; as a worst case, the reference values of bentazone may apply to this metabolite.
Regarding 6-hydroxy-bentazone, EFSA is of the opinion that insufficient toxicological information is available to conclude on its toxicological profile.
The RMS is of the opinion that based on the structural similarities between 6-OH-bentazone and 8-OH-bentazone it would be reasonable to assume that 6-OH-bentazone would also be less than the parent. We therefore consider that the reference values of the parent are also applicable to 6-hydroxy-bentazone

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

5.1.3. Residue definitions – bentazone

In the following Table 3, the residue definitions for enforcement and risk assessment purpose are compared:

Table 3: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Bentazone The residue is not fat soluble	Bentazone (sum of bentazone, its salts and 6-hydroxy- (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone)
	Animal commodities		Sum of bentazone, its salts and 6-hydroxy (free and conjugated), expressed as bentazone Not fat soluble
RD-RA	Plant commodities		MRL review: same as RD for enforcement Peer review: Sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone
	Animal commodities		
Comments: In 2014 CCPR, the Delegations of the European Union did not support the advancement of the proposed draft MRLs for beans (dry); beans, except broad bean and soybean; beans, shelled (succulent immature seeds); cereal grains; eggs; herbs; linseed; milks; onion, bulb; peanut; peas (pods and succulent = immature seeds); potato; poultry meat (fat); poultry, edible offal of; soya bean (dry); spring onion; sweet corn (corn-on-the-cob) because of the different residue definitions established by JMPR and in the EU. Thus, CXLs established in 2014 are not compatible with the EU MRL legislation			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

5.1.4. Consumer risk assessment – bentazone

The result for the consumer risk assessment is presented in Table 4.

Table 4: Summary of the consumer risk assessment for bentazone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An tentative short-term dietary risk assessment was performed for the crops for which CXLs are in place and previously no acute risk assessment was performed (i.e. onions, bulb, spring onions, sweet corn, peas (pods and succulent seeds), beans except broad beans and soya beans, beans, shelled, potatoes, peanuts, herbs), using the HR values derived by JMPR The ARfD derived by JMPR was used The risk assessment is tentative since the risk assessment residue definition derived by JMPR is not comparable with the EU residue definition which is wider. Thus, the risk assessment may underestimate the exposure in terms of the EU residue definition (sum of bentazone and conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone) **Results:** The exposure to parent bentazone, accounted for less than 1% of the ARfD for all crops relevant for Codex	Not relevant	JMPR also performed a short-term dietary risk assessment for commodities assessed in 2013 (HR for all commodities, except cereal grains, linseeds, milk, soya beans where the STMR value was used for the short-term dietary risk assessment)

RA: risk assessment; CXL: Codex Maximum Residue Limit; HR: highest residue; ARfD: acute reference dose; STMR: supervised trials median residue.

5.2. Picoxystrobin (258)

In 2012, picoxystrobin was evaluated by JMPR, but due to data gaps regarding the toxicological relevance of two metabolites, no residue definitions could be derived. In particular, data on the potential genotoxicity for two metabolites (IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid metabolite) were missing. For metabolite IN-H8612, toxicological data (a mouse micronucleus study) was provided in 2013 which showed no evidence of genotoxicity.

For the 2016 JMPR meeting, a new plant metabolism study in soya beans was provided. Although the second metabolite 2-(2-formylphenyl)-2-oxoacetic acid was not identified in this study, JMPR

concluded that further information was required on the possible interconversion of IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid - an structural isomer of IN-H8612.

In the framework of the peer review, no final residue definitions could be derived due to open issues related to metabolites.

6. Comments on JMPR report chapter 5 (individual substances assessed)

In the following sections, the active substances assessed by JMPR in the most recent assessment are presented (FAO, 2016). The terms in brackets after the name of the active substance in the header of the sections refer to the code number used by JMPR; the second parenthesis provides information whether the substance was assessed for toxicological properties (T) and/or for residues (R). The substances are sorted according to the codex number.

6.1. Deltamethrin (135) (R)

6.1.1. Background information

Deltamethrin was assessed by JMPR for the new uses. In the Table 5, some background information on deltamethrin is presented.

Table 5: Background information on deltamethrin

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Decision 2003/5/EC[(a)]	UK	EFSA conclusion	No	–
			MRL review	Yes	EFSA (2015n)
			MRL applications	Yes	Potatoes: EFSA (2010f) MRLs in celeries, Florence fennels and rhubarbs: EFSA (2017) MRL in kale: Additional data requested

(a): 2003/5/EC: Commission Directive 2003/5/EC of 10 January 2003 amending Council Directive 91/414/EEC to include deltamethrin as active substance. OJ L 8, 14.1.2003, p. 7–9.

6.1.2. Toxicological reference values – deltamethrin

The following toxicological reference values derived at EU level and by JMPR are presented in Table 6.

Table 6: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (European Commission, 2002)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.01 mg/kg bw per day	JMPR 2002	0.01 mg/kg bw per day	1-year study on dogs, with safety factor 100
ARfD	0.05 mg/kg bw		0.01 mg/kg bw	Same as the ADI
Conclusion: –				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.1.3. Residue definitions – deltamethrin

In the following Table 7, the residue definitions for enforcement and risk assessment purpose are compared:

Table 7: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Sum of deltamethrin and its α-R-and *trans*-isomers The residue is fat soluble	Deltamethrin
	Animal commodities		
RD-RA	Plant commodities		Sum of deltamethrin ant its alpha-*R* isomer and *trans*-isomer (tentative) The residue is fat soluble
	Animal commodities		
Comments: The current EU residue definitions are comparable with the residue definitions derived by JMPR			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.1.4. Codex MRL proposals – deltamethrin

In the Table 8, the Codex MRL proposals are compared with the EU MRLs.

Table 8: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Rape seed	**0.2**	0.1	The proposed Codex MRL is based on 16 residue trials. The proposal is acceptable
General comment: –			

MRL: maximum residue limit.

6.1.5. Consumer risk assessment – deltamethrin

The result for the consumer risk assessment is presented in Table 9.

Table 9: Summary of the consumer risk assessment for deltamethrin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for rape seed The EU ARfD was used **Results:** No short-term exposure concern was identified (0.8% of the ARfD)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015n) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for rape seed **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 51% of the ADI The contribution of rape seed to the exposure was 0.4% of the ADI	–

RA: risk assessment; ARfD: acute reference dose; STMR: supervised trials median residue; ADI: acceptable daily intake.

6.2. Methoprene (147) (R)

6.2.1. Background information

Methoprene was assessed by JMPR for the new uses. In the Table 10, some background information on methoprene is presented.

Table 10: Background information on methoprene

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Not approved under Directive 91/414/EC	Regulation (EC) No 2076/2002[(a)]	–	EFSA conclusion	No	No MRL review foreseen under Reg. 396/2005
			MRL review	No	
			MRL applications	No	

(a): Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances (Text with EEA relevance), OJ L 319, 23.11.2002, p. 3–11.

6.2.2. Toxicological reference values – methoprene

The following toxicological reference values derived at EU level and by JMPR are presented in Table 11.

Table 11: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI (*R*,*S*-racemate methoprene)	0.09 mg/kg bw per day	For the *R*,*S* racemate	–	No toxicological reference values established in EU
ARfD (*R*,*S*-racemate methoprene)	Unnecessary		–	
ADI (*S*-methoprene)	0.05 mg/kg bw per day	For *S*-methoprene	–	
ARfD (*S*-methoprene)	Unnecessary		–	
Conclusion: No toxicological reference values established in EU.				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.2.3. Residue definitions – methoprene

In the following Table 12 the residue definitions for enforcement and risk assessment purpose are compared:

Table 12: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	JMethoprene The residue is considered fat soluble	Methoprene (Annex III of Reg. 396/2005) The residue definition is not labelled as fat soluble
	Animal commodities		
RD-RA	Plant commodities		–
	Animal commodities		
Comments: At EU level, no risk assessment residue definitions have been set since methoprene was never assessed for its residue behaviour. Considering the log $_{Pow}$, the modification of the residue definition, including the label (F) for fat-soluble substances should be considered in the EU. The residue definition of JMPR was based on metabolism studies in wheat (post-harvest treatment), alfalfa and rice (both foliar application). No specific metabolism studies are available for oilseeds (post-harvest treatment)			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.2.4. Codex MRL proposals – methoprene

In the Table 13 the Codex MRL proposals are compared with the EU MRLs.

Table 13: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Oilseed except peanut	**4** Po	0.05*	The proposed MRL is based on 4 residue trials reflecting the GAP (2.4–3.2 g ai/tonnes). Since some of the oilseeds are major crops, at least 8 residue trials would be required. In addition, the metabolic behaviour in oilseeds following post-harvest treatment with S-methoprene should be investigated No studies investigating the nature of residues in processed products (following typical processing practices) and the magnitude of residues in processed oilseeds are available. In particular, data for oil and for by products used as feed would be required JMPR mentioned in its report that the use in oilseed did not have a significant impact on the dietary burden of farm animals. It would be desirable that the calculations are presented in the report to verify the statement
General comment: –			

MRL: maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.

6.2.5. Consumer risk assessment – methoprene

The result for the consumer risk assessment is presented in Table 14.

Table 14: Summary of the consumer risk assessment for methoprene

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: No short-term dietary risk assessment was performed; at EU level no toxicological reference values have been derived. JMPR considered the setting of an ARfD not necessary	**RA assumptions:** EFSA calculated a tentative long-term risk assessment, including the current EU MRLs and the STMR values derived by JMPR for oilseeds The JMPR ADI derived for S-methoprene was used (0.05 mg/kg bw per day) The risk assessment is tentative, since the substance was never assessed in the EU and therefore no definitive EU residue definitions and toxicological reference values are available **Results:** The overall chronic exposure accounted for 126% of the ADI The contribution of the oilseeds (expressed as percentage of the ADI) were approximately 10% The main contributor to the overall exposure is the EU MRL for wheat (5 mg/kg) (up to 85%) and rye (44%). Further refinements could not be performed as no detailed information is available for these uses	–

RA: risk assessment; ARfD: acute reference dose; MRL: maximum residue limit; STMR: supervised trials median residue.

6.3. Buprofezin (173) (R)

6.3.1. Background information

Buprofezin was assessed by JMPR for the new uses. In the Table 15, some background information on buprofezin is presented.

Table 15: Background information on buprofezin

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Decision 2011/6/EU[(a)] Commission Regulation (EU) 2017/360[(b)] (restriction to non-edible corps)	UK	EFSA conclusion	Yes	EFSA (2008a), EFSA (2010d) Confirmatory data (residue Section, consumer risk assessment) EFSA (2015b) Peer review in view of conf data: EFSA (2015i)
			MRL review	No	–
			MRL applications	No	–

(a): 2011/6/EU: Commission Directive 2011/6/EU of 20 January 2011 amending Council Directive 91/414/EEC to include buprofezin as active substance. OJ L 18, 21.1.2011, p. 38–40.
(b): Commission Implementing Regulation (EU) 2017/360 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance buprofezin, OJ L 54, 1.3.2017, p. 11–13.

6.3.2. Toxicological reference values – buprofezin

The following toxicological reference values derived at EU level and by JMPR are presented in Table 16.

Table 16: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2010d)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.009 mg/kg bw per day	JMPR (2008)	0.01 mg/kg bw per day	2-year rat, with safety factor 100
ARfD	0.5 mg/kg bw		0.5 mg/kg bw	90 days dog, 100, 40% oral absorption
Conclusion: The toxicological reference values do not differ significantly				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.3.3. Residue definitions – buprofezin

In the following Table 17, the residue definitions for enforcement and risk assessment purpose are compared:

Table 17: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Buprofezin The residue is not fat soluble	Buprofezin
	Animal commodities		Peer review: Not proposed, since not considered necessary for the representative uses Reg. 396/2005: Buprofezin The residue is fat soluble
RD-RA	Plant commodities		Sum buprofezin and BF4 conjugates analysed as BF9 + BF12 under acidic conditions and expressed as buprofezin
	Animal commodities		Not assessed
Comments: The residue definitions for enforcement are comparable. For risk assessment additional metabolites are included in the EU RD. Thus, the exposure calculation based on JMPR HR/STMR values is likely to underestimate the exposure. In the peer review a default CF of 1.1 was proposed for citrus, tomato and lettuce			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.3.4. Codex MRL proposals – buprofezin

In the Table 18, the Codex MRL proposals are compared with the EU MRLs.

Table 18: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Avocado	**0.1**	0.05*	The MRL proposal is based on 4 residue trials in mangos which were extrapolated to avocado. The proposal is acceptable
Basil	1.5	4	The MRL proposal is based on 3 trials. At EU level at least 4 trials would be required. For MRL, proposals derived before 2016 JMPR, 3 trials may be acceptable
Soya bean, dry	0.01	0.05*	The proposed MRL is based on 8 trials. The proposal is sufficiently supported by data
General comment: In the EU, the approval conditions for buprofezin were recently restricted to non-edible crops due to the possible formation of aniline during processing			

MRL: maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.

6.3.5. Consumer risk assessment – buprofezin

The result for the consumer risk assessment is presented in Table 19.

Table 19: Summary of the consumer risk assessment for buprofezin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for avocados The risk assessment is tentative since the EU and JMPR residue definitions for risk assessment are different The EU residue definition comprises additional metabolites. EFSA used the default conversion factor derived in the peer review. However, since the validity of the conversion factor for avocados has not been demonstrated, the result of the risk assessment may underestimate the acute exposure according to the EU residue definition **Results:** No short-term exposure concern was identified (avocado: 0.3% of the ARfD)	**RA assumptions:** Only a limited long-term risk assessment could be performed since the MRL review has not yet been completed. Thus, the existing MRLs were used for all commodities, except for avocado where the STMR of 0.015 mg/kg was used since the proposed MRL is higher than the existing EU MRL. Conversion factors for the risk assessment RD derived for citrus, tomatoes and lettuce were applied to all crops, including avocados Under standard hydrolysis conditions, buprofezin degraded; the formation of potentially harmful products (aniline) was noted **Results:** The overall chronic exposure accounted for 650% of the ADI The main contributors were existing MRLs in apples, oranges, olives and tomatoes Avocados were a minor contributor to the total long-term exposure (0.03% of the ADI) Following the recent restriction of the use of buprofezin, the EU MRLs will be reconsidered, triggering a revision of the risk assessment	The HR and STMR values derived by JMPR for avocados are not clear. According to EFSA, the data would suggest an HR of 0.05 mg/kg instead of 0.01 mg/kg and an STMR of 0.015 mg/kg

RA: risk assessment; ARfD: acute reference dose; MRL: maximum residue limit; RD: residue definition; ADI: acceptable daily intake; STMR: supervised trials median residue; HR: highest residue.

6.4. Penconazole (182) (R)

6.4.1. Background information

Penconazole was assessed by JMPR for the new uses. In the Table 20 some background information on penconazole is presented.

Table 20: Background information on penconazole

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Decision 2009/77/EC[(a)]	DE	EFSA conclusion	Yes	EFSA (2008c)
			MRL review	No/Yes	In progress
			MRL applications	Yes	Blackberries and raspberries: EFSA (2014c) MRL application in grape is under assessment Notified for MRLs in gooseberries and cucurbit with inedible peel

(a): 2009/77/EC: Commission Directive 2009/77/EC of 1 July 2009 amending Council Directive 91/414/EEC to include chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as active substances. OJ L 172, 2.7.2009, p. 23–33.

6.4.2. Toxicological reference values – penconazole

The following toxicological reference values derived at EU level and by JMPR are presented in Table 21.

Table 21: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
Penconazole				
ADI	0.03 mg/kg bw per day	Based on the 1-year dog study, using a safety factor of 100	0.03 mg/kg bw per day	Based on the combined (90-day/1-year dog study, applying an uncertainty factor of 100
ARfD	0.8 mg/kg bw	Based on increased incidence of microphthalmia and hydrocephalus in the developmental rabbit study (NOAEL 75)	0.5 mg/kg bw	Based on maternal effects during the first days in the rabbit developmental study, applying an uncertainty factor 100)
1,2,4-triazole				
ADI	0–0.2 mg/kg bw per day	Based on the rat multigeneration study (NOAEL 16 for testicular effects), supported by new 12-month rat study with NOAEL 21	0.02 mg/kg bw per day	Based on the rat multigeneration study with 1,2,4-triazole, applying an increased uncertainty factor of 1,000 due to the limited data available
ARfD	0.3 mg/kg bw	Based on the rabbit developmental study (NOAEL 30 based on alterations of urogenital system in fetuses and clinical signs of neurotox in dams)	0.06 mg/kg bw	Based on the rat developmental study with 1,2,4-triazole, applying an increased uncertainty factor of 500 due to the limited data available and reproductive toxicity
Triazole acetic acid				
ADI	0–1 mg/kg bw per day	Group ADI with triazole alanine: based on new rabbit developmental study, new rat developmental study	0.02 mg/kg bw per day	Same value as for 1,2,4-triazole
ARfD	3 mg/kg bw	Group ARfD with triazole alanine: Based on new rat developmental study	0.06 mg/kg bw	Same value as for 1,2,4-triazole
Triazole alanine				
ADI	0–1 mg/kg bw per day	Group ADI with triazole acetic acid: based on rat developmental study, new rabbit developmental study	0.1 mg/kg bw per day	Based on the rat developmental study with triazole alanine, applying an increased uncertainty factor of 1,000 due to the limited data available
ARfD	3 mg/kg bw	Group ARfD with triazole alanine	0.1 mg/kg bw	Based on the rat developmental study with triazole alanine, applying an increased uncertainty factor of 1,000 due to the limited data available

Conclusion:
Penconazole: For the ARfD, the JMPR evaluation is based on developmental effects in a chinchilla rabbit study with doses of 0–25–75–150 mg/kg bw per day. The NOAEL was 75 mg/kg bw per day. The EU review has used a lower NOAEL for acute maternal effects in the second rabbit developmental study with doses of 0–10–50–200 mg/kg bw per day. The acute effects in does were confined to the top dose level with a NOAEL of 50 mg/kg bw per day. These acute effects in dams were not considered toxicologically adverse in the JMPR evaluation. Both approaches are scientifically comprehensible.
Triazole derivative metabolites: For these compounds (triazole acetic acid, triazole alanine, 1,2,4-triazole, and also triazole lactic acid), due to the limited data available and the known reproductive toxicity of 1,2,4-triazole (classified as Reproductive toxicant category 2, H361d Suspected of damaging the unborn child), the EU review applied increased uncertainty factors when deriving reference values. Since this review, new data have been provided, and further needs for discussions have been identified after a first commenting round.
The JMPR evaluation is considering a totally different approach with regard to grouping and use of increased safety factors, taking into account the additional data not yet included in the EU review.
Toxicity of metabolites included in EU RA RD: During the EU peer review, CGA 127841 was considered as a major rat metabolite covered by the studies performed with penconazole. CGA 132465 and CGA 190503 were considered likely to be of the same or lower toxicity than penconazole, based on their structural similarity with the parent compound and some rat metabolites.

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight; NOAEL: no observed adverse effect level.

6.4.3. Residue definitions – penconazole

In the following Table 22 the residue definitions for enforcement and risk assessment purpose are compared:

Table 22: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2008c)
RD-enf	Plant commodities	Penconazole	Penconazole
	Animal commodities		No residue definition was derived during the peer review RD in Reg. 396/2005: Penconazole
RD-RA	Plant commodities	Sum of penconazole and 4-(2,4-dichlorophenyl)-5-[1,2,4]triazol-1-yl-pentan-2-ol (free and conjugated) (CGA132465), expressed as penconazole	Penconazole + CGA 132465 + CGA 190503 + CGA 127841 and the conjugates of the metabolites, expressed as penconazole (provisional)
	Animal commodities	Sum of penconazole, 4-(2,4-dichlorophenyl)-5-[1,2,4]triazol-1-yl-pentan-2-ol (free and conjugated) (CGA 132465) and 4-(2,4-dichloro-phenyl)-5-[1,2,4]triazol-1-yl pentanoic acid (CGA177279), expressed as penconazole The residue is fat soluble	No residue definition was derived during the peer review

Comments:
Plant commodities: JMPR derived the residue definition for enforcement as penconazole, based on metabolism studies on grapes, tomatoes and apples. It is noted that CGA 132465 (free and conjugates) was found up to 62% of TRRs; since no analytical methods able to analyse these metabolites was available, the residue definition was limited to the parent penconazole. For the risk assessment, JMPR included also the CGA 132465 into residue definition. A conversion factor of 5 was proposed by JMPR.
JMPR received metabolism studies only for fruit crops (i.e. grapes, tomatoes and apples). Although a Codex MRL was proposed for a leafy crop (artichokes), a crop group for which no metabolism studies are available, the RMS is of the opinion that the lack of metabolism studies representative for leafy corps might be acceptable, considering that in the available fruit metabolism studies the metabolic behaviour in leafy was investigated and that artichokes are considered to be comparable with fruit crops. However, if Codex MRLs will be requested in future for other crops that are not covered by the metabolism studies in fruit crops, further metabolism studies would be required.
At EU level during the peer review (EFSA 2008c), the same metabolism studies were assessed, however the grape metabolism study was considered not acceptable due to various deficiencies; thus, the EU residue definition for enforcement, derived as penconazole only, was considered as provisional. The EU risk assessment residue definition was is more complex comprising two additional metabolites (CGA 190503, CGA 127841) compared with the one derived by JMPR. In the peer review, a conversion factor of 6 was derived to recalculate residues expressed for the residue definition for enforcement to the residue definition for risk assessment
It should be noted that the MRL review under art 12 MRL review is on-going and the residue definitions might be reconsidered.
Animal commodities: Although the level of the major metabolites CGA 132465 and CGA177279 in animal commodities was significant (i.e. up to 41% in muscle CGA 132465) JMPR derived residue definition for enforcement as parent penconazole only, since no analytical methods are available to determine these metabolites. For the risk assessment, the above mention metabolites were included in the residue definition.
At EU level, no residue definition was derived during the peer review (EFSA 2008c), since the available data were not relevant for animal commodities. In the framework of the MRL review, the residue definitions for enforcement and risk assessment on animal might be proposed.

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.4.4. Codex MRL proposals – penconazole

In the Table 23, the Codex MRL proposals are compared with the EU MRLs.

Table 23: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Apple	0.1	0.2	The CXL proposal for apples and pear is based on 18 residue trials (14 apples and 4 pears), conducted in EU and matching the Italian GAP (3 × 0.068 kg/ha). The CXL proposal is acceptable
Artichoke, globe	0.06	0.2	The CXL proposal is based on 7 residue trials conducted in EU matching the Italian GAP (4 x 0.05 kg/ha, 14-day PHI). The lack of specific metabolism studies representative for leafy crops is noted (see also comments on residue definition)
Blackcurrant	**2**	0.5	The CXL proposal is based on 5 residue trials matching the UK GAP (4 x 0.05 kg/ha, PHI 28 days). The MRL proposal is acceptable
Cattle meat	W (0.05*)	0.05*	The CXL was extended to all mammalians. The proposed withdrawal is acceptable
Cattle milk	W (0.01*)	0.01*	See the comment on meat
Cattle, Edible offal of	W (0.05*)	0.05*	See the comment on meat
Chicken eggs	W (0.05*)	0.05*	See the comment below
Chicken meat	W (0.05*)	0.05*	The CXL on chicken is withdrawn to be extended to all poultries. See also the comment on poultry
Cucumber	0.06	0.1	The CXL proposal is based on 8 residue trials matching the German GAP (4 × 0.05 kg/ha, PHI 3 days). The CXL proposal is extrapolated to gherkins and summer squash
Dried grape (=currants, raisins and sultanas)	1.5		A dehydration factor of 3.8 was derived based on 4 processing studies
Edible offal (Mammalian)	0.05*	0.05*	The CXL proposal is acceptable
Egg plant	0.09	0.1	The CXL proposal is based on 14 residue trials on tomatoes, including trials in cherry tomatoes which were extrapolated to egg plants
Eggs	0.05*	0.05*	The CXL proposal is acceptable
Gherkin	0.06	0.1	See the comment on cucumbers
Grapes	**0.4**	0.2	The CXL proposal is based on 14 trials conducted in the EU (NEU and SEU) match the Spanish GAP (3 x 0.04 kg/ha). The NEU and SEU data were pooled. At EU level, pooling of NEU and SEU data would be only acceptable, if statistical tests demonstrate that the trials belong to the similar population Currently, the assessment of an MRL application in grapes is in progress (NEU use with 3 × 30 g/ha, 28-day PHI). An MRL of 0.4 mg/kg was requested
Hops, dry	W (0.5)	0.5	
Mammalian fats (except milk fats)	0.05*	0.05*	The CXL proposal is acceptable
Meat (from mammals other than marine mammals)	0.05*	0.05*	The CXL proposal is acceptable
Melons, except watermelon	**0.15**	0.1	The CXL proposal is based on 7 EU indoor trials on melons. At least 8 trials would be required for melons, since it is a major crop
Milks	0.01*	0.01*	The CXL proposal is acceptable
Nectarine	W (0.1)	0.1	See comment on peaches
Peach	W (0.1)	0.1	The withdrawal of CXL is acceptable, no residue matching the GAP were available

Commodity	Codex MRL proposal	EU MRL	Comment
Peaches (including nectarines and apricots)	0.08	0.1	The CXL proposal is based on twelve trials conducted in EU. Since 11 trials were overdosed (cGAP: 3 × 0.075 kg/ha: trials conditions: 3 × 0.1 kg/ha, PHI 14 days) a scaling factor of 0.75 was used
Pear	0.1	0.2	See the comment on apples
Pepper, Sweet	0.2	0.2	The CXL proposal is based on 8 EU indoor residue trials matching the GAP from Germany. The CXL proposal is acceptable
Pome fruits	W (0.2)	0.2	The withdrawn of CXL is acceptable
Poultry meat	0.05*	0.05*	The CXL proposal is acceptable
Poultry, Edible offal of	0.05*	0.05*	The CXL proposal is acceptable
Squash, summer	0.06	0.1	See the comment on cucumbers
Strawberry	**0.5**	0.1*	The CXL proposal is based on combined data set (17 outdoor and 8 indoor) trials conducted in EU according to Belgian GAP. JMPR proposed to derive a CXL based on combined protected & outdoor trials since no statistical variation was observed (U test < 5%). In the EU, a different policy on pooling of data is in place: outdoor data can be pooled if the number of trials per zone is sufficient and the trials belong to a similar population. Indoor/protected and outdoor data would not be pooled From the 8 indoor trials, a MRL proposal of 0.3 mg/kg would be sufficient. For the outdoor trials, JMPR did not report details where the trials were performed (NEU or SEU). Thus, no MRL calculation can be performed
Tomato	0.09	0.1	The CXL proposal is based on 14 residue trials on tomatoes, incl. trials in cherry tomatoes. The CXL proposal is acceptable
Apple juice	–	–	A PF of 0.25 was derived from metabolism studies. The validity of the PF is questionable. A robust PF should be derived, based on the processing studies representing realistic processing conditions
Apple sauce	–	–	A PF of 0.17 was derived based on four studies. The PF is acceptable
Blackcurrant juice	–	–	See the comment on apple juice
Grape juice	–	–	See the comment on apple juice
Strawberry Jam, sterilised	–	–	A PF of 0.84 was derived based on four studies. The PF is acceptable
Strawberry, canned pasteurised	–	–	A PF of 0.55 was derived based on four studies. The PF is acceptable
Wine	–	–	A PF of 0.25 was proposed based on metabolism studies; PF was extrapolated to grape juice, apple juice and black currant juice. The validity of the PF is questionable. A robust PF should be derived, based on the processing studies representing realistic processing conditions
General comment: It should be highlighted that the EU MRL review under Article 12 is currently on-going			

MRL: maximum residue limit; CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; cGAP: critical GAP; PF: processing factor;
*: Indicates that the MRL is set at the limit of quantification.

6.4.5. Consumer risk assessment – penconazole

The result for the consumer risk assessment is presented in Table 24.

Table 24: Summary of the consumer risk assessment for penconazole

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR as derived by JMPR. The risk assessment is tentative since the EU residue definition is wider. Thus, the calculated exposure is likely to underestimate the exposure according to the EU RD The EU ARfD was used No risk assessment was performed for the TDMs **Results:** For none of the commodities under discussion the exposure exceeded the ARfD (max. for table grapes with 21% of ARfD; for the other commodities the exposure was below than 10% ARfD)	**RA assumptions:** The most recent risk assessment (EFSA, 2014c) was updated for the crops under consideration, including the STMR values derived by JMPR for blackcurrants, grapes, melons and strawberries The risk assessment is tentative, since the EU MRL review is not yet completed and a final decision on the residue definitions has not yet been taken No risk assessment was performed for the TDMs **Results:** Considering the existing MRLs, no long-term consumer health risk was identified The overall chronic exposure accounted for 62% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to wine grapes (2% of the ADI)	–

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; RD: residue definition; ARfD: acute reference dose; STMR: supervised trials median residue.

6.5. Fenpropimorph (188) (T)

6.5.1. Background information

JMPR assessed the previously submitted toxicological data in addition to new published and unpublished toxicological studies. In the Table 25 below some background information on fenpropimorph is presented.

Table 25: Background information on fenpropimorph

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Decision 2008/107[(a)]	DE	EFSA conclusion	Yes	EFSA (2008b)
			MRL review	Yes	EFSA (2015c)
			MRL applications	Yes	EFSA (2013g)

(a): 2008/107: Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances. OJ L 316, 26.11.2008, p. 4–11.

6.5.2. Toxicological reference values – fenpropimorph

The following toxicological reference values derived at EU level and by JMPR are presented in Table 26.

Table 26: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2008b)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.004 mg/kg bw per day	Rat, 2-year	0.003 mg/kg bw per day	Rat, 2-year, with uncertainty factor of 100
ARfD	Women of child-bearing age: 0.1 mg/kg bw General population: 0.4 mg/kg bw	Rabbit, developmental studies	0.03 mg/kg bw	Rabbit, developmental, with uncertainty factor of 500
Conclusion: The JMPR evaluation considers the derivation of two ARfD, one applicable to women of child-bearing age (0.1 mg/kg bw with a margin of 300 to the LOAEL for teratogenicity) and one applicable to the general population (0.4 mg/kg bw based on maternal effects in the rabbit studies). In EU, only one ARfD is derived. In the case of fenpropimorph, the ARfD has the same basis than in the JMPR evaluation (i.e. the teratogenic effect in the rabbit studies), but an additional uncertainty factor of 5 has been applied, resulting in a margin of safety of 1,000 with respect to the LOAEL for the teratogenic effect. No information on the toxicological profile of the metabolite included in the current JMPR residue definition for animal commodities (i.e. 2-methyl-2-{4-[2-methyl-3-(*cis*-2,6-dimethylmorpholin-4-yl)propyl]phenyl}propionic acid, BF 421-2) is provided in the 2016 JMPR report			

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.5.3. Residue definitions – fenpropimorph

In the following Table 27, the residue definitions for enforcement and risk assessment purpose are compared:

Table 27: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2015c)
RD-enf	Plant commodities	Fenpropimorph	Fenpropimorph (sum of isomers)
	Animal commodities	2-methyl-2-{4-[2-methyl-3-(*cis*-2,6-dimethylmorpholin-4-yl)propyl]phenyl} propionic acid (=BF 421-2), expressed as fenpropimorphThe residue is not fat soluble	Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2), expressed as fenpropimorph (sum of isomers)
RD-RA	Plant commodities	Fenpropimorph	Sum of fenpropimorph, fenpropimorph alcohol (BF 421-1, free and conjugated) and 2,6-dimethylmorpholine (BF 421-10), expressed as fenpropimorph (sum of isomers)
	Animal commodities	2-methyl-2-{4-[2-methyl-3-(cis-2,6-dimethylmorpholin-4-yl)propyl]phenyl} propionic acid, expressed as fenpropimorph The residue is not fat soluble	Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2), expressed as fenpropimorph (sum of isomers)
Comments: –			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.6. Teflubenzuron (190) (T/R)

6.6.1. Background information

Teflubenzuron was evaluated by JMPR under the periodic review programme of CCPR. In the Table 28, some background information on teflubenzuron is presented.

Table 28: Background information on teflubenzuron

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Directive 2009/37/EC[(a)]	FR	EFSA conclusion	Yes	EFSA (2009a)
			MRL review	Yes	EFSA (2014e)
			MRL applications	Yes	Solanaceae and cucurbits (edible peel) and to delete the MRLs for pomefruit: EFSA (2012d) peppers: EFSA (2008d) MRL in various crops: assessment ongoing, data requested

(a): 2009/37/EC: Commission Directive 2009/37/EC of 23 April 2009 amending Council Directive 91/414/EEC to include chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin as active substances. OJ L 104, 24.4.2009, p. 23–32.

6.6.2. Toxicological reference values – teflubenzuron

The following toxicological reference values derived at EU level and by JMPR are presented in Table 29.

Table 29: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2009a)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.005 mg/kg bw per day	Mouse (carcinogenicity)	0.01 mg/kg bw per day	Mouse (carcinogenicity), with safety factor 200
ARfD	Unnecessary		Not applicable	–

Conclusion:
At EU and JMPR level, the point of departure for setting the ADI was based on the same study. Both JMPR and EFSA concluded that the lowest dose tested in the 18-month carcinogenicity study should be considered as a LOAEL. During the EU evaluation, EFSA proposed an additional UF of 2 because of lack of NOAEL, whereas JMPR in the absence of a NOAEL re-analysed the data using a BMD approach for defining the PoD. Both approaches taken by EFSA and JMPR are considered acceptable.
At EU and JMPR level, the setting of ARfD was deemed not necessary

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.6.3. Residue definitions – teflubenzuron

In the following Table 30, the residue definitions for enforcement and risk assessment purpose are compared:

Table 30: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2014e)
RD-enf	Plant commodities	Teflubenzuron	Teflubenzuron
	Animal commodities	The residue is fat soluble	The residue is fat soluble
RD-RA	Plant commodities		
	Animal commodities		

Comments:
The residue definitions derived by JMPR and at EU level are identical. However, in the EU, a lack of valid metabolism studies for leafy crops was noted

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.6.4. Codex MRL proposals – teflubenzuron

In the Table 31, the Codex MRL proposals are compared with the EU MRLs.

Table 31: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Apple	0.5	1 (ft)	12 residue trials with 4 × 0.045 kg ai/ha at 10 days interval and sampling 1 DALA were provided. The trials did not exactly match the critical GAP (3 × 0.045–0.06 kg ai/ha, 1-day PHI, spray interval not specified). Since the seasonal application rate in the trials was equivalent to the seasonal application rate of the GAP and no decline was observed, JMPR considered the trials as acceptable. According to EFSA, the residue trials are not appropriate to derive a MRL proposal considering that the active substance is not systemic and that the crop development during the period when the application occurs has an influence on the terminal residues The existing EU MRL was derived from the current CXL. In the framework of the MRL review, no uses for apples were notified
Brussels sprouts	W	0.5 (ft)	–
Cabbages, Head	W	0.2 (ft)	–
Cauliflower	0.01*	0.01*	The MRL proposal is based on 7 residue trials that matched the Central American GAP (application rate and PHI). The trials were performed with 3 applications, while in the GAP the number of treatments is not defined. It is noted that considering the plant metabolism cauliflower belongs to the group of leafy crops for which in the EU MRL review additional metabolism studies were requested
Coffee beans	**0.3**	0.05*	The MRL proposal is based on 8 residue trials, 7 of them scaled down to match the BR GAP
Cucumber	0.5	0.5	The MRL proposal is based on the same residue trials assessed in the framework of the EU MRL review (8 trials considered compliant with the Dutch indoor GAP)
Edible offal (Mammalian)	0.01*	0.05 (ft)	The proposed MRL is consistent with the dietary burden calculation and the feeding study. It is noted that in the EU MRL review, additional validation data for the analytical method were requested
Eggs	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)
Gherkin	1.5	1.5	The MRL proposal is based on the same residue trials assessed in the framework of the EU MRL review (4 trials considered compliant with the Dutch indoor GAP)
Grapes	**0.7**	0.01*	12 residue trials that were scaled down to match the BR GAP were used to derive the MRL proposal. The proposed MRL is sufficiently supported by data
Maize	0.01*	0.01*	The MRL proposal is based on 9 residue trials (1–4 × 0.0225 kg/ha, harvest 30 or 45 DALA). All results were below the LOQ. Although the trials did not fully match the critical GAP (2× up to 0.0225 kg/ha PHI 45 days), the proposed MRL is acceptable
Maize oil, edible	0.015		
Mammalian fats (except milk fats)	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)
Meat from mammals (other than marine mammals)	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)

Commodity	Codex MRL proposal	EU MRL	Comment
Melons, except watermelon	**0.3**	0.01*	The MRL proposal is based on 8 residue trials matching the critical BR GAP (± 25%) JMPR derived a STMR for risk assessment from 4 results on melon pulp. For the trial with the highest residues (0.19 mg/kg), information on the concentration in the pulp was available (0.02 mg/kg)
Milk fats	0.01*		
Milk of cattle, goats and sheep	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)
Orange oil	126		Rounding of the MRL should be recommended
Papaya	**0.4**	0.01*	The MRL proposal is based on 4 residue trials matching the BR GAP. According to the consumption category defined in the guidance document to facilitate the establishment of MRLs for minor crop, at least 5 trials would be required for papaya
Plums (including fresh prunes)	W (0.1)	0.1*	–
Pome fruits	W (1)	1	–
Potato	W(0.05)	0.05	–
Poultry fats	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)
Poultry meat	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)
Poultry, Edible offal of	0.01*	0.05 (ft)	See comment on Edible offal (Mammalian)
Soya bean (dry)	**0.05**	0.02*	The MRL proposal is based on 10 residue trials matching the Central American GAP in terms of application rate and spray interval and PHI. However, it was noted that the GAP does not specify the number of treatments. (The trials were performed with 3 applications)
Soya bean hulls	0.2		
Lemons and limes (includes all commodities in this subgroup)	**0.5**	0.01*	The MRL proposal is based on 5 residue trials which were scaled down to match the critical BR GAP. For comment on STMR, see oranges
Oranges, Sweet and Sour (includes all commodities in this subgroup)	**0.5**	0.01*	The MRL proposal is based on 11 residue trials which were scaled down to match the critical BR GAP JMPR derived a STMR for risk assessment from 3 results on orange pulp and 3 results in lemon pulp where no quantifiable residues were detected
Sugar cane	0.01*	0.01*	4 residue trials reflecting the BR GAP were provided. All results were < 0.01 mg/kg. The MRL proposal is sufficiently supported by data
Sunflower seed	**0.3**	0.02*	8 residue trials reflecting the BR GAP were provided. The MRL proposal is sufficiently supported by data
Tomato	1.5	1.5 (ft)	Most of the trials used by JMPR were also provided to EFSA in the framework of the MRL review. The data set comprises also some trials in cherry tomatoes. In the MRL review, the lack of standard hydrolysis studies was highlighted, leading to the need to provide confirmatory data. JMPR received a study that demonstrated that the a.s. is stable under conditions representing sterilisation; however, the study was not completely in line with the standard conditions (no information on the behaviour under boiling for 60 min at pH 5 and pasteurisation for 20 min at 90°C at pH 4)
Orange juice	–	–	–
Apple juice	–	–	–
Apple purée	0.04	–	–

Commodity	Codex MRL proposal	EU MRL	Comment
Grapes young wine	0.0029	–	–
Peeled tomatoes	0.024	–	–
Tomato juice	0.051	–	–
Tomato purée	0.14	–	–
Canned tomatoes	0.021	–	–
Soya bean oil, refined	0.005	–	–
Sunflower seed oil, edible	0.001	–	–
Maize flour	0.01	–	–
Maize grits	0.005	–	–
Maize meal	0.005	–	–
Maize starch	0.005	–	–
Sugar cane, sugar	0	–	–
Roasted coffee beans	0.001	–	–
Coffee liquor extract	0.001	–	–
Instant coffee	0.001	–	–
General comment: (ft): confirmatory data were required following the MRL review under Art. 12 of Regulation (EC) No 396/2005 (i.e. standard hydrolysis studies investigating the nature of residues under typical processing conditions (mainly relevant for tomatoes and apples which were the main contributors to dietary exposure), metabolism studies in leafy crops with radiolabelling on both the aniline and the benzoyl rings and an ILV and confirmatory analytical methods for animal products)			

MRL: maximum residue limit; DALA: days after last application; GAP: Good Agricultural Practice; PHI: preharvest interval; CXL: Codex Maximum Residue Limit; LOQ: limit of quantification; STMR: supervised trials median residue; a.s.: active substance; *: Indicates that the MRL is set at the limit of quantification.

6.6.5. Consumer risk assessment – teflubenzuron

The result for the consumer risk assessment is presented in Table 32.

Table 32: Summary of the consumer risk assessment for teflubenzuron

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2014e) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL. For oranges, lemons and melons EFSA used the STMR reflecting the whole fruit The EU ADI was used **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 80.5% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to oranges (4.2% of the ADI) and wine grapes (3.8% of the ADI)	–

RA: risk assessment; STMR: supervised trials median residue; MRL: maximum residue limit; ARfD: acute reference dose; ADI: acceptable daily intake.

6.7. Fipronil (202) (R)

6.7.1. Background information

Fipronil was assessed by JMPR for the new uses. In the Table 33 some background information on fipronil is presented.

Table 33: Background information on Fipronil

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Directive 2007/52/EC[(a)]	FR	EFSA conclusion	Yes	EFSA (2006b) Concl revision: under consideration Conf data: in progress Art 21 risk to bees: in progress
			MRL review	Yes	EFSA (2012e)
			MRL applications	Yes	Modification following the withdrawal of the authorised uses on kale and head cabbage: EFSA (2014a) Poultry fat: EFSA (2012g) MRL application under assessment for potatoes, maize, rice, sugar cane

(a): 2007/52/EC: Commission Directive 2007/52/EC of 16 August 2007 amending Council Directive 91/414/EEC to include ethoprophos, pirimiphos-methyl and fipronil as active substances. OJ L 214, 17.8.2007, p. 3–8.

6.7.2. Toxicological reference values – fipronil

The following toxicological reference values derived at EU level and by JMPR are presented in Table 34.

Table 34: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.0002 mg/kg bw per day	JMPR evaluation in 2000	0.0002 mg/kg bw per day	Long term study in rats, with safety factor 100, EFSA (2006b)
ARfD	0.003 mg/kg bw		0.009 mg/kg bw	90-day oral study in rat and 90-day/1-year dog, 1 year with safety factor 100. EFSA(2006b)

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.7.3. Residue definitions – fipronil

In the Table 35, the residue definitions for enforcement and risk assessment purpose are compared:

Table 35: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2014a)
RD-enf	Plant commodities	Fipronil	Sum of fipronil and its sulfone metabolite (MB 46136) expressed as fipronil The residue is fat soluble
	Animal commodities	Sum of fipronil and 5-amino-3-cyano-1-(2,6-dichloro-4-trifluoromethylphenyl)-4- trifluoromethylsulfonylpyrazole (MB 46136), expressed as fipronil The residue is fat soluble	
RD-RA	Plant commodities	Fipronil	
	Animal commodities	Sum of fipronil and 5-amino-3-cyano-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-trifluoromethylsulfonylpyrazole (MB 46136), expressed as fipronil	

Comments: The JMPR residue definitions are not consistently reported in different documents.
In the JMPR report 2001 (p. 76f), the following residue definitions were proposed: MRL compliance plant commodities: fipronil.
MRL compliance animal commodities: sum of fipronil and fipronil-sulfone (MB46136), expressed as fipronil
Risk Assessment plant + animal commodities: sum of fipronil, fipronil-desulfinyl (MB46513), fipronil-sulfone (MB46136) and fipronil-thioether, expressed as fipronil.
JMPR report 2016, page 43 (425) + Codex Alimentarius Web Database:
MRL compliance + Risk Assessment plant commodities: fipronil
MRL compliance + Risk Assessment animal commodities: sum of fipronil and fipronil-sulfone (MB46136), expressed as fipronil.
In the 2016 JMPR report (p. 91), the residue definitions for estimation of dietary intake is reported as fipronil, fipronil-desulfinyl, fipronil-sulfone and fipronil-thioether expressed as fipronil (for plant and animal products) with MRLs. It should be clarified if JMPR decided to change the residue definition without updating the MRL database available on the website.
The residue definitions for plant commodities set at EU level and by JMPR are not comparable (in the EU the sulfone metabolite was included while this metabolite was considered by JMPR only for the residue definitions for animal products).
The MRLs derived at Codex level are therefore not compatible with the EU legislation.

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.7.4. Codex MRL proposals – fipronil

In the Table 36, the Codex MRL proposals are compared with the EU MRLs.

Table 36: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Basil	**1.5**	0.005*	JMPR described 5 trials that were submitted in support of the Thai GAP. Apparently, the samples were analysed with a method that determines not only parent fipronil, but also fipronil-desulfinyl, fipronil-sulfone and fipronil-thioether (the thioether was analysed only in three trials) It is noted that the residue definition for plants (enforcement and risk assessment covers only parent compound. Thus, the results of the trials do not reflect the residue definitions. It is concluded that the derived MRL proposal is not appropriate
General comment: Since the EU and the JMPR residue definitions for enforcement are different, the proposed MRL for basil is not compatible with the EU MRL legislation			

MRL: maximum residue limit; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of quantification.

6.7.5. Consumer risk assessment – fipronil

The result for the consumer risk assessment is presented in Table 37.

Table 37: Summary of the consumer risk assessment for fipronil

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed as outlined in Section 'Assessment' for basil, using the HR derived by JMPR. Since HR derived by JMPR covers fipronil, fipronil-desulfinyl, fipronil-sulfone and partially fipronil-thioether, the HR is likely to be higher than the HR that would be derived in an EU assessment, based on the same trials **Results:** No short-term exposure concern was identified (4.4% of the ARfD)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2014a) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for basil The risk assessment is tentative, since the STMR value does not cover the JMPR residue definitions are different. This difference implies that the risk assessment may underestimate the actual exposure/ may slightly overestimate the actual exposure **Results:** The overall chronic exposure accounted for 86% of the ADI. Basil contributed to a maximum of 3.8% of the ADI	–

RA: risk assessment; HR: highest residue; ARfD: acute reference dose; STMR: supervised trials median residue; ADI: acceptable daily intake.

6.8. Dimethomorph (225) (R)

6.8.1. Background information

Following short-term dietary intake concerns identified in 2014 for lettuce, JMPR assessed an alternative GAP for lettuce. In the Table 38, some background information on dimethomorph is presented.

Table 38: Background information on dimethomorph

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Directive 2007/25/EC[(a)]	NL	EFSA conclusion	Yes	EFSA (2006c)
			MRL review	Yes	EFSA (2011e)
			MRL applications	Yes	Papaya: EFSA (2016c) Lettuce: EFSA (2012i)

(a): 2007/25/EC: Commission Directive 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances. OJ L 106, 24.4.2007, p. 34–42.

6.8.2. Toxicological reference values – dimethomorph

The following toxicological reference values derived at EU level and by JMPR are presented in Table 39.

Table 39: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation 2007		EU evaluation (EFSA, 2006c)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.2 mg/kg bw per day	Dog, 13 week and 1 year, (NOAEL 15.2 mg/kg bw per day) SF 100	0.05 mg/kg bw per day	Dog, 1-year study with safety factor 100)
ARfD	0.6 mg/kg bw	Rat, developmental study, SF 100	0.6 mg/kg bw	Rat, developmental study with safety factor 100)

Conclusion:
The RMS provided the following additional information: 'We are currently evaluating dimethomorph for the renewal of the active substance. At the moment we are not proposing any changes to the reference values based on this dossier.
For the renewal a new extended one-generation study was submitted which was not yet available for the JMPR evaluation in 2007. In this study we see some effects on developmental endpoints such as preputial separation and anogenital distance that appear to be linked to an anti-androgenic effect that was reported in literature which indicates that dimethomorph is an endocrine disruptor. However, the renewal process is still ongoing'

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight; NOAEL: no observed adverse effect level.

6.8.3. Residue definitions – dimethomorph

In the Table 40, the residue definitions for enforcement and risk assessment purpose are compared:

Table 40: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Dimethomorph (sum of isomers) The residue is not fat soluble	Dimethomorph (sum of isomers) The residue is not fat soluble
	Animal commodities		
RD-RA	Plant commodities		
	Animal commodities		

Comments:
The residue definitions are identical.
The RMS provided the following additional information: 'We are currently evaluating dimethomorph for the renewal of the active substance. Although at this moment we only have an initial version of the RAR (almost) available, and the peer review process is therefore in an early stage, we would like to share that the residue definition for risk assessment for plants is provisionally proposed as: sum of dimethomorph and M550F002 and M550F007, expressed as parent. The relevance of inclusion of metabolite morpholine into the residue definition for risk assessment can only be concluded after submission of supervised residue trials in which this metabolite has been measured.
The residue definition for monitoring for plants is proposed to remain the same: dimethomorph (sum of isomers)'

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.8.4. Codex MRL proposals – dimethomorph

In the Table 41, the Codex MRL proposals are compared with the EU MRLs.

Table 41: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Lettuce, Leaf	9	15	The EU MRL is an import tolerance that was derived from a combined data set of leafy and head forming lettuce varieties The data submitted to JMPR reflect a less critical GAP (Italian GAP). The proposed Codex MRL is sufficiently supported by data (9 outdoor trials). The proposal is acceptable. However, since the EU MRL is higher, it will not impact the EU MRL legislation

General comment:
JMPR did not derive an MRL proposal for head lettuce (Italian GAP, indoor and outdoor use with 3 × 0.144 kg/ha with 3-day PHI), since the number of greenhouse trials was not sufficient. The outdoor use however is supported by 8 trials and an MRL could be derived. Using the OECD calculator a MRL of 3 mg/kg is derived for head lettuce

MRL: maximum residue limit; GAP: Good Agricultural Practice.

6.8.5. Consumer risk assessment – dimethomorph

The result for the consumer risk assessment is presented in Table 42.

Table 42: Summary of the consumer risk assessment for dimethomorph

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
The proposed Codex MRL does not have an impact on the EU risk assessment (the existing EU MRL for the crop concerned is higher than the proposed Codex MRL)	**RA assumptions:** The new Codex MRLs proposal is lower than the existing EU MRL. Thus, the most recent long-term risk assessment (EFSA, 2016c) is still valid **Results:** The overall exposure accounted for 16% of ADI	–

MRL: maximum residue limit; ADI: acceptable daily intake.

6.9. Chlorantraniliprole (230) (R)

6.9.1. Background information

Chlorantraniliprole was assessed by JMPR for the new uses. In the Table 43, some background information on chlorantraniliprole is presented.

Table 43: Background information on chlorantraniliprole

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Implementing Regulation (EU) No 1199/2013[(a)]	IE	EFSA conclusion	Yes	EFSA (2013d)
			MRL review	Yes	In progress
			MRL applications	Yes	Hops: EFSA (2016g) Import tolerance: EFSA (2015k) Tuber and oilseeds: EFSA, (2013e) Carrots, parsnips, parsley root and celeriac: EFSA (2012n) Various crop: EFSA (2012a) Various crop and animal origin: EFSA (2011b) Carrots: EFSA (2010e)

(a): 1199/2013: Commission Implementing Regulation (EU) No 1199/2013 of 25 November 2013 approving the active substance chlorantraniliprole, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 315, 26.11.2013, p. 69–73.

6.9.2. Toxicological reference values – chlorantraniliprole

The following toxicological reference values derived at EU level and by JMPR are presented Table 44.

Table 44: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2013d)	
	Value	**Comments**	**Value**	**Comments**
ADI	2 mg/kg bw per day	JMPR 2008	1.56 mg/kg bw per day	Rat, 2-year study, supported by the mouse, 18-month study with safety factor 100
ARfD	Unnecessary		Not applicable	Not required
Conclusion: The different ADI values set at EU level and by JMPR are resulting from different policies for rounding				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.9.3. Residue definitions – chlorantraniliprole

In the following Table 45, the residue definitions for enforcement and risk assessment purpose are compared.

Table 45: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Chlorantraniliprole The residue is fat soluble	Chlorantraniliprole The residue is fat soluble
	Animal commodities		
RD-RA	Plant commodities		Chlorantraniliprole
	Animal commodities		Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole

Comments:
The EU risk assessment residue definition for animal commodities comprises additional metabolites.
IN-HXH44 and IN-KPT00 were found to be a major metabolites in milk, each occurring at the same level as the parent compound. IN-HXH44 was also found in ruminant muscle, but in lower amounts (ca. 25% of the parent compound). For poultry these two metabolites were of less relevance

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.9.4. Codex MRL proposals – chlorantraniliprole

In the Table 46, the Codex MRL proposals are compared with the EU MRLs

Table 46: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Eggs	**0.2**	0.1	The proposed MRL is based on an updated dietary burden calculation and a feeding study in poultry. The proposal is plausible
Peanut	**0.06**	0.01*	The proposed MRL is sufficiently supported by data (5 trials reflecting the US GAP)
Poultry fat	**0.08**	0.01*	The proposed MRL is based on an updated dietary burden calculation and a feeding study in poultry. The proposal is plausible
Poultry meat	**0.02**	0.01*	The proposed MRL is based on an updated dietary burden calculation and a feeding study in poultry. The proposal is plausible. It is noted that in the EU MRLs are set for muscle while the proposed Codex MRL refers to meat which is a mixture of muscle and fat
Poultry, Edible offal of	**0.07**	0.01*	The proposed MRL is based on an updated dietary burden calculation and a feeding study in poultry. The proposal is plausible
Straw, fodder (dry) and hay of cereal grains and other grass-like plants (except corn and rice)	30 (dw)	–	–

General comment: –

MRL: maximum residue limit; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of quantification.

6.9.5. Consumer risk assessment – chlorantraniliprole

The result for the consumer risk assessment is presented in Table 47.

Table 47: Summary of the consumer risk assessment for chlorantraniliprole

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant since no ARfD was considered necessary	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2016g) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for commodities where the proposed MRLs are higher than the existing EU MRL The risk assessment is tentative, since the EU and JMPR residue definitions are different. This difference implies that the risk assessment may underestimate the actual exposure according to the EU residue definition **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 2.2% of the ADI Among the commodities under consideration, the highest contribution to the exposure was related to eggs (< 0.01% of the ADI)	–

ARfD: acute reference dose; STMR: supervised trials median residue; ADI: acceptable daily intake.

6.10. Saflufenacil (251) (R)

6.10.1. Background information

Saflufenacil was assessed by JMPR for new uses. In the Table 48, some background information on Saflufenacil is presented.

Table 48: Background information on saflufenacil

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Not approved under Directive 91/414/EC	–	–	EFSA conclusion	No	–
			MRL review	No	–
			MRL applications	Yes	Import tolerances on a wide range of food commodities: EFSA (2012b) Various crops, considering the risk related to the metabolite trifluoroacetic acid (TFA): EFSA (2014b) Import tolerance assessment ongoing (data requested)

6.10.2. Toxicological reference values – saflufenacil

The following toxicological reference values derived at EU and JMPR level are presented in Table 49.

Table 49: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.05 mg/kg bw per day	JMPR (2011)	0.046 mg/kg bw per day	EFSA (2012b) (Mouse, 18-month carcinogenicity with an uncertainty factor of 100)
ARfD)	Unnecessary		0.05 mg/kg bw	EFSA (2012b) (Rat, developmental toxicity with an uncertainty factor of 100)
TFA (Trifluoroacetic acid)				
ADI	–	–	0.05 mg/kg bw per day	(90-day oral rat study with an uncertainty factor of 200) EFSA (2014b)

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ARfD	–	–	0.05 mg/kg bw	(90-day oral rat study with a safety factor 200) EFSA (2014b)

Conclusion:
Although saflufenacil was not assessed for approval in the EU, the toxicological properties of the compound were assessed in the framework of import tolerance requests (EFSA, 2012b)
The metabolite trifluoroacetic acid (TFA) was assessed in the framework of a request under Art 43 of Regulation 396/2005 (EFSA, 2014b).
For the ARfD, the findings in the rat developmental study were considered relevant in the EU evaluation. Based on the available JMPR evaluation, it is not clear if the same database was available and how the findings were interpreted

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.10.3. Residue definitions – saflufenacil

In the following Table 50, the residue definitions for enforcement and risk assessment purpose are compared:

Table 50: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Saflufenacil The residue is not fat soluble	EFSA (2014b): Sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil; Regulation 396/2005: Saflufenacil (sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil)
	Animal commodities		
RD-RA	Plant commodities		EFSA (2014b): Sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil; Regulation 396/2005: Saflufenacil (sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil) The residue is not fat soluble (EFSA, 2012b)
	Animal commodities		

Comments:
The metabolism studies were investigated by JMPR in 2011 for both uses as herbicide (preplanting, pre-emergence use) in maize, soya beans and tomatoes and as preharvest desiccant use in soyabeans
The major metabolites found in soyabeans and tomatoes were M800H11 (up to 13% of TRRs) and M800H35 (up to 13%) representative for the herbicide uses. For the desiccant uses (preharvest application), saflufenacil was the predominant residue (up to 26% of TRR); the most abundant metabolite was M800H02 which accounted up 26% of the TRRs.
Based on that data, JMPR derived the residue definition for plant as saflufenacil.
In addition to the metabolism studies assessed in 2011, JMPR received a new study on rice conducted at the application rate of 100 g ai/ha, (BBCH 22-24).
EFSA is of the opinion that the new metabolism study on rice is not representative for the desiccant use in cereals because of early the application time (BBCH 22-24). Thus, the available information is not sufficient to derive a conclusion on the metabolic pattern in cereals following preharvest treatment.
Overall, it is highlighted that due to different residue definitions established in the EU and by JMPR the proposed Codex MRLs cannot be taken over in the EU legislation.
The RMS agreed with this position. However, it was noted that some of the issues raised may be addressed by the data being assessed for the ongoing import tolerance application, which is currently stopped due to missing data identified by EFSA in the framework of the completeness check (EFSA asked for additional information on the following issues: justification of the use of saflufenacil as a desiccant with a short PHI, data on the metabolite M800H02 and whether it needs to be included in the RD for RA, a standard hydrolysis study, evidence of the toxicity of the metabolites M800H10, H11, and H35 and whether they are covered by the tox reference value for saflufenacil, storage stability data in animal matrices). The assessment of the requested data will not be concluded by the time of the CCPR meeting. Once the import tolerance application has been fully concluded, it may be possible/necessary to revisit the Codex proposals

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.10.4. Codex MRL proposals – saflufenacil

In the Table 51 the Codex MRL proposals are compared with the EU MRLs.

Table 51: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Pomegranate	0.01*	0.03*	The CXL proposal is based on 3 trials matching the critical GAP. All the residue trials were < 0.01 mg/kg. The MRL proposal is supported by data
Barley	**1**	0.03*	The CXL proposal is based on 14 trials matching the cGAP in US (1 × 50 g ai/ha, PHI 3 days) on barley. It is noted that the preharvest use in cereals is not sufficiently supported by metabolism data (see general comment on residue definitions)
Barley bran (unprocessed)	3	–	–
Triticale	**0.7**	0.03*	See comment on wheat
Wheat	**0.7**	0.03*	The MRL proposal is based on 25 residue trials matching the US GAP (1 × 50 ai/ha, PHI 3 days). Using the OECD calculator, a MRL of 0.5 mg/kg would be sufficient. It is noted that the preharvest use in cereals is not sufficiently supported by metabolism data (see general comment on residue definitions)
Sugar cane	0.03	0.03*	The CXL proposal is based on 9 residue trials matching the GAP in Brazil (1 × 98 ai/ha, PHI 7 days). The CXL proposal is sufficiently supported by data
Sugar cane molasses	1		
Peanut	0.01*	0.03*	The CXL proposal is based on 8 trials in peanut conducted according to Nicaraguan GAP; (pre-emergence application); the MRL proposal is acceptable
Sunflower seed	0.7	1	The CXL proposal is based on 3 residue trials matching the GAP from Canada/US (preharvest use). The number of trials is not sufficient to derive a MRL proposal for a major crop
Alfalfa fodder, dry	0.06	–	–
Hay or fodder (dry) of grasses	30	–	According to the OECD calculator, a MRL of 23 mg/kg would be sufficient
Barley straw and fodder, dry	10	–	The proposed MRL is derived from a combined data set (barley and wheat) considering that the data are from similar population
Triticale straw and fodder, dry	10	–	See the comment on wheat straw
Wheat straw and fodder, dry	10	–	See the comment on barley straw
Edible offal (Mammalian)	**60**	0.3	The CXL proposal is derived from the max DB (30 mg/kg). Three feeding levels were conducted (5, 17.8 and 62.5 ppm). The quality of the study should be assessed since it was noted the residues in particular in liver, kidney and fat did not correlate with the feeding levels. At the 2nd feed level (17.8 ppm), the residues were higher than in the 3rd feed level. For liver, see also results of consumer risk assessment
Mammalian fats (except milk fats)	**0.05**	0.01*	The same comment as on edible offal (mammalian)
Meat (from mammals other than marine mammals)	0.01	0.01*	The CXL proposal is acceptable
Milks	0.01	0.01*	The CXL proposal is acceptable
Eggs	0.01*	0.01*	The CXL proposal is acceptable
Poultry fats	0.01*	0.01*	The CXL proposal is acceptable
Poultry meat	0.01*	0.01*	The CXL proposal is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Poultry, Edible offal of	0.01*	0.01*	The CXL proposal is acceptable
Peanut	0.01*	0.03*	The CXL proposal is supported by data
General comment: Considering the different residue definitions for plant and animal products, the proposed Codex MRLs cannot be taken over in the EU legislation			

MRL: maximum residue limit; CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; cGAP: critical GAP; PHI: preharvest interval; OECD: Organisation for Economic Co-operation and Development; ai: active ingredient.
*: Indicates that the MRL is set at the limit of quantification.

6.10.5. Consumer risk assessment – saflufenacil

The result for the consumer risk assessment is presented in Table 52.

Table 52: Summary of the consumer risk assessment for saflufenacil

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR values reported in the JMPR report The risk assessment is tentative since the EU and JMPR residue definitions for risk assessment are different Since the EU residue definition comprises additional metabolites, the risk assessment may underestimate the acute exposure according to the EU residue definition The EU ARfD was used **Results:** The risk assessment identified potential consumer risks for bovine liver (871% of the ARfD) and swine liver (120% of the ARfD). For the remaining crops/commodities, no short-term consumer health risk was identified	**RA assumptions:** The risk assessment is tentative, since the EU and JMPR residue definitions are different. This difference implies that the risk assessment may underestimate the actual exposure, may slightly overestimate the actual exposure according to the EU residue definition **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 34% of the ADI. The major contributors were animal products (edible offal, liver)	–

MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.11. Sulfoxaflor (252) (T)

6.11.1. Background information

Sulfoxaflor was assessed by JMPR for the new uses. However, since no information on the authorised GAPs was provided, JMPR did not derive new MRL proposals.

6.12. Benzovindiflupyr (261) (R)

6.12.1. Background information

Benzovindiflupyr was assessed by JMPR for the new uses. In the Table 53, some background information on benzovindiflupyr is presented.

Table 53: Background information on benzovindiflupyr

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009	Commission Implementing Regulation (EU) 2016/177[(a)]	FR	EFSA conclusion	Yes	EFSA (2015d)
			MRL review	No	–
			MRL applications	No	EFSA (2016h) Import tolerance

(a): (EU) 2016/177: Commission Implementing Regulation (EU) 2016/177 of 10 February 2016 approving the active substance benzovindiflupyr, as a candidate for substitution, 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, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 35, 11.2.2016, p. 1–5.

6.12.2. Toxicological reference values – benzovindiflupyr

The following toxicological reference values derived at EU level and by JMPR are presented in Table 54.

Table 54: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.05 mg/kg bw per day	–	0.05 mg/kg bw per day	EFSA (2015d) (Rat, 2-year study with safety factor 100)
ARfD	0.1 mg/kg bw		0.1 mg/kg bw	EFSA (2015d) (Rat, acute neurotoxicity study with safety factor 100)

Conclusion:
The toxicological reference values derived at EU level and by JMPR are identical

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.12.3. Residue definitions – benzovindiflupyr

In the following Table 55, the residue definitions for enforcement and risk assessment purpose are compared:

Table 55: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2015d)
RD-enf	Plant commodities	Benzovindiflupyr The residue is fat soluble	Benzovindiflupyr The residue is not fat soluble (EFSA, 2015d)
	Animal commodities		
RD-RA	Plant commodities		Benzovindiflupyr
	Animal commodities		Benzovindiflupyr and mono-hydroxylated benzovindiflupyr, free and conjugated (SYN546039), expressed as benzovindiflupyr

Comments:
The residue definitions for plant commodities are identical.
For animal commodities, the EU RD for risk assessment is wider; furthermore, the residues are not considered fat soluble in the EU

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.12.4. Codex MRL proposals – benzovindiflupyr

In the Table 56, the Codex MRL proposals are compared with the EU MRLs.

Table 56: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL/art 10 (EFSA, 2016h)	Comment
Pome fruits	0.2	0.01*/0.2	The proposed Codex MRL is sufficiently supported by data
Grapes	1	0.01*/1	The proposed Codex MRL is sufficiently supported by data
Fruiting vegetables, Cucurbits	**0.2**	0.01*/0.08 (edible peel) 0.01* inedible peel	The MRL proposal is based on 6 trials in cucumbers, 5 trials in summer squash and 6 trials in melons matching with the US GAP. The data were combined since they were found to belong to the same population. At EU level, separate MRLs would be established for cucurbits with edible and inedible peel. From the trials, the following MRLs would be calculated: 0.08 mg/kg for cucurbits (edible peel); 0.3 mg/kg for cucurbits (inedible peel) For melons (inedible peel) in the EU, the number of trials would not be sufficient (at least 8 trials would be required, but 6 residue trials are considered enough at Codex level. The same residue trials were provided for the EU import tolerance request
Fruiting vegetables other than Cucurbits	**0.9**	0.01*/0.7 (tomato aubergines) 1 (sweet pepper and okra)	The MRL proposal is based on 11 trials in tomatoes and 9 trials in peppers matching with the US GAP. The data were combined since they were found to belong to the same population. At EU level, separate MRLs would be established. From the trials, the following MRLs would be calculated: 0.07 mg/kg for tomatoes with the possibility to extrapolate to aubergines; 1 mg/kg for peppers. However, considering that the difference is small, the RMS proposed to accept the MRL proposal derived from the combined data set. The same residue trials were provided for the import tolerance request recently assessed by EFSA
Sweet corn (corn-on-the-cob)	0.01*	0.01*/0.01*	The proposed Codex MRL is sufficiently supported by data
Beans (dry)	0.15	0.01*/0.2	The proposed MRL is sufficiently supported by data (13 residue trials that matched the GAP from Canada)
Peas (dry)	**0.2**	0.01*/0.08	The proposed MRL is sufficiently supported by data (11 residue trials matching the US/CA GAP. All except the 2 trials leading to the highest residues have been submitted to EFSA for the import tolerance request
Soya bean (dry)	**0.08**	0.04	The proposed MRL is sufficiently supported by data (18 residue trials that matched the GAP from USA and Canada)
Potato	0.02	0.01*/0.02	The proposed MRL is sufficiently supported by data (12 residue trials that matched the US GAP
Barley	1	0.5/1.5	The proposed MRL is sufficiently supported by data (12 residue trials that matched the Canadian GAP)
Oats	1	0.5/1.5	The MRL proposal was derived from the trials in barley
Wheat	0.1	0.04/0.1	The proposed MRL is sufficiently supported by data (30 residue trials that matched the GAP from Canada)
Rye	0.1	0.04/0.1	The MRL proposal was derived from the trials in wheat
Triticale	0.1	0.04/0.1	The MRL proposal was derived from the trials in wheat
Sugar cane	0.04	0.04	The proposed MRL is sufficiently supported by data (7 residue trials that matched the GAP from Brazil)
Peanut	**0.04**	0.01*/0.01*	The proposed MRL is sufficiently supported by data (6 residue trials that matched the GAP from Brazil)

Commodity	Codex MRL proposal	EU MRL/art 10 (EFSA, 2016h)	Comment
Rape seed	**0.2**	0.01*/0.15	The proposed MRL is sufficiently supported by data (9 residue trials that matched the GAP from USA and Canada)
Coffee beans	**0.15**	0.05*/3 options proposed (0.05*, 0.03 or 0.1)	The proposed MRL is based on 6 residue trials matching the GAP from Brazil. It is noted that for coffee at least 8 trials should be provided in the EU. According to the guidance document to facilitate the establishment of MRLs for minor crops, coffee is also classified as a major crop. The RMS proposed that the data set should be considered as sufficient, since the MRL would be only slightly increased
Dried grapes (=currants, raisins and sultanas)	3	–	–
Peppers Chilli, dried	9	–	The proposed MRL was derived from the merged data set of tomato and pepper trials, using the default dehydration factor. It would be more correct, to use only the trials on peppers, excluding the trials on tomatoes. However, the use of the combined data set might have a low impact
Barley straw and fodder, Dry	15 (dw)	–	–
Oat straw and fodder, Dry	15 (dw)	–	–
Rye straw and fodder, Dry	15 (dw)	–	–
Triticale straw and fodder, Dry	15 (dw)	–	–
Wheat straw and fodder, Dry	15 (dw)	–	–
Pea hay or fodder, dry	8 (dw)	–	–
Peanut fodder	15 (dw)	–	–
Edible offal (Mammalian)	**0.1**	0.01*/0.03 or 0.06 (liver)	From the feeding study and the dietary burden calculation it is concluded, that a lower MRL would be sufficient (i.e. 0.07 mg/kg)
Eggs	0.01*	0.01*	The proposed MRL is acceptable
Mammalian fats (except milk fats)	**0.03**	All mammalians 0.02, except swine 0.01*	From the feeding study and the dietary burden calculation it is concluded, that a lower MRL would be sufficient (i.e. 0.02 mg/kg)
Meat (from mammals other than marine mammals)	**0.03(F)**	0.01*	See comment on mammalian fats. At EU level, the residues are not considered fat soluble. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Milks	0.01*	0.01*	The proposed MRL is acceptable
Poultry fats	0.01*	0.01*	The proposed MRL is acceptable
Poultry meat	0.01*	0.01*	The proposed MRL is acceptable
Poultry, Edible offal of	0.01*	0.01*	The proposed MRL is acceptable
General comment: –			

MRL: maximum residue limit; CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; dw: dry weight.
*: Indicates that the MRL is set at the limit of quantification.

6.12.5. Consumer risk assessment – benzovindiflupyr

The result for the consumer risk assessment is presented in Table 57.

Table 57: Summary of the consumer risk assessment for benzovindiflupyr

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR as derived by JMPR The risk assessment is tentative because the EU and JMPR residue definitions for risk assessment (only animal products) are different Since the EU residue definition comprises additional metabolites, the result of the risk assessment may slightly underestimate the acute exposure according to the EU residue definition **Results:** No short-term exposure concern was identified (39% of the ARfD for peppers, 36% for tomatoes, 24% for melons, other commodities < 20%)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2016h) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL The risk assessment is tentative, since the EU and JMPR residue definitions for animal commodities are different. This difference implies that the risk assessment may slightly underestimate the actual exposure the actual exposure according to the EU residue definition **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 2.9% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to tomatoes (0.5% of the ADI)	–

MRL: maximum residue limit; ARfD: acute reference dose; STMR: supervised trials median residue; ADI: acceptable daily intake.

6.13. Bixafen (262) (R)

6.13.1. Background information

Bixafen was assessed by JMPR for the new uses. In the Table 58 some background information on bixafen is presented.

Table 58: Background information on bixafen

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009	Commission Implementing Regulation (EU) No 350/2013[(a)]	UK	EFSA conclusion	Yes	EFSA (2012l)
			MRL review	No/Yes	In progress
			MRL applications	Yes	Oilseed rape, linseed, poppy seed and mustard seed: EFSA (2012j) Oil seed rape, linseed, mustard seed and poppy seed: EFSA (2011d) Cereals and products of animal origin: EFSA (2009c)

(a): 350/2013: Commission Implementing Regulation (EU) No 350/2013 of 17 April 2013 approving the active substance bixafen, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 108, 18.4.2013, p. 9–12.

6.13.2. Toxicological reference values – bixafen

The following toxicological reference values derived at EU level and by JMPR are presented in Table 59.

Table 59: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.02 mg/kg bw per day	–	0.02 mg/kg bw per day	EFSA (2012l), (2-year rat, with safety factor 100)
ARfD	0.2 mg/kg bw		0.2 mg/kg bw	EFSA (2012l), (Rat developmental, with safety factor 100)

Conclusion:
The toxicological reference values set at EU level and derived by JMPR are identical

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.13.3. Residue definitions – bixafen

In the following Table 60, the residue definitions for enforcement and risk assessment purpose are compared:

Table 60: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Bixafen	Reg. 396/2005: Bixafen Peer review: • Bixafen (restricted to cereals (foliar treatment); • Open for rotational crops
	Animal commodities	Sum of bixafen and *N*-(3′,4′-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1*H*-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen The residue is fat soluble	Sum of bixafen and desmethyl-bixafen (M21), expressed as bixafen The residue is fat soluble (EFSA, 2012l)
RD-RA	Plant commodities	Bixafen	Sum of bixafen and desmethyl-bixafen (M21) expressed as bixafen equivalents-restricted to cereals (foliar treatment) Open for rotational crops
	Animal commodities	Sum of bixafen and *N*-(3′,4′-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1*H*-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen	Sum of bixafen and desmethyl-bixafen (M21), free and conjugated expressed as bixafen equivalent

Comments:
While the EU and JMPR residue definition for enforcement for plants and the risk assessment residue definition for animal products are the same, the risk assessment residue definition for plants differ. In the EU residue definition, an additional metabolite was included for cereals.
It is noted that the residue definition in Regulation (EC) 396/2005 should be labelled as fat soluble (see EFSA, 2012l)

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.13.4. Codex MRL proposals – bixafen

In the Table 61 the Codex MRL proposals are compared with the EU MRLs.

Table 61: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	0.4	0.5	The proposed MRL is based on sufficient data (19 trials matching the UK GAP)
Barley, straw and fodder	20 (dw)	–	–

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (mammalian)	**4**	0.02*	The proposed MRL derived from the feeding study and the dietary burden calculation is plausible
Eggs	**0.05**	0.02* Eggs	The proposed MRL derived from the feeding study and the dietary burden calculation is plausible
Mammalian fats (except milk fats)	**2**	0.4 (bovine, sheep, goat) 0.02* (equine, other farmed terrestrial animals)	The proposed MRL was derived from the feeding study and the dietary burden calculation. According to EFSA, a MRL of 1.5 mg/kg would be sufficient
Meat (from mammals other than marine mammals)	**2 (fat)**	0.02* (swine, equine, and others farmed animals) 0.15* (bovine, sheep, goat)	The proposed MRL was derived from the feeding study and the dietary burden calculation. According to EFSA, a MRL of 1.5 mg/kg would be sufficient In general, in the EU, an MRL would be set for muscle in addition to the MRL for fat
Milk fat	5		In the EU, no MRL is set for milk fat, but for milk
Milks	**0.2**	0.04 (cattle, sheep, goat) 0.02* (horse and others)	The proposed MRL was derived from the feeding study and the dietary burden calculation. According to EFSA, a MRL of 0.15 mg/kg would be sufficient
Oats	0.4	0.5	The MRL proposal was derived by extrapolation from barley
Oats, straw and fodder	20 (dw)	–	–
Poultry, Edible offal of	**0.05**	0.02*	The proposed MRL derived from the feeding study and the dietary burden calculation is plausible
Poultry fats	**0.05**	0.02*	The proposed MRL derived from the feeding study and the dietary burden calculation is plausible
Poultry meat	0.02*	0.02*	The proposed MRL derived from the feeding study and the dietary burden calculation is plausible
Rape seeds	0.04	0.07	The proposed MRL is based on sufficient data (10 trials matching the UK GAP)
Rape seed oil, refined	0.08		
Rye	0.05	0.05	The MRL proposal was derived by extrapolation from wheat
Rye, straw and fodder	20 (dw)		
Triticale	0.05	See wheat	The MRL proposal was derived by extrapolation from wheat
Triticale, straw and fodder	20 (dw)		
Wheat	0.05	0.05	The proposed MRL is based on sufficient data (20 trials matching the UK GAP)
Wheat, bran	0.15	–	–
Wheat, straw and fodder	20 (dw)	–	–
General comment: For rape seed, barley and wheat some processing studies were provided to JMPR. It is noted that for each processed product only one processing study was available. Thus, the data basis is not robust enough to derive reliable processing factors			

MRL: maximum residue limit; GAP: Good Agricultural Practice; dw: dry weight.
*: Indicates that the MRL is set at the limit of quantification.

6.13.5. Consumer risk assessment – bixafen

The result for the consumer risk assessment is presented in Table 62.

Table 62: Summary of the consumer risk assessment for bixafen

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compare to the EU MRLs, using the HR/STMR as derived by JMPR The discrepancy of the risk assessment residue definitions for plants does not impact this risk assessment, because the risk assessment was calculated only for animal products **Results:** No short-term exposure concern was identified (max. for bovine liver: 16% of the ARfD)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2012l) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 19% of the ADI Among the commodities under consideration, the highest contribution to the exposure was related to milk (12% of the ADI)	–

MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.14. Fluensulfone (265) (T/R)

6.14.1. Background information

Fluensulfone was assessed by JMPR previously in 2013 and 2014. In the Table 63, some background information on fluensulfone is presented.

Table 63: Background information on fluensulfone

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Not assessed in the EU	–	–	EFSA conclusion	No	–
			MRL review	No	–
			MRL applications	No	–

6.14.2. Toxicological reference values – fluensulfone

The following toxicological reference values derived at EU level and by JMPR are presented in Table 64.

Table 64: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.01 mg/kg bw per day	–	–	No EU assessment
ARfD	0.3 mg/kg bw		–	

Conclusion:
The active substance was never assessed at EU level.
In 2015, EFSA provided comments on the toxicological reference values derived by JMPR. EFSA noted that the basis of the ARfD was an acute neurotoxicity study. The results of the subchronic neurotoxicity were not in line with results of the acute neurotoxicity study. A much higher NOAEL in the subchronic toxicity study was observed compared to the point of departure (POD) after acute exposure raising uncertainties about the appropriateness of the ARfD.
From the metabolism studies assessed in 2014 by JMPR, it was concluded that parent fluensulfone was not expected to be present in food consumed in significant concentrations. Instead, three metabolites were identified as candidates to be included in the RD: TSA, BSA, and MeS.

- Metabolite M3625 (TSA) was found to be less toxic than fluensulfone over 90 days of exposure in rats.
- Metabolite M-3627 (BSA) appeared to be of similar toxicity to fluensulfone over 28 days of dietary of exposure in rats (non-GLP study).
- For metabolite M3626 (MeS), no repeated dose toxicity data and genotoxicity data *in vivo* were provided. In 2014 JMPR estimated the chronic intake and compared it with the TTC values for a Cramer class III compound (1.5 μg/kg bw per day for chronic and 5 μg/kg bw for acute exposure). Since the IEDI and IESTI was below, JMPR concluded that MeS is not a relevant plant or animal metabolite of fluensulfone for the crops under consideration.

Based on the considerations regarding the metabolites observed, JMPR proposed in 2014 to set the RD as BSA.
In 2016, JMPR assessed an additional study on metabolite BSA and information on the mode of action for lung tumours induced by fluensulfone.
For metabolite M3627 (BSA), a NOAEL of 851 mg/kg bw per day was derived from a 90 day study (2016). Based on this study JMPR concludes that BSA is significantly less toxic than the parent.
According to the JMPR 2016 report, two negative *in vivo* studies are available, namely an *in vivo* micronucleus assay and an *in vivo* unscheduled DNA synthesis assay. However, it is noted that the *in vivo* UDS would not be accepted for the EU peer review as a follow up to a positive *in vitro* gene mutation study in line with the EFSA Scientific Opinion on genotoxicity testing. Thus, further genotoxicity testing is required.
The previously raised concerns regarding the genotoxic potential of metabolite MeS are still valid. Further genotoxicity tests would be needed to follow-up positive results *in vitro*. The use of the TTC approach is not considered a practical approach (see also comments below on the residue definition)

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.14.3. Residue definitions – fluensulfone

In the following Table 65, the residue definitions for enforcement and risk assessment purpose are compared:

Table 65: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.	–
	Animal commodities	Fluensulfone	–
RD-RA	Plant commodities	Fluensulfone	–
	Animal commodities	Fluensulfone Residue is fat soluble	–

Comments:
Since the active substance has never been assessed at EU level and no specific MRLs are established in Annex II or III, currently the default residue definition covering the parent compound only is applicable.
In 2015, EFSA provided comments on the residue definition. According to the metabolism studies assessed by the JMPR in 2014 on tomatoes, lettuce and potatoes, the main plant metabolites of fluensulfone following the soil/early foliar (lettuce) treatment are thiazole sulfonic acid (TSA, M3625) (67–85% TRR) and butane sulfonic acid (BSA, M3627 (44–68% TRR). Parent fluensulfone was present at trace levels. TSA was also found to accumulate in rotational crops. The JMPR did not include TSA in the risk assessment and enforcement residue definition for plants because of its low toxicological relevance and because a separate analytical enforcement method has to be used to determine TSA residues.
M-3626 (MeS) has not been identified in metabolism studies, but was present in several field trials. Applying TTC approach, MeS was not considered by JMPR to be a relevant plant metabolite (see comments on toxicological reference values in the table above).
The metabolism studies on lactating goats and laying hens indicate possibly different metabolic pathways. The only compounds identified at quantifiable levels were fluensulfone in poultry fat (55% TRR) and TSA in poultry liver (2.7% TRR). JMPR concluded that a residue definition for animal commodities in not necessary since parent compound in treated plants is present at insignificant levels and TSA is only a minor livestock metabolite.

In 2015, the Delegation of EU raised a reservation in the CCPR meeting, related to the use of non-GLP studies in assessing the toxicological relevance of the metabolites BSA and TSA, the genotoxic potential of metabolite MeS and the use of the TTC approach to decide that MeS is not of relevance.

The use of the TTC approach has not yet been used in the EU for regulatory purposes. JMPR calculated the TTC in 2014, considering the crops assessed in 2014. For the new uses assessed in 2016, JMPR concluded that since no information on MeS was available, the previous calculations are still valid. However, the lack of information on MeS is not sufficient to conclude that the TTC value is not exceeded. Even if in metabolism studies MeS was not detected, it cannot be excluded that it occurs in residue trials. Also for cucurbits metabolism studies were not sufficient to exclude the presence of MeS residues.

Based on the new data provided to JMPR in 2016, JMPR revised the previously proposed residue definitions[(a)] as reported in the table above.

Overall, the metabolism studies seem to be not representative for the residue behaviour observed in trials condition; in residue trials metabolites were detected that were not found in significant levels in the metabolism study.

According to EFSA, the information currently available is not sufficient to derive sound residue definitions

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.
(a): The following RD were derived by JMPR in 2014: RD-enf plant commodities: BSA {3,4,4-trifluorobut-3-ene-1-sulfonic acid}, RD-enf animal commodities: Not necessary; RD-RA plant commodities: BSA {3,4,4-trifluorobut- 3-ene-1-sulfonic acid}, RD-RA Animal commodities: Not necessary).

6.14.4. Codex MRL proposals – fluensulfone

In the Table 66 the Codex MRL proposals are compared with the EU MRLs.

Table 66: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Beetroot	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Brassica (cole or cabbage) vegetables, Head cabbage,	**1.5**	0.01*	The proposed MRL was derived from a combined data set on cabbage head (6 trials) and cauliflower (5 trials) reflecting the US GAP for leafy *Brassica*. See general comments At EU level data on cauliflower and head cabbage would not be merged; instead individual MRLs would be derived, provided that sufficient trials are available (both crops are major crops in the EU) It should be clarified if the code is correctly assigned to the proposed MRL (VB 0400 refers to broccoli); the code corresponding with the description of the commodity is VB 0040

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Carrot	**4**	0.01*	The proposed MRL was derived from a combined data set in carrots (11 trials) and radish (4 trials) compliant with the US GAP. See general comment
Celeriac	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Celery	**2**	0.01*	The proposed MRL was derived from 6 trials in celery compliant with the US GAP. See general comment
Chervil, Turnip-rooted	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Cucumber	**0.7**	0.01*	The proposed MRL was derived from a combined data set (10 trials in cucumbers and 8 trials in summer squash. See general comments
Edible offal (Mammalian)	0.01*	0.01*	The MRL proposal was derived from the metabolism study in lactating goat. No residues of BSA, TSA or fluensulfone were detected in any goat matrix
Eggs	0.01*	0.01*	The MRL proposal was derived from the metabolism study in laying hen. No residues of fluensulfone were detected in eggs
Fruiting vegetables, Cucurbits	W (0.3)	0.01*	Previous MRL was proposed to be withdrawn and replaced by a new MRL (see below)
Fruiting vegetables, other than Cucurbits, except sweetcorn and mushroom	**0.7**	0.01*	The proposed MRL was derived from a combined data set in tomatoes (18 trials) and peppers (14 trials) matching the US GAP. In the EU, it would not be required to combine results from both cucumber and summer squash to derive an MRL for cucumber and summer squash. See general comment
Horseradish	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Komatsuma	**9**	0.01* (land cress & mustard greens)	The proposed MRL was derived from 4 trials compliant with the US GAP. See general comment
Leafy vegetables (not specified elsewhere)	**1 (R)**	0.01*	The proposed MRL was derived from rotational crop studies in lettuce. It is confusing that this MRL is derived for the food code VL 0053, which covers crops for which specific MRLs are proposed (see also lettuce, head)
Legume vegetables	**0.1 (R)**	0.01*	The proposed MRL was derived from rotational crop studies in beans with pods
Lettuce, Head	**0.8**	0.01*	The proposed MRL was derived from 6 trials compliant with the US GAP. In the EU, the number of trials would not be sufficient, but is in line with Codex rules. See general comment. It is noted that the MRL proposal for VB 0053 derived from rotational crop studies is higher than the MRL proposal for the use in lettuce following primary crop treatment
Low-growing berries	**0.5**	0.01* (cranberries, strawberries, muntries, cloudberries)	The proposed MRL was derived from 8 trials compliant with the US GAP. See general comment
Mammalian fats (except milk fats)	0.01*	0.01*	See edible offal (mammalian)
Meat (from mammals other than marine mammals)	0.01* (fat)	0.01*	See edible offal (mammalian)

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Melons, except watermelon	**0.3**	0.01*	The proposed MRL was derived from 9 residue trials in melons reflecting the US GAP. See general comment
Milks	0.01*	0.01*	The proposed MRL was derived from the metabolism study in lactating goat. No residues of BSA, TSA or fluensulfone were detected in milk
Mustard greens	**20**	0.01*	The proposed MRL was derived from 5 trials compliant with the US GAP. See general comment
Parsnip	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Peppers, chilli, dried	7	–	–
Potato	**0.8**	0.01*	The proposed MRL was derived from 18 trials in potatoes compliant with the US GAP. See general comment
Potato, dried	2	–	–
Poultry, Edible offal of	0.01*	0.01*	The MRL proposal was derived from the metabolism study in laying hen. No residues of fluensulfone were detected in poultry matrices except fat
Poultry fats	0.01	0.01*	See poultry, edible offal
Poultry meat	0.01*	0.01*	See poultry, edible offal
Radish	**4**	0.01*	The proposed MRL was derived from a combined data set in carrots (11 trials) and radish (4 trials) compliant with the US GAP. See general comment
Radish Japanese	**4**		The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Radish leaves	**50**		The proposed MRL was derived from 4 trials compliant with the US GAP. See general comment
Root and tuber vegetables (not specified elsewhere)	**3 (R)**	0.01*	The proposed MRL was derived from rotational crop studies in radish root. It is confusing that this MRL is derived for the food code VR 0075, which covers crops for which specific MRLs are proposed (e.g. beetroot, carrots, celeriac etc.). See general comment
Spinach	**4**	0.01*	The proposed MRL was derived from 6 trials compliant with the US GAP.. In the EU, the number of trials would not be sufficient, but is in line with Codex rules. See general comment
Squash, summer	**0.7**	0.01*	–
Swede	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Sweet potato	**0.8**	0.01*	The MRL proposals were derived by extrapolation from potatoes
Tomato, dried	1.5	–	–
Tomato paste	1.5	–	–
Turnip, Garden (root)	**4**	0.01*	The proposed MRL was derived by extrapolation from carrots and radish. See general comment
Turnip greens (leaves)	**10**		The proposed MRL was derived from 4 trials compliant with the US GAP. See general comment
Watermelon	**0.3**	0.01*	The proposed MRL was derived by extrapolation from melons. See general comment

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
General comment: Currently, no specific MRLs are established in Annex II or III of Regulation (EC) No 396/2005. Thus, the default MRLs are currently applicable in the EU. The metabolism studies provided to JMPR are considered to be not representative for the residue behaviour observed in trials condition, since in residue trials metabolites were detected that were not found in significant levels in the metabolism studies. Pending a decision on reliable residue definitions, a conclusion on the acceptability of the proposed Codex MRLs is not possible. At EU level, risk managers should discuss the possibility to include the metabolites identified in the metabolism studies/residue trials performed with fluensulfone in the EU residue definition (e.g. BSA, TSA and MeS) considering that parent fluensulfone is not a reliable marker for use of fluensulfone. It is noted that MRLs derived from rotational crop studies are specifically labelled. This element is increasing the transparency and should be considered for other substances as well			

MRL: maximum residue limit; GAP: Good Agricultural Practice; (R): maximum residue level relation to rotational crops.
*: Indicates that the MRL is set at the limit of quantification.

6.14.5. Consumer risk assessment – fluensulfone

The result for the consumer risk assessment is presented in Table 67.

Table 67: Summary of the consumer risk assessment for fluensulfone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An tentative short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR as derived by JMPR The ARfD derived by JMPR was used The risk assessment is tentative since the residue definitions derived by JMPR are not acceptable Lacking information on MeS as regards the potential genotoxicity, the RD derive by JMPR are not acceptable **Results:** The exposure to parent fluensulfone, accounted for 11% of the ARfD for carrots, 9% for celeriac and swedes and 8% for celery	**RA assumptions:** EFSA calculated a tentative long-term risk assessment, including the STMR values derived by JMPR for crops where the MRL proposals were made; for the remaining crops the existing EU MRL was used as input value. The ADI derived by JMPR was used The risk assessment is tentative, since the residue definitions derived by JMPR are not acceptable **Results:** The long-term exposure accounted for 10% of the ADI	–

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.15. Tolfenpyrad (269) (R)

6.15.1. Background information

Tolfenpyrad was assessed by JMPR for the new uses. In the Table 68 some background information on tolfenpyrad is presented.

Table 68: Background information on tolfenpyrad

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Never notified and authorised in the EU	–	–	EFSA conclusion	–	–
			MRL review	–	–
			MRL applications	–	–

6.15.2. Toxicological reference values – tolfenpyrad

The following toxicological reference values derived at EU level and by JMPR are presented in Table 69.

Table 69: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.006 mg/kg bw per day	–	–	–
ARfD	0.01 mg/kg bw		–	
Conclusion: Tolfenpyrad was never assessed at EU level. In 2014 CCPR the EU delegation did not comment on the ADI/ARfD values derived by JMPR				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.15.3. Residue definitions – tolfenpyrad

In the following Table 70, the residue definitions for enforcement and risk assessment purpose are compared:

Table 70: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Tolfenpyrad	–
	Animal commodities	Sum of tolfenpyrad and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl] phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonylaminomethyl] phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad	
RD-RA	Plant commodities	Tolfenpyrad	
	Animal commodities	Sum of tolfenpyrad and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl] phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonylaminomethyl] phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad.The residue is not fat soluble.	
Comments: Since no specific MRLs are established in the EU, the default residue definition covering only parent compound are used for enforcement purpose			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.15.4. Codex MRL proposals – tolfenpyrad

In the Table 71 the Codex MRL proposals are compared with the EU MRLs.

Table 71: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Pecan	0.01*	0.01*	The proposed Codex MRL is based on 5 trials matching the US GAP. The proposal is acceptable
Potato	0.01*	0.01*	The proposed Codex MRL is based on 15 trials matching the US GAP and one overdosed trial; in none of the trials detectable residues were found. The proposal is acceptable
General comment: –			

MRL: maximum residue limit; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of quantification.

6.15.5. Consumer risk assessment – tolfenpyrad

The result for the consumer risk assessment is presented in Table 72.

Table 72: Summary of the consumer risk assessment for tolfenpyrad

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for potatoes and pecan nuts, using the proposed MRL as input value The JMPR ARfD was used The risk assessment is tentative since the active substance was never assessed in the EU **Results:** The risk assessment did not identify potential consumer risks for the two crops (potatoes: 16% of the ARfD; pecans: 0.2% of the ARfD)	**RA assumptions:** The long-term risk assessment is based on the current default MRLs of 0.01 mg/kg, including the MRLs derived by JMPR for potatoes and pecans The JMRP ADI was used The risk assessment is tentative, since the active substance was never assessed at EU level **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 11.3% of the ADI The contribution of potatoes to the total long-term exposure (expressed as percentage of the ADI) was 0.5% of the ADI	–

RA: risk assessment; MRL: maximum residue limit; ARfD: acute reference dose; ADI: acceptable daily intake.

6.16. Metrafenone (278) (R)

6.16.1. Background information

Metrafenone was assessed by JMPR for the new uses. In the Table 73 some background information on metrafenone is presented.

Table 73: Background information on metrafenone

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Directive 2007/6/EC[(a)]	LV	EFSA conclusion	Yes	EFSA (2006a)
			MRL review	Yes	EFSA (2013a)
			MRL applications	Yes	Globe artichoke: assessment ongoing (additional data requested) Hops: EFSA (2015f) Various crops: EFSA (2013h) Table and wine grapes: EFSA (2011a)

(a): 2007/6/EC: Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, Bacillus subtilis, spinosad and thiamethoxam as active substances. OJ L 43, 15.2.2007, p. 13–18.

6.16.2. Toxicological reference values – metrafenone

The following toxicological reference values derived at EU level and by JMPR are presented in Table 74.

Table 74: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.3 mg/kg bw per day	–	0.25 mg/kg bw per day	EFSA (2015f, 2013a) confirmed by European Commission (2006) (rat 2-year study, with safety factor 100)
ARfD	Unnecessary		Not applicable	–
Conclusion: The toxicological endpoints derived in the EU and by JMPR are comparable. The difference in the ADI value may result from different rules for rounding				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.16.3. Residue definitions – metrafenone

In the following Table 75, the residue definitions for enforcement and risk assessment purpose are compared:

Table 75: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Metrafenone The residue is fat soluble	Metrafenone
	Animal commodities		Metrafenone (risk management decision to restrict the residue definition to parent compound) Fat soluble
RD-RA	Plant commodities		Metrafenone
	Animal commodities		Two options were proposed during MRL review Option 1: Sum of CL 1500698 and CL 1023363, expressed as metrafenone (residues are not fat soluble) Option 2: Metrafenone (fat soluble)
Comments: The residue definitions for enforcement derived by JMPR and set in the EU are identical. For the animal products, EFSA derived 2 options for risk assessment residue definitions. Option 2 would be compatible with the JMPR residue definition			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.16.4. Codex MRL proposals – metrafenone

In the Table 76, the Codex MRL proposals are compared with the EU MRLs.

Table 76: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Pome fruits	**1.0**	0.01*	The Codex MRL proposal is based on 11 trials on apples and 6 trials in pears matching the US GAP (3 × 0.336 kg ai/ha, 7-day PHI). Thus the proposal is sufficiently supported by data
Cherries	**2.0**	0.01*	The Codex MRL proposal is sufficiently supported by data (12 trials reflecting the US GAP)
Peaches	**0.7**	0.01*	The Codex MRL proposal is supported by 12 trials in peaches reflecting the US GAP. The MRL proposal was extrapolated to apricots. The proposal is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Fruiting vegetables, Cucurbits	**0.5**	0.2 (cucumbers, gherkins) 0.15 (courgettes) 0.1 (cucurbits with inedible peel)	The proposed MRL is based on 6 trials in cucumbers 14 trials in summer squash and 12 trials in melons reflecting the US and Canadian GAP (3 × 0.336 kg ai/ha, 0-day PHI). All trials were merged since the median residues were within a fivefold range and the data sets were not from different populations (Kruskal–Wallis test) At EU level, the data for melons would not be merged with cucurbits with edible peel. However, the same MRL was calculated for melons and for cucurbits (edible peel)
Cucumber	W(0.2)	–	–
Gherkin	W(0.2)	–	–
Squash, Summer	W(0.06)	–	–
Peppers, Sweet (including Pimento or pimiento)	2	2	The MRL proposal is based on 9 residue trials reflecting the US/CA GAP (3 × 0.336 kg ai/ha, 0-day PHI). The MRL proposal is acceptable
Peppers, Chilli	2	2	The MRL was derived from the trials in peppers (see above)
Peppers Chilli, dried	20		A default factor of 10 was applied to recalculate the MRL from fresh peppers to chilli peppers, dried
Tomato	**0.6**	0.4	19 trials matching the US/CA GAP were provided. The MRL proposal is based on sufficient data
Egg plant	**0.6**	0.3	The proposed MRL for tomatoes was extrapolated to eggplants. The proposal is acceptable
Hops, dry	70	80	The MRL proposal is sufficiently supported by data. It is noted that using the OECD calculator a MRL of 80 mg/kg would be derived
Apple juice	–	–	No robust processing factor was derived (only 1 processing study)
Apples, dried	–	–	No robust processing factor was derived (only 1 processing study)
Apple sauce	–	–	No robust processing factor was derived (only 1 processing study)
Tomato juice	–	–	No robust processing factor was derived (only 1 processing study)
Tomato paste	–	–	No robust processing factor was derived (only 1 processing study)
Tomato purée	–	–	No robust processing factor was derived (only 1 processing study)
Tomato (canned)	–	–	No robust processing factor was derived (only 1 processing study)
Beer	–	–	No robust processing factor was derived (only 1 processing study)
General comment: No specific comments			

MRL: maximum residue limit; GAP: Good Agricultural Practice; ai: active ingredient; PHI: preharvest interval.
*: Indicates that the MRL is set at the limit of quantification.

6.16.5. Consumer risk assessment – metrafenone

The result for the consumer risk assessment is presented in Table 77.

Table 77: Summary of the consumer risk assessment for metrafenone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015f) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL The EU ADI was used **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 2.6% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to apples (1.1% of the ADI) and tomatoes (0.14% of the ADI)	–

RA: risk assessment; STMR: supervised trials median residue; MRL: maximum residue limit; ADI: acceptable daily intake.

6.17. Flonicamid (282) (R)

6.17.1. Background information

Flonicamid was assessed by JMPR to recalculate the dietary burden for livestock, including *Brassica* leafy vegetables (HR and STMR derived by JMPR in 2015). In the Table 78 some background information on flonicamid is presented.

See also assessment following the submission of the concern form (Section 4.3).

Table 78: Background information on flonicamid

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC	Commission Decision 2010/29/EU[(a)]	FR	EFSA conclusion	Yes	EFSA (2010b)
			MRL review	Yes	EFSA (2014f)
			MRL applications	Yes	Apricot: in progress Herbs: EFSA (2016d) Several crops: EFSA (2015h) Various crop: EFSA (2010a) MRLs in various crops: in progress Notified MRL in radishes and fresh herbs

(a): 2010/29/EU: Commission Directive 2010/29/EU of 27 April 2010 amending Council Directive 91/414/EEC to include flonicamid (IKI-220) as active substance. OJ L 106, 28.4.2010, p. 9–11.

6.17.2. Toxicological reference values – flonicamid

The following toxicological reference values derived at EU level and by JMPR are presented in Table 79.

Table 79: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.07 mg/kg bw per day	–	0.025 mg/kg bw per day	European Commission (2010), confirmed in EFSA (2014f) (Rabbit development, with safety factor 100)
ARfD	Unnecessary		0.025 mg/kg bw	
Conclusion: –				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.17.3. Residue definitions – flonicamid

In the following Table 80 the residue definitions for enforcement and risk assessment purpose are compared:

Table 80: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2014f)
RD-enf	Plant commodities	Flonicamid	Sum of flonicamid, TFNA and TFNG, expressed as flonicamid
	Animal commodities	Flonicamid and the metabolite TFNA-AM, expressed as flonicamid	Sum of flonicamid and TFNA-AM, expressed as flonicamid
RD-RA	Plant commodities	Flonicamid	Sum of flonicamid, TFNA and TFNG expressed as flonicamid
	Animal commodities	Flonicamid and the metabolite TFNA-AM, expressed as flonicamid The residue is not fat soluble	Sum of flonicamid and TFNA-AM expressed as flonicamid The residue is not fat soluble
Comments: While the residue definitions for animal products derived by JMPR and set at EU level are identical, the residue definitions for plant products are not compatible, since in the EU additional metabolites were included			

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.17.4. Codex MRL proposals – flonicamid

In the Table 81, the Codex MRL proposals are compared with the EU MRLs.

Table 81: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Meat (from mammals other than marine mammals)	**0.15**	Swine: 0.02* Other mammals: 0.03	The proposed MRL is acceptable. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Mammalian fats	**0.05**	0.02*	The proposed MRL is acceptable
Edible offal (Mammalian)	**0.20**	Swine: 0.03 Other mammals: 0.04	The proposed MRL is acceptable
Milks	**0.15**	0.02*	The proposed MRL is acceptable
Poultry meat	**0.1**	0.03	The proposed MRL is plausible. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Poultry fats	**0.05**	0.03	The proposed MRL is plausible. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Poultry, Edible offal of	**0.10**	0.03	The proposed MRL is acceptable
Eggs	**0.15**	0.04	The proposed MRL is acceptable
General comment: In 2015, JMPR recalculated the dietary burden for livestock, including *Brassica* leafy vegetables, which were not included in 2014, although MRL proposals were derived The results of the revised dietary burden calculations are significantly higher (slightly exceeding the highest feeding level for of the feeding study in ruminants), triggering new proposals for food of animal origin			

MRL: maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.

6.17.5. Consumer risk assessment – flonicamid

The result for the consumer risk assessment is presented in Table 82.

Table 82: Summary of the consumer risk assessment for flonicamid

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR as derived by JMPR For the short-term risk assessment, the MRL proposals were used (JMPR did not derive HR values since according to JMPR no ARfD was considered necessary) The EU ARfD was used **Results:** In the short-term exposure assessment, the higher MRL proposals did not exceed the ARfD (among the animal products, the highest short-term exposure was calculated for milk (25% of the ARfD)) For the commodities with draft MRL proposals at step 4, the risk assessment was performed last year Possible consumer risks were identified for kale (2,247%), Chinese cabbage (1,234%), head cabbage (226%), cauliflower (145%, broccoli (129%)	**RA assumptions:** EFSA updated the risk assessment performed in 2016, including the new STMR values for mammalian fats, meat, milks, edible offal and for poultry products in the long-term risk assessment. In addition, the commodities with proposed draft MRLs at step 4 were included The EU ADI was used The risk assessment is tentative, since the EU and JMPR residue definitions for plant products are different. This difference implies that the risk assessment may underestimate the actual exposure according to the EU residue definition **Results:** The overall long-term exposure including the higher input values for animal commodities accounted for ca. 34% of the ADI	–

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.18. Fluazifop-P-butyl (283) (R)

6.18.1. Background information

Fluazifop-P-butyl was assessed by JMPR for the new uses. In the Table 83, some background information on fluazifop-P-butyl is presented.

Table 83: Background information on fluazifop-P-butyl

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009	Commission Implementing Regulation (EU) No 788/2011[(a)]	FR	EFSA conclusion	Yes	Conf data: EFSA, (2014h) (ecotox and fate) EFSA, (2012m) EFSA (2010g)
			MRL review	Yes	EFSA (2015j)
			MRL applications	No/Yes	Several commodities: EFSA (2015e) Pumpkin seeds: EFSA (2016e); in progress for carrot, tomato and courgette

(a): 201/2013: Commission Implementing Regulation (EU) No 788/2011 of 5 August 2011 approving the active substance fluazifop-P, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC. OJ L 203, 6.8.2011, p. 21–25. Amended by Commission Implementing Regulation (EU) No 201/2013 of 8 March 2013 amending Implementing Regulations (EU) No 788/2011 and (EU) No 540/2011 as regards an extension of the uses for which the active substance fluazifop-P is approved OJ L 67, 9.3.2013, p. 6–9.

6.18.2. Toxicological reference values – fluazifop-P-butyl

The following toxicological reference values derived at EU level and by JMPR are presented in Table 84.

Table 84: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.004 mg/kg bw per day	2- and 3-generation reproductive toxicity studies in rats	0.01 mg/kg bw per day	EFSA (2010g) 2-year rat study with fluazifop acid supported by 81-weeks mice and multigeneration studies in rats (uncertainty factor 100); the ADI and ARfD are expressed as fluazifop acid
ARfD	0.4 mg/kg bw	Acute neurotoxicity study in rats	0.017 mg/kg bw	
Conclusion: ADI: JMPR and EU evaluation used a different conversion factor in the two- and three-generation reproductive toxicity studies from ppm to mg/kg bw per day that might explain the differences in setting the ADI. In the two- and three-generation reproductive toxicity studies JMPR and EU evaluation set the NOAEL at the same dose level of 10 ppm but resulting in a different value (0.4 mg/kg bw per day and 0.8 mg/kg bw per day, respectively). The resulting NOAEL of 0.8 mg/kg bw per day in EU lead to an overall NOAEL of 1 mg/kg bw per day including the two- and three-generation reproductive toxicity studies and the long-term toxicity studies whereas a lower NOAEL (i.e. 0.4 mg/kg bw per day) was considered by JMPR. Regarding the setting of the ARfD, it is not clear if JMPR and EU evaluation considered different developmental toxicity studies in rats. Some effects in rat developmental toxicity studies reported in the EU assessment (i.e. kinked ureters and/or dilated ureter) were not reported in the JMPR assessment. These effects were the basis for setting the ARfD at EU level whereas the basis at JMPR level was the acute neurotoxicity study. In the absence of further details concerning developmental toxicity studies in rats used by JMPR and how the conversion from ppm to mg/kg bw per day in the three- and two-generation studies in rats was done by JMPR, EFSA would propose to use the health-based guideline values ADI and ARfD as set during the EU evaluation. Toxicity studies provided for 5-(trifluoromethyl)-2(1*H*)-pyridinone (referred to as compound X) indicated that it is unlikely to be development toxicant. The genotoxic potential of the metabolite was extensively discussed during the EU assessment and finally considered unlikely to be genotoxic. The ADI of the parent fluazifop-P is applicable to Compound X. The ARfD of Compound X is 0.6 mg/kg bw based on the NOAEL of 60 mg/kg bw per day for maternal and developmental toxicity in rat, 100 safety factor applied. JMPR considered compound X unlikely to be genotoxic but considered that this requires confirmation. JMPR also considered that the metabolite may be more acutely toxic than parent in mice on the basis of clinical signs observed in the *in vivo* MN test in mice. EFSA would support these conclusions, in particular further confirmation of the non-genotoxic potential of the metabolite			

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.18.3. Residue definitions – fluazifop-P-butyl

In the following Table 85 the residue definitions for enforcement and risk assessment purpose are compared:

Table 85: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2015j)
RD-enf	Plant commodities	Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop The residue is fat soluble
	Animal commodities	Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid	
RD-RA	Plant commodities	Sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy) pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid	
	Animal commodities	Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid The residue is fat soluble	

Comments:
The EU residue definition covers not only the *R*-enantiomer (fluazifop-P) but all constituent isomers while JMPR restricted the residue definition to fluazifop-P butyl, fluazifop-P-acid and their conjugates. Since the analytical methods do not allow to discriminate between fluazifop-P and fluazifop-S (and the related metabolites), it would seem more appropriate to include the *S*-enantiomer in the JMPR residue definition, considering that the residue trials were also analysed for the total fluazifop residues (*R*- and *S*-isomer).
It is noted that JMPR included a number of metabolites in the risk assessment residue definition for plants which are not covered by the EU residue definition (i.e. 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL) and 5-trifluoromethyl-2-pyridone (X)). Since these metabolites were not analysed in the residue trials, JMPR used adjustments factors derived from the metabolism studies and molecular weight correction factors to cover their contribution to the risk exposure calculation (see also the risk consumer section). The adjustment factor however was not used for calculating the dietary burden in livestock. 5-Trifluoromethyl-2-pyridone (X) metabolite was found in significant amounts in the rational crops studies, representing > 60% in most crop commodities. The inclusion of this metabolite in the EU residue definition should be considered.
RD for animal commodities: Apart the fact that the JMPR residue definition for animal commodities is restricted to the active isomer (i.e. fluazifop-P), the residue definition at EU and JMPR level are comparable

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.18.4. Codex MRL proposals – fluazifop-P-butyl

In the Table 86, the Codex MRL proposals are compared with the EU MRLs.

Table 86: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL/art 12 EFSA	Comment
Citrus fruits	0.01*	0.2 except oranges 0.1/0.01*	The proposed Codex MRL was derived from a mixed data set of trials in citrus fruit, pome fruit, stone fruit, grapes, olives, bananas, tree nuts, coffee beans performed in different locations and reflecting different GAPs. The heterogeneous data set was considered sufficient to assume a no residue situation. Considering that fluazifop-P-butyl is an herbicide, the proposed Codex MRL is considered acceptable
Pome fruits	0.01*	0.5 except apples and pears 0.2/0.01*	See comments on citrus fruit
Stone fruits	0.01*	0.5 except peach 0.2/0.01*	See comments on citrus fruit
Cane berries	0.01*	0.2/0.01* (cane fruits)	The proposed Codex MRL is acceptable
Currants, black, red, white	0.01*	0.2/0.1	The proposed Codex MRL is based on 3 residue trials (2 on currants and 1 on gooseberries) matching the UK GAP (1 × 0.38 kg ai/ha, leaves unfolding to bud burst). All results were below 0.05 mg/kg; the MRL proposal is based on the non-residue situation for weed directed sprays and the LOQ of the enforcement method. The proposed Codex MRL is considered to be sufficiently supported by data
Gooseberries	0.01*	0.2/0.1	See comment on currants
Grapes	0.01*	0.2/0.01*	The proposed Codex MRL is acceptable. Based on significantly overdosed residue trials, a no residue situation was demonstrated
Strawberries	**0.3**	0.2/0.2 (ft)	The proposed Codex MRL is based 15 scaled residue trials conducted in the EU (NEU and SEU trials were pooled) representative for the Dutch and French GAP (1 × 0.38 kg/ha PHI 42 days). The proposed Codex MRL is supported by data The EU MRL was derived from the critical SEU GAP (identical with the GAP assessed by JMPR). Since only 7 SEU trials were provided, the MRL will be reviewed in 2018

Commodity	Codex MRL proposal	EU MRL/art 12 EFSA	Comment
Table Olives	0.01*	0.2/0.01*	See comments on citrus fruit
Olives for oil production	0.01*	0.2/0.01*	See comments on citrus fruit
Banana	0.01*	0.2/0.01*	See comments on citrus fruit
Onion, Bulb	0.3	0.3	The Codex MRL proposal is based on ten scaled trials representative for the US GAP (2 × 0.42 kg/ha, PHI 45 days) The extrapolation to garlic and shallots is proposed. The proposed Codex MRL is acceptable
Garlic	0.3	2/0.3	See the comments on onion
Shallots	0.3	2/0.3	See the comments on onion
Cabbages, Head	**3**	0.3/0.01*	The French GAP was identified as the critical GAP (1× 0.25 kg/ha, PHI 42 days). The proposed MRL is derived from 6 residue trials compliant with the GAP At EU level, head cabbage is major crop and at least 8 GAP compliant trials would be required. Thus, the proposed Codex MRL is not sufficiently supported by data. In addition, an acute exposure risk was identified. See consumer risk calculation
Eggplant	0.4	0.5/1	The MRL proposal was derived from residue trials in tomatoes that were extrapolated to eggplants. The extrapolation is acceptable
Tomato	**0.4**	0.3/0.01*	The proposed Codex MRL is based on eight under dosed trials (1 × 0.31 kg/ha, PHI 35–42 days) that were scaled to match the French GAP (0.38 kg/ha, PHI 35 days). It is noted that in the EU MRL review 16 residue trials representing a slightly less critical SEU GAP were submitted (1 × 0.31 kg/ha, 30-day PHI). No NEU GAP was reported. It seems that some of the trials were also assessed by/provided to JMPR. Apparently, 5 trials with the highest residues were not available to JMPR Considering that in the EU MRL review EFSA identified an acute exposure concern, the EU MRL was lowered to the LOQ and consequently the SEU GAP should have been revoked. Thus, the basis for the Codex MRL proposal (French GAP) is not valid
Lettuce, Leaf	0.01*	0.2/0.02	The proposed Codex MRL is based on 7 residue trials on open leaf lettuce, matching the Brazilian GAP (1 × 0.25 kg/ha, PHI 28 days) (± 25%). In none of the trials, quantifiable residues were found (< 0.01 mg/kg). The proposed Codex MRL is sufficiently supported by data
Beans, except broad bean and soya bean (green pods and immature seeds)	**6**	1/1.5	The proposed Codex MRL is based on 14 trials approximating the Belgium GAP (1 × 0.38 kg/ha, PHI 28 days). For this Codex MRL proposal, EFSA identified an acute exposure risk (see section on consumer risk assessment) In the EU MRL review, the same NEU GAP was assessed. From the NEU trials, a MRL of 0.9 mg/kg was derived. Based on the residue trials reflecting the SEU GAP (1×.31 kg/ha, 28-day PHI), a MRL of 1.5 mg/kg was derived. The data submitted in support of the EU MRL review were different to the trials assessed by JMPR (the residue trials leading to the highest residues were not available or were not considered valid in the EU). JMPR pooled NEU and SEU trials

Commodity	Codex MRL proposal	EU MRL/art 12 EFSA	Comment
Peas (pods and succulent = immature seeds)	**2**	1/1.5	The proposed Codex MRL is based on 5 residue trials matching the Belgium GAP (1 × 0.38 kg/ha, PHI 28 days) within the tolerance 25%. The proposed Codex MRL is acceptable It is noted that for the EU MRL review no trials on peas were provided. Instead, the MRL derived for beans with pods was extrapolated to peas
Peas, shelled (succulent seeds)	**15**	1.5	The proposed Codex MRL is based on 6 trials approximating matching the Dutch GAP (0.38 kg/ha, PHI 56 days). EFSA noted an acute intake concern (see section on consumer risk assessment) The EU MRL was derived from pooled NEU and SEU residue trials reflecting the same application rate but a shorter PHI (35-day PHI). Apparently, the residue trials with longer PHI lead to higher residues. The EU MRL should be reviewed whether the submitted trials represented the worst case in terms of residue concentration expected in the harvested product and dietary exposure
Beans (dry)	**40**	4	The proposed Codex MRL is based on 12 US trails matching the US GAP (2 × 0.42 kg ai/ha, PHI 59–75 days) (± 25% deviation). EFSA noted an acute intake concern (see section on consumer risk assessment)
Field pea (dry)	3	5/4	The proposed Codex MRL is based on 14 NEU trials matching the Belgium GAP (1 × 0.38 kg/ha, application before bloom). The proposed Codex MRL is acceptable
Soya bean (dry)	15	5/15	The proposed Codex MRL is based on 12 trials from Brazil, Italy, France (N+S) which were scaled to match the cGAP from Brazil (1 × 0.25 kg/ha, PHI 60 days). The proposed Codex MRL is acceptable
Carrot	**0.6**	0.3/0.3 (ft)	The proposed Codex MRL was derived from 7 trials approximating the EU GAP (1 × 0.38 kg/ha, PHI 56 days). JMPR pooled the trials from UK and Southern France. EFSA noted an acute intake concern (see section on consumer risk assessment) In the framework of the EU MRL review, apparently, different residue trials were submitted. Since for the NEU GAP an exceedance of the ARfD was identified, the data from SEU were used to derive a lower MRL
Celeriac	0.4	0.5	The proposed Codex MRL is based on 4 French trials approximating the NEU GAP (1 × 0.38 kg/ha PHI 56 days). The proposed Codex MRL is acceptable
Potato	**0.6**	0.1/0.15	The proposed Codex MRL is based on 10 residue trials performed in Brazil, Southern France, Germany that were scaled to match the Brazilian GAP (1 × 0.25 kg/ha, PHI 28 days). The representativeness of German trials for Brazil is questionable. EFSA noted also an acute intake concern (see section on consumer risk assessment)
Sugar beet	0.5	0.5	The proposed Codex MRL is based on residue trials representing the UK GAP (1× 0.38 kg/ha, 56-day PHI). The proposed MRL is acceptable

Commodity	Codex MRL proposal	EU MRL/art 12 EFSA	Comment
Swede	**4**	0.5	The proposed Codex MRL is based on 4 residue trials in turnips, matching the GAP from Belgium (1 × 0.38 kg/ha, 56-day PHI) within the 25% tolerance. EFSA noted an acute intake concern (see section on consumer risk assessment) The EU MRL was derived in the MRL review on the basis of residue trials in carrots and celeriac, reflecting the Belgium GAP (see above). Apparently, the residue trials in turnips were not submitted in the MRL review process in the EU, biasing the results of the MRL assessment
Turnip, Garden	**4**	0.5	See comment on swede
Sweet potato	**2**	0.3/0.01*	The proposed Codex MRL is based on 6 trials matching the US GAP (4 × 0.21 kg/ha, PHI 14 days) ±25% tolerance. EFSA noted an acute intake concern (see section on consumer risk assessment)
Yams	**2**	0.3/0.15	The proposed MRL was derived by extrapolation from sweet potatoes. An intake concern was identified also for yams
Sugar cane	0.01*	0.05*/0.01*	The proposed Codex MRL is based on four trials matching the critical Brazilian GAP (desiccant use, 1 × 0.075 kg/ha, PHI 42 days) ±25% tolerance. Since no residue situation occurred (<0.01 mg/kg), the number of trials was considered sufficient. The proposed Codex MRL is acceptable
Almonds	0.01*	0.2/0.01*	See comments on citrus fruit
Macadamia nuts	0.01*	0.2/0.01*	See comments on citrus fruit
Pecan	0.01*	0.2/0.01*	See comments on citrus fruit
Walnuts	0.01*	0.2/0.01*	See comments on citrus fruit
Cotton seed	**0.7**	15/0.01*	The proposed Codex MRL is based on 22 residue trials matching the US GAP (2 × 0.42 kg/ha, PHI 90 days) ±25% tolerance. The proposed Codex MRL is acceptable
Sunflower seed	**7**	0.2/0.1	The proposed Codex MRL is based on 8 trials from Brazil, Italy and Spain that were partially scaled to match the critical GAP from Brazil (1 × 25 kg/ha, PHI 59 days). While half of the trials had no quantifiable residues, in four trials significant residues up to 3.7 mg/kg were found. It is noted that for the EU GAP (1 × 0.38 kg/ha, PHI 90 days) residues were all at or below 0.06 mg/kg. The reason for the extremely high residues found in the residue trials used by JMPR to derive the MRL proposal should be examined
Coffee beans	0.01*	0.1/0.05*	See comments on citrus fruit
Meat (from mammals other than marine mammals)	**0.09(fat)**	0.05*/0.02 (ft)	The proposed Codex MRL is derived from a feeding study where the highest dosing level was lower than the calculated maximum DB for beef cattle (10.3 ppm highest feed level, 13.8 ppm estimated dietary burden). See also the general comment on animal commodities. In general, in the EU in addition to the MRL for fat, an MRL would be set for muscle
Mammalian fats (except milk fats)	**0.09**	0.05*/0.04 (ft)	See comment on meat
Edible offal (mammalian)	**0.2**	0.05*/0.03 (liver); 0.07 all kidney except swine 0.06	See comment on meat
Milks	**0.2**	0.1/0.08 (ft)	The MRL proposal is plausible It is noted that a MRL proposal for milk fat should be derived, considering that fluazifop residues were classified as fat soluble

Commodity	Codex MRL proposal	EU MRL/art 12 EFSA	Comment
Poultry meat	**0.03**	0.05*/0.02 (ft)	The Codex MRL proposal for meat is based on the results of a feeding study where the residues were analysed in 'mixed tissues of fat and muscle' without specifying the ratio of fat and muscle. Thus, the appropriateness of the MRL proposal cannot be verified See also the general comment on animal commodities. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Poultry fats	**0.03**	0.05*/0.02 (ft)	See comments on poultry fat See also the general comment on animal commodities
Poultry, Edible offal of	**0.09**	0.05*/0.04 (ft)	The MRL proposal is plausible See also the general comment on animal commodities
Eggs	**0.03**	0.05*/0.02 (ft)	The proposed MRL is plausible See also the general comment on animal commodities
General comment: It is highlighted that the proposed Codex MRL are not acceptable for head cabbages, beans (green pods and immature seeds), peas shelled (succulent seeds), beans (dry) carrot, potatoes, sweet potatoes, yams, swedes, turnips, since an acute intake consumer was identified for the European consumers. General comment on animal commodities: It is noted that for the dietary burden calculation the contribution of metabolite X was not taken into account. Thus, the STMR/HR values derived for total fluazifop-P were not multiplied by the adjustment factors. Thus, the calculated dietary burden may underestimate the livestock exposure			

MRL: maximum residue limit; GAP: Good Agricultural Practice; ai: active ingredient; LOQ: limit of quantification; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union.
*: Indicates that the MRL is set at the limit of quantification.

6.18.5. Consumer risk assessment – fluazifop-P-butyl

The result for the consumer risk assessment is presented in Table 87.

Table 87: Summary of the consumer risk assessment for fluazifop-P-butyl

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs than the EU MRLs, using the HR/STMR as derived by JMPR. It should be noted that, since the residue definition for the risk assessment at JMPR level comprises additional metabolites, not analysed in the field trials, compensated by the adjustments factors. These factors were derived from the metabolism studies and the molecular weight The EU ARfD was used **Results:** The risk assessment identified consumer risks for swedes (1,460% of the ARfD), head cabbage (1,145% of the ARfD, turnips (1,014%), potatoes (904%), yams (512%), turnips (422%) peas (without pods) (390%), beans with pods (327%), beans (258%), carrots (257%), sweet potatoes (240%), beans (without pods) (200%) of the ARfD) It should be highlighted that the exceedance of the ARfD is not impacted by the use of the adjustments factors anyway For the remaining crops, no short-term consumer health risk was identified	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2016e) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL The EU ADI was used **Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 71.5% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to milk (38% of the ADI), followed by sweet potatoes (35%) and beans (dry) (19%)	JMPR did not identify acute intake risks, but an exceedance of the ADI was noted for Cluster diet 16

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.19. Flupyradifurone (285) (R)

6.19.1. Background information

Flupyradifurone was assessed by JMPR for the new uses. In the Table 88 some background information on flupyradifurone is presented.

Table 88: Background information on flupyradifurone

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009	Commission Implementing Regulation (EU) 2015/2084[(a)]	NL	EFSA conclusion (incl. MRL setting)	Yes	EFSA (2015a) In the framework of the approval process, MRLs were established for a number of crops
			MRL review	No	–
			MRL applications	Yes	Strawberries, blackberries and raspberries: EFSA (2016a)

(a): 2015/2084: Commission Implementing Regulation (EU) 2015/2084 of 18 November 2015 approving the active substance flupyradifurone, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 302, 19.11.2015, p. 89–92.

6.19.2. Toxicological reference values – flupyradifurone

The following toxicological reference values derived at EU level and by JMPR are presented in Table 89.

Table 89: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.08 mg/kg bw per day	Rat, two-generation study, SF 100; NOAEL 7.8 mg/kg bw per day calculated from 100 ppm	0.064 mg/kg bw per day	EFSA (2015a), (Rat, two-generation study, with safety factor 100)
ARfD	0.2 mg/kg bw	(Rabbit, developmental study, SF 100; NOAEL 15 mg/kg bw per day)	0.15 mg/kg bw	EFSA (2015a), (Rabbit, developmental study, with safety factor 100)

Conclusion:
The ADI/ARfD values derived by JMPR were presented in the 2016 CCPR meeting. The EU delegation did not raise a concern/reservation.
Regarding DFA (metabolite found in plants, livestock and environment, the peer review experts concluded that the reference values of the parent are applicable

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.19.3. Residue definitions – flupyradifurone

In the following Table 90 the residue definitions for enforcement and risk assessment purpose are compared:

Table 90: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2015a)
RD-enf	Plant commodities	Flupyradifurone	1) Flupyradifurone 2) DFA (expressed as DFA)
	Animal commodities	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents	

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2015a)
RD-RA	Plant commodities	Sum of flupyradifurone, difluoroacetic acid and 6-chloronicotinic acid, expressed as parent equivalents	Sum flupyradifurone and DFA expressed as flupyradifurone The residue is not fat soluble (EFSA, 2015a)
	Animal commodities	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents The residue is not fat soluble	

Comments:
The residue definitions derived by JMPR and established in the EU are not fully compatible. In the EU, in addition to MRLs for the parent compound, MRLs are set for the metabolite difluoroacetic acid (DFA). DFA residues are expected in rotational crops.
The JMPR residue definition for risk assessment for plants is wider than the respective EU residue definition, covering also the metabolite 6-chloronicotinic acid, a metabolite that is not specific for flupyradifurone (this metabolite is also observed in metabolism of other neonicotinoids).

Due to the discrepancies regarding the enforcement residue definition for animal products, the Codex MRLs for animal products are not compatible with the EU MRL legislation.
For plant products, specific MRLs for DFA need to be set in the EU. No corresponding MRLs are proposed by JMPR

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.19.4. Codex MRL proposals – flupyradifurone

In the Table 91, the Codex MRL proposals are compared with the EU MRLs.

Table 91: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Alfalfa hay (dry weight)	30	–	–
Apples, dried	2	–	–
Beans, dry	**0.4**	0.01*	The proposed MRL is based on 9 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR, JMPR added the mean residue found in rotational crop studies in dry field peas (i.e. 2.49 mg/kg) to the STMR for beans dry. See general comments below
Beans, shelled (succulent = immature seeds)	**0.2**	0.01*	The proposed MRL is based on 8 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in French beans (i.e. 0.98 and 1.8 mg/kg) to the STMR and HR for beans. See general comments below
Beans, except broad bean and soya bean (green pods and immature seeds)	**1.5**	0.01*	The proposed MRL is based on 9 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in French beans (i.e. 0.98 and 1.8 mg/kg) to the STMR and HR for beans. See general comments below
Bean hay (dry weight)	30	–	–
Bulb vegetables, except Fennel, Bulb	0.01*	0.01*	No use was reported for bulb vegetables. The MRL was proposed to be set at the LOQ. However, JMPR derived risk assessment values from rotational crop studies in leek (STMR: 0.18 mg/kg, HR: 0.39 mg/kg; no residues of parent were found). See general comments below

Commodity	Codex MRL proposal	EU MRL	Comment
Bush berries	**4**	0.01* (currant, gooseberries, cowberry, bearberry, huckleberries, rosehips, seabuckthom)	The MRL proposal is based on 8 residue trials in blueberries which were extrapolated to the whole group which also covers blueberries, currants, gooseberries, rosehips and related minor crops At EU level, this extrapolation is not foreseen
Cabbages, Head	**1.5**	0.01*	The proposed MRL is based on 9 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in lettuce (i.e. 0.12 mg/kg and 0.41 mg/kg) to the STMR and HR for cabbage (i.e. 0.36 and 2.6 mg/kg). See general comments below
Cauliflower	**6**	0.01*	The proposed MRL is based on 6 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI). In the EU, at least 8 trials would be required, but 6 trials may be in line with the JMPR requirements. For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in lettuce (i.e. 0.12 mg/kg and 0.41 mg/kg) to the STMR and HR for cauliflower (i.e. 0.36 and 2.6 mg/kg). See general comments below
Celery	**9**	0.03 (ft)	The proposed MRL is based on 10 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in leek (i.e. 0.18 and 0.39 mg/kg) to the STMR and HR for celery (i.e. 2.2 and 6.8 mg/kg). See general comments below. An exceedance of the ARfD was identified. See also below EFSA RA
Cereal grains (except maize and rice)	**3**	0.01*	JMPR received 20 trials in barley, 29 trials in wheat and 9 in sorghum, all reflecting the US GAP (2 × 205 g ai/ha, 21-day PHI). Although the statistical test demonstrated that the data sets are statistically different, they were pooled to derive a MRL for the whole group of cereals, because the mean resides differed less than fivefold It would be appropriate to set separate MRLs for wheat/rye, barley/oat and sorghum Extrapolation to buckwheat and millet would not be acceptable in the EU
Cotton seed	**0.8**	0.01*	The MRL proposal is based on 12 trials reflecting the US GAP. For deriving the STMR and HR, JMPR added the mean residue found in rotational crop studies in rape seed (i.e. 0.16 mg/kg) to the STMR for cotton (i.e. 0.235 mg/kg). See general comments below
Cucumber	0.4	0.6	The MRL proposal was derived from 9 residues (foliar application, 2 × 205 g/ha, PHI 1 days). JMPR did not derive an HR and STMR because in decline studies the residues did not reach a maximum Thus, EFSA is of the opinion that trials with sampling at longer PHIs would be required. Without having the possibility to perform a sound risk assessment, the MRL proposal is not acceptable. It is noted that for cucumber, results from rotational crop studies were not considered necessary
Dried grapes	8	–	–
Edible offal (Mammalian)	**4**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study

Commodity	Codex MRL proposal	EU MRL	Comment
Eggs	**0.7**	0.01*	A lower MRL would be sufficient (0.5 mg/kg)
Grapes	**3**	0.8	The proposed MRL is based on 11 residue trials reflecting the US GAP (2 × 205 g ai/ha, 0-day PHI)
Lemons and limes (including citron)	**1.5**	0.01*	The proposed MRL is based on 7 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI)
Lettuce, Head	4	5	The proposed MRL is based on 8 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI). For deriving the STMR and HR, JMPR did not see the need to add residue concentrations from rotational crop studies, because they were considered negligible, compared to the residues in primary crops (mean and highest residue found in rotational crop studies in lettuce: 0.12 mg/kg and 0.41 mg/kg). Residue decline studies should be checked whether residues are likely to increase with time
Lettuce, Leaf	**15**	5	The proposed MRL is based on 8 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI). The risk assessment performed with the HR derived from the primary crop residue trials lead to an exceedance of the ARfD. See also below EFSA RA
Mandarins	**1.5**	0.01*	The proposed MRL is based on 7 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI)
Mammalian fats (except milkfats)	**1**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study
Meat (from mammals otherthan marine mammals)	**1.5**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Maize	**0.015**	0.01*	JMPR received 16 trials in maize reflecting the US GAP (2 × 205 g ai/ha, 21-day PHI). In all trials, except 1, the residues were below the LOQ. The risk assessment values were derived by adding the mean residue from rotational crop studies in barley to the STMR in maize. See general comments below
Maize bran	0.05	–	–
Melons, except watermelon	**0.4**	0.01*	The proposed MRL is based on 5 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in cucumber (i.e. 0.44 mg/kg and 0.69 mg/kg) to the STMR and HR for melons (pulp). See general comments below
Milks	**0.7**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study
Mustard greens	**40**	0.01*	The proposed MRL is based on 8 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI) The risk assessment performed with the HR derived from the primary crop residue trials lead to an exceedance of the ARfD. See also below EFSA RA
Oranges, Sweet, Sour	**4**	0.01*	The proposed MRL is based on 10 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI)
Peanut	**0.04**	0.01*	The MRL proposal is based on 9 trials reflecting the US GAP. For deriving the STMR and HR, JMPR added the mean residue found in rotational crop studies in rape seed (i.e. 0.16 mg/kg and 0.26 mg/kg) to the STMR and HR for peanuts (i.e. 0.065 mg/kg and 0.09 mg/kg). See general comments below

Commodity	Codex MRL proposal	EU MRL	Comment
Peanut hay (dry weight)	30	–	–
Peas (dry)	**3**	0.01*	The proposed MRL is based on 10 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR, JMPR added the mean residue found in rotational crop studies in dry field peas (i.e. 2.49 mg/kg) to the STMR for beans dry. See general comments below
Pea hay (dry weight)	50		
Peas (pods and succulent =immature seeds)	**3**	0.01*	The proposed MRL is based on 6 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in French beans (i.e. 0.98 mg/kg and 1.8 mg/kg) to the STMR and HR for peas. See general comments below
Peas, shelled (succulent seeds)	**3**	0.01*	The proposed MRL is based on 6 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). In the EU, peas are considered major crop and therefore at least 8 trials would be required. For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in French beans (i.e. 0.98 mg/kg and 1.8 mg/kg) to the STMR and HR for peas. See general comments below
Pecan	**0.015**	0.01*	The proposed MRL is based on 5 trials reflecting the US GAP. All except one result was below the LOQ. The MRL proposal is acceptable
Peppers	**0.9**	0.9	The proposed MRL is based on 14 residue trials reflecting the US GAP (foliar use, 2 × 205 g ai/ha, 1-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in cucumbers (i.e. 0.44 mg/kg and 0.69 mg/kg) to the STMR and HR for peppers. See general comments below
Peppers Chilli, dried	9		The MRL proposal was derived from the data in peppers, using a standard dehydration factor of 10
Pome fruits	**0.9**	0.4 (all pome fruits except persimmons, 0.01*)	The proposed MRL is based on 9 residue trials in pears reflecting the US GAP (2 × 205 g ai/ha, 10-day PHI). In addition, 10 residue trials in apples were provided (same GAP). Since the residues in pears were higher (U-Test identified they do not belong to the same population), the MRL was calculated from the trials in pears only. For apples, a MRL of 0.5 mg/kg would be sufficient
Potato	**0.05**	0.01*	The proposed MRL is based on 20 residue trials reflecting the US GAP (foliar use, 2 × 205 g ai/ha, 7-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in potatoes (i.e. 0.23 mg/kg and 0.43 mg/kg) to the STMR and HR for potatoes. See general comments below
Poultry fats	**0.3**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study
Poultry meat	**0.8**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study. In general, the MRLs for meat would not be taken over in the EU legislation, due to the different policy to set MRLs for muscle
Poultry, Edible offal of	**1**	0.01*	The proposed MRL seems to be consistent with the calculated dietary burden and the feeding study

Commodity	Codex MRL proposal	EU MRL	Comment
Pummelo and Grapefruits	**0.7**	0.01* (grapefruits)	The proposed MRL is based on 6 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI)
Root and tuber vegetables (except potato)	**0.7**	0.01*	The proposed MRL is based on 10 residue trials in carrots and 7 trials in radish (merged data sets) reflecting the US GAP (foliar use, 2 × 205 g ai/ha, 7-day PHI). The applied extrapolation by the JMPR is not in line with the acceptable EU extrapolations. Extrapolation from carrots would only be possible to the subgroup 'other root and tuber vegetables except sugar beets'. Subsequently, MRLs for these crops could be proposed For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in carrots and turnip roots (i.e. 0.1 mg/kg and 0.27 mg/kg) to the STMR and HR for root and tuber vegetables. See general comments below
Soya bean (dry)	**1.5**	0.01*	The proposed MRL is based on 20 residue trials reflecting the US GAP (2 × 205 g ai/ha, 21-day PHI). For deriving the STMR, JMPR added the mean residue found in rotational crop studies in dry field peas (i.e. 2.49 mg/kg) to the STMR for beans dry. See general comments below
Soya bean hay (dry weight)	40		
Spinach	**30**	0.03 (ft)	The proposed MRL is based on 9 residue trials reflecting the US GAP (2 × 205 g ai/ha, 1-day PHI). The risk assessment performed with the HR derived from the primary crop residue trials lead to an exceedance of the ARfD. See also below EFSA RA
Straw and fodder, dry of cereal grains (dry weight)	40		
Strawberry	**1.5**	0.05*	The proposed MRL is based on 10 residue trials reflecting the US GAP (2 × 205 g ai/ha, 0-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in French beans (i.e. 0.98 mg/kg and 1.8 mg/kg) to the STMR and HR for strawberries (i.e. 0.525 and 0.94 mg/kg). Thus, the HR and the STMR were calculated to be 2.74 mg/kg and 1.5 mg/kg, respectively. This approach is not a standard practice and should be further discussed The use of rotational crops studies with strawberries would be the preferred option. Data from other fruiting crops (e.g. cucumbers) could be considered as alternative (see also draft OECD guidance document on rotational crops)
Squash, Summer	0.2	0.6	The proposed MRL is based on 8 residue trials reflecting the US GAP (foliar use, 2 × 205 g ai/ha, 1-day PHI). For deriving the STMR and HR, JMPR used the results of residue trials reflecting the soil use pattern (US GAP: 1× 409 g ai/ha, 21-day PHI) and added the mean and highest residue found in rotational crop studies in cucumbers (i.e. 0.44 mg/kg and 0.69 mg/kg) to the STMR and HR for summer squash. See general comments below In cucumbers, the decline studies gave an indication that the residues may increase with longer PHI. Thus, considering that in summer squash similar residue behaviour may be observed, the decline studies on summer squash should be checked again to ensure that the MRL proposal and the STMR/HR reflect the worst case situation

Commodity	Codex MRL proposal	EU MRL	Comment
Sweet corn (corn-on-the-cob)	**0.05**	0.01*	The proposed MRL is based on 13 residue trials reflecting the US GAP (2 × 205 g ai/ha, 7-day PHI). For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in barley grain (i.e. 0.43 mg/kg and 1.3 mg/kg) to the STMR and HR for sweet corn (i.e. 0.13 and 0.29 mg/kg). See general comments below
Sweet potato	**0.05**	0.01*	MRL proposal derived by extrapolation from potatoes
Tomato	**1**	0.7	The proposed MRL is based on 19 residue trials reflecting the US GAP (foliar use, 2 × 205 g ai/ha, 1-day PHI) For deriving the STMR and HR, JMPR added the mean and highest residue found in rotational crop studies in cucumber (i.e. 0.44 mg/kg and 0.69 mg/kg) to the STMR (foliar use) and HR derived from the soil application) in tomatoes. See general comments below In cucumbers, the decline studies gave an indication that the residues may increase beyond the PHI. Thus, considering that in tomatoes similar residue behaviour may be observed, the decline studies on tomatoes should be checked again to ensure that the MRL proposal and the STMR/HR reflect the worst case situation
Wheat bran, unprocessed	8	–	For processed commodities, only one processing study was available, respectively
Wheat germ	5	–	
Wheat wholemeal	5	–	

General comment:
The application rate tested in rotational crop studies is not clearly reported; from the available documentation it seems that the worst-case GAP in primary crop is higher than the application rate of rotational crop study (cucurbits: 409 g ai/ha).
For many crops, the STMR and HR values were calculated by adding the mean and highest residue found in rotational crop studies to the STMR and HR derived from the primary crop residue trials. The detailed conditions for applying this approach should be further discussed.
It was noted that for cucumbers residues in primary crops following soil application were lower than the results of rotational crops studies. This unexpected finding should be explained.
JMPR did not propose MRLs for broccoli due to insufficient residue trials. However, since residues may occur in broccoli grown in crop rotation, an STMR and HR should be derived to perform the risk assessment.
An application for import tolerances is currently ongoing and the Netherlands are currently finalising Evaluation Report

MRL: maximum residue limit; GAP: Good Agricultural Practice; ai: active ingredient; PHI: preharvest interval; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; RA: risk assessment; OECD: Organisation for Economic Co-operation and Development.
*: Indicates that the MRL is set at the limit of quantification.

6.19.5. Consumer risk assessment – flupyradifurone

The result for the consumer risk assessment is presented in Table 92.

Table 92: Summary of the consumer risk assessment for flupyradifurone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR as derived by JMPR The EU ARfD was used The risk assessment is tentative since the EU and JMPR residue definitions for risk assessment are different Since the JMPR residue definition comprises one additional metabolite, the result of the risk assessment may slightly overestimate the acute exposure according to the EU residue definition **Results:** The risk assessment identified potential consumer risks for mustard greens (equivalent to Chinese cabbage) (620% of the ARfD), spinach (290%), celery (220%), oranges (195%), lettuce leaves (140%), cauliflower (130%), melons (110%); slight exceedances were also noted for table grapes and peppers (100.4% and 100.3%, respectively) For the remaining crops, no short-term consumer health risk was identified	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2016a) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL The EU ADI was used The risk assessment is tentative, since the EU and JMPR residue definitions are different **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 45% of the ADI The highest contribution of the crops under consideration (expressed as percentage of the ADI) were: • wheat: 17% of the ADI • spinach: 9.4% • rye: 9% • apples: 8.5%	JMPR identified an exceedance of the ARfD for mustard greens, spinach, lettuce leaf and celery

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.20. Acibenzolar-S-methyl (288) (T/R)

6.20.1. Background information

Acibenzolar-S-methyl was assessed by JMPR for the first time. In the Table 93, some background information on acibenzolar-S-methyl is presented.

Table 93: Background information on acibenzolar-S-methyl

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC and renewed	Commission Directive 2001/87/EC[(a)]	FR	EFSA conclusion	Yes	EFSA (2014g)
			MRL review	Yes	EFSA (2013b)
			MRL applications	Yes	Lettuce EFSA (2012c), Peaches and apricots EFSA (2009b), Kiwi, under assessment

(a): 2001/87: Commission Directive 2001/87/EC of 12 October 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl as active substances. OJ L 276, 19.10.2001, p. 17–20.

6.20.2. Toxicological reference values – acibenzolar-S-methyl

The following toxicological reference values derived at EU level and by JMPR are presented in Table 94.

Table 94: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2014g)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.08 mg/kg bw per day	Rat, 2-year study, 100 UF	0.03 mg/kg bw per day	Rat, developmental toxicity study, 300 UF
ARfD	0.5 mg/kg bw	Rat developmental toxicity study, 100 UF	0.03 mg/kg bw	Rat, developmental toxicity study, 300 UF

Conclusion:
The ADI set by the JMPR is based on the NOAEL of 7.77 mg/kg bw per day for haemosiderosis in the spleen observed in a 2-year study in rats. The ARfD is based on a NOAEL of 50 mg/kg bw per day for early decreased maternal feed consumption and equivocal increase in malformations in a rat developmental toxicity study.
The EU evaluation based both the ADI and ARfD on a developmental toxicity study in rats where malformations (defects of the abdominal wall – umbilical hernia) were observed at the LOAEL of 10 mg/kg bw per day in the absence of maternal toxicity, which may require classification regarding developmental toxicity. An increased uncertainty factor (UF) of 300 was applied (standard 100 and additional 3) since the point of departure is a LOAEL.
A different conclusion was reached between the JMPR and EU evaluations with regards to the interpretation of the results of the developmental toxicity studies in rats. EFSA supports the interpretation given by the EU evaluation.
The reference values for acibenzolar-S-methyl apply to the metabolite CGA 210007 (acibenzolar acid). However, insufficient toxicological information has been provided to conclude on the toxicological profile of the other metabolites CGA 323060 (4-OH acibenzolar acid) and CGA 324041

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.20.3. Residue definitions – acibenzolar-S-methyl

In the following Table 95, the residue definitions for enforcement and risk assessment purpose are compared:

Table 95: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid) (free and conjugates), expressed in terms of acibenzolar-S-methyl	Acibenzolar-S-methyl (sum of acibenzolar- S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl
	Animal commodities	The residue is not fat soluble	Peer review (EFSA, 2014g): Not necessary due to low livestock exposure, even considering all registered uses at EU level, and low level of residues in available metabolism studies Reg. 396/2005: same RD as for plant commodities The residue is not fat soluble (EFSA, 2014g)
RD-RA	Plant commodities	Sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid), (free and conjugated) and 1,2,3-benzothiadiazole-4-hydroxy-7-carboxylic acid (4-OH acibenzolar acid) (free and conjugated), expressed as acibenzolar-S-methyl	Sum of acibenzolar-S-methyl and acibenzolar acid and its conjugates expressed as acibenzolar-S-methyl (EFSA, 2013b) Peer review (EFSA, 2014g): depending on residue and tox data the metabolite 4-OH acibenzolar acid could be considered in residue definition (this metabolite was mainly identified in metabolism studies in leafy crops)

	Commodity group	JMPR evaluation	EU evaluation
	Animal commodities	Sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid) (free and conjugates), expressed in terms of acibenzolar-S-methyl	EFSA, 2013b, 2014g: Not necessary

Comments:
The enforcement residue definitions derived by JMPR and at EU level are comparable.
For plant commodities, the JMPR risk assessment residue definition is wider (covering metabolite 4-OH acibenzolar acid). This metabolite was only of relevance for leafy crops. An adjustment factor of 1.5 was used by JMPR to derive the risk assessment input values since the leafy crops were analysed only for the residue definition proposed for enforcement

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.20.4. Codex MRL proposals – acibenzolar-S-methyl

In the Table 96, the Codex MRL proposals are compared with the EU MRLs.

Table 96: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex EMRL proposal	EU MRL	Comment
Apple	**0.3**	0.1	The proposed Codex MRL is based on 16 residue trials in apples, reflecting the Italian GAP. The proposal is acceptable
Banana	0.06	0.08	The MRL proposal is based on 15 trials in unbagged banana that according to JMPR should reflect the GAP of some Latin American countries (40 g/ha, 30–40-day interval, PHI 0 days)
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	**0.7**	0.01*	The proposed MRL is based on overdosed residue trials in cabbages and broccoli (scaled to match with the US GAP, i.e. 4 × 35 g/ha, 7-day PHI). The extrapolation would not be acceptable in the EU See result of risk assessment below
Brassica leafy vegetables	**1**	0.01*	The proposed MRL is based on 5 scaled trials on mustard greens reflecting the US GAP which were extrapolated to the whole group. The number of trials would not be sufficient in the EU See result of risk assessment below
Citrus fruits	**0.015**	0.01*	The proposed Codex MRL is based on a data set of 10 trials in oranges, 5 trials in lemons and 6 trials in grapefruit, reflecting the US GAP (soil application under trees of 112 g/ha, PHI 0 days; max. rate per year: 448 g ai/ha) It is noted that no metabolism studies are available representative for soil treatment Residues in citrus fruits following soil treatment may increase over time. Thus, samples taken on the day of the treatment are most likely not leading to measurable residues
Edible offal (Mammalian)	0.02*	0.02*	The proposed MRL is acceptable
Eggs	0.02*	0.02*	The proposed MRL is acceptable

Commodity	Codex EMRL proposal	EU MRL	Comment
Fruiting vegetables, Cucurbits	**0.8**	0.01*	The proposed MRL is based on 12 scaled trials in melons reflecting the US GAP (8 × 35 g/ha which were extrapolated to the whole group It is noted that 4 trials summer squash and 11 trials in cucumbers were also available. However, since the data sets were found to be significantly different (Kruskal–Wallis test), these trials were not used. These trials indicate that for cucurbits (edible peel) a MRL of 0.6 mg/kg would be sufficient See result of risk assessment below
Garlic	**0.15**	0.01*	The MRL proposal derived from the residue trials in onions is acceptable
Kiwifruit	**0.03**	0.01*	The proposed MRL is based on 14 residue trials reflecting the NZ GAP (soil application of 4 × 100 g/ha; PHI 14 days) It is noted that no metabolism studies are available representative for soil treatment
Lettuce, Head	0.2	0.3	The proposed MRL is based on 6 trials. The proposal is acceptable
Lettuce, Leaf	**0.4**	0.3	The proposed MRL is based on 6 trials. The proposal is acceptable
Low growing berries (including strawberries)	**0.15**	0.01* strawberries, cranberries	The proposed MRL is based on 10 trials in strawberries reflecting the US GAP (26 g/ha, PHI 0 days). The extrapolation is not in line with the EU extrapolation rules
Mammalian fats (except milk fats)	0.02*	0.02*	The proposed MRL is acceptable
Meat (from mammals other than marine mammals)	0.02*	0.02*	The proposed MRL is acceptable
Milks	0.01*	0.01*	The proposed MRL is acceptable
Onion, Bulb	**0.15**	0.01*	The proposed MRL is sufficiently supported by data (12 trials reflecting the US GAP). The proposal is acceptable
Peaches (including nectarines and apricots)	0.2	0.2	The proposed Codex MRL is based 7 trials in peaches and 4 trials in apricots reflecting the Italian GAP. The proposal is acceptable
Poultry fats	0.02*	0.02*	The proposed MRL is acceptable
Poultry meat	0.02*	0.02*	The proposed MRL is acceptable
Poultry, Edible offal of	0.02*	0.02*	The proposed MRL is acceptable
Shallot	**0.15**	0.01*	The MRL proposal that was derived from the residue trials in onions is acceptable
Spinach	**0.6**	0.3	The proposed MRL is based on 7 trials. The proposal is acceptable, although the number of trials is slightly below the number of trials that would be required in the EU
Tomato	0.3	0.9	The proposed MRL is sufficiently supported by data. The proposal is acceptable
General comments: –			

MRL: maximum residue limit; GAP: Good Agricultural Practice; ai: active ingredient; PHI: preharvest interval.
*: Indicates that the MRL is set at the limit of quantification.

6.20.5. Consumer risk assessment – acibenzolar-S-methyl

The result for the consumer risk assessment is presented in the Table 97.

Table 97: Summary of the consumer risk assessment for acibenzolar-S-methyl

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs than the EU MRLs, using the HR/STMR as derived by JMPR The EU ARfD was used **Results:** The risk assessment identified potential consumer risks for melons (240% of the ARfD), watermelons (190% of the ARfD, broccoli (120%), cauliflower (140%), head cabbage (110%) and kale (180% of the ARfD) The exceedance of the ARfD for broccoli, cauliflower, head cabbage and kale are resulting from the different variability factor used in the IESTI equation (risk assessment methodology). For the remaining crops, the exceedance is related to the lower EU ARfD For the remaining crops, no short-term consumer health risk was identified	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2013b) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL The EU ADI was used **Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 4.2% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to cucumbers (1% of the ADI)	It is noted that in the acute RA of JMPR, kiwi fruit were not considered

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake; IESTI: International estimated of short-term intake.

6.21. Imazethapyr (289) (T/R)

6.21.1. Background information

Imazethapyr was assessed by JMPR for the first time. In the Table 98, some background information on imazethapyr is presented.

Table 98: Background information on imazethapyr

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Not approved under Directive 91/414/EC	Commission Decision 2004/129/EC[(a)]	–	EFSA conclusion	No	–
			MRL review	No	–
			MRL applications	No/Yes	Setting import tolerance of new MRLs in various crops: additional data requested

(a): 2004/129/EC: Commission Decision of 30 January 2004 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 37, 10.2.2004, p. 27–31.

6.21.2. Toxicological reference values – imazethapyr

The following toxicological reference values derived at EU level and by JMPR are presented in Table 99.

Table 99: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.6 mg/kg bw per day	Rat, 2-year study, 100 UF	–	–
ARfD	Unnecessary	–	–	

Conclusion:
The active substance has never been assessed at EU level. Thus, no EU toxicological reference values are available. It is noted that a dossier was submitted within an import tolerance application; as the dossier was incomplete, the evaluation has not been initiated.
The ADI derived by JMPR is based on a NOAEL of 55 mg/kg bw per day for decreased body weight gain in females in the 2-year study in rats. The setting of an ARfD was considered not necessary for imazethapyr by JMPR

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.21.3. Residue definitions – imazethapyr

In the following Table 100, the residue definitions for enforcement and risk assessment purpose are compared.

Table 100: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Sum of imazethapyr, 5-hydroxyethyl-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin2-yl)nicotinic acid, expressed as imazethapyr	No EU assessment completed
	Animal commodities	Sum of imazethapyr, 5-hydroxyethyl-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin2-yl)nicotinic acid, expressed as imazethapyr The residue is not fat soluble	
RD-RA	Plant commodities	Sum of imazethapyr, and 5-hydroxyethyl-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)nicotinic acid (OH-imazethapyr), and 5-[1-(β-D-glucopyranozyloxyethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)nicotinic acid (Glu-OH-Imazethapyr), expressed as imazethapyr	
	Animal commodities	Sum of imazethapyr, 5-hydroxyethyl-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin2-yl)nicotinic acid, expressed as imazethapyr	

Comments:
Imazethapyr is not listed in Annex II, III or IV of Regulation (EC) No 396/2005. Thus, the default residue definition covering only the parent compound is currently applicable.
The residue definition proposed by the EMS in the import tolerance request (currently on clock-stop) are not fully comparable with the JMPR residue definition; in contrast to the JMPR RD for enforcement for plants and animal products, in the import tolerance application the inclusion of the conjugate of the metabolite was suggested

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.21.4. Codex MRL proposals – imazethapyr

In the Table 101, the Codex MRL proposals are compared with the EU MRLs.

Table 101: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Clover hay or fodder	1.5 (dw)	0.01*	
Edible offal (Mammalian)	0.01*	0.01*	See mammalian fats
Eggs	0.01*	0.01*	No feeding study was available. However, from metabolism in laying hens it was concluded that no residues at or above the LOQ are expected at the calculated dietary burden
Lentil (dry)	**0.1***	0.01*	The proposed MRL is based on 6 trials in imidazolinone-tolerant lentils considered representative for the Canadian GAP. The data are considered sufficient
Maize	**0.1***	0.01*	No trials were available that matched the critical GAP from Argentina. JMPR based the MRL proposal on 18 US/CA trials in imidazolinone-tolerant maize (overdosed trials and trials where the last treatment was performed at a later growth stage); in all these trials the residues were below the LOQ
Maize fodder	0.1* (dw)	0.01*	
Mammalian fats (except milk fats)	0.01*	0.01*	The MRL proposal was derived from a feeding study in lactating cows; no residues are expected at the dietary burden resulting from the crops assessed by JMPR
Meat (from mammals other than marine mammals)	0.01*	0.01*	See Mammalian fats
Milks	0.01*	0.01*	See Mammalian fats
Peanut	**0.1***	0.01*	The proposed MRL is based on 5 overdosed trials scaled down to match the critical Argentinean GAP. The proposal is acceptable
Poultry fats	0.01*	0.01*	See Eggs
Poultry meat	0.01*	0.01*	See Eggs
Poultry, Edible offal of	0.01*	0.01*	See Eggs
Rape seed	**0.1***	0.01*	JMPR received 13 trials performed with exaggerated application rates (13 times overdosed) in imidazolinone-tolerant rape seed; since no residues above the LOQ were detected, the trials were considered acceptable. It is noted that the trials were not analysed for all components of the risk assessment residue definition (no results for Glu-OH-imazethapyr)
Rice	**0.1***	0.01*	The MRL proposal is based on 8 trials in imidazolinone-tolerant rice. In all trials, the residues were below the LOQ (RD for enforcement); in one trial residues above the LOQ were detected when analysed for the RD-RA
Rice straw and fodder, dry	0.15* (dw)	0.01*	
Soya bean (dry)	**0.03**	0.01*	The proposed MRL was derived from 8 US residue trials in glyphosate-tolerant soya beans that matched with the Brazilian GAP
Maize oil	–	0.01*	–
Soya bean oil, refined	–	0.01*	–

General comment:
It is noted that imidazolinone-tolerant varieties expressing variants of AHAS genes which give imidazolinone tolerance are commercially available (e.g. lentils, maize, rape seed). Import of these genetically modified varieties in the EU would require an approval in accordance with Regulation (EC) No 1829/2003

MRL: maximum residue limit; LOQ: limit of quantification; GAP: Good Agricultural Practice; RD-RA: residue definition for risk assessment.
*: Indicates that the MRL is set at the limit of quantification.

6.21.5. Consumer risk assessment – imazethapyr

The result for the consumer risk assessment is presented in Table 102.

Table 102: Summary of the consumer risk assessment for imazethapyr

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant	**RA assumptions:** EFSA calculated the exposure using the existing default MRLs and the STMR values derived by JMPR for the crops under consideration (only if the STMR is > 0.01 mg/kg) The JMPR ADI was used The risk assessment is tentative, since no decision on the EU toxicological reference values and the EU residue definition has been taken so far **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 0.1% of the ADI	–

RA: risk assessment; MRL: maximum residue limit; STMR: supervised trials median residue; ADI: acceptable daily intake.

6.22. Isofetamid (290) (T/R)

6.22.1. Background information

Isofetamid was assessed by JMPR for the first time. In the Table 103, some background information on isofetamid is presented.

Table 103: Background information on isofetamid

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009 (No authorisation in place)	Commission Implementing Regulation (EU) 2016/1425[(a)]	BE	EFSA conclusion (including MRL application)	Yes	EFSA (2015m)
			MRL review	No	Not applicable
			MRL applications	No	The UK has received applications as a following MS in the zonal authorisation process with the core assessment being undertaken by the zonal RMS which is Belgium

(a): 2016/1425: Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 231, 26.8.2016, p. 30–33.

6.22.2. Toxicological reference values – isofetamid

The following toxicological reference values derived at EU level and by JMPR are presented in Table 104.

Table 104: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.05 mg/kg bw per day	90-day and 1-year toxicity studies (dog), with uncertainty factor 100 Developmental toxicity study (rabbit) with uncertainty factor 100	0.02 mg/kg bw per day	EFSA (2015m), (dog, 1-year, with uncertainty factor 100) Developmental toxicity study (rabbit) with uncertainty factor 100
ARfD	3 mg/kg bw		1 mg/kg bw	

Conclusion:
Two different ADIs were set by JMPR and EFSA: JMPR based the ADI on the NOAEL of the 90-day evaluation in the 1-year dog study, while EFSA based the ADI on the 1-year dog study considered also by JMPR (NOAEL 1.57 mg/kg bw per day). Two different ARfDs were derived by JMPR and EFSA and were based on the same developmental toxicity study in rabbit: JMPR based the ARfD on a NOAEL of 300 mg/kg bw per day based on maternal (decreased body weight and food consumption) and embryo and fetal (skeletal anomalies) toxicity, while EFSA used a NOAEL of 100 mg/kg bw per day based on maternal (decreased food consumption and increased liver weight) and developmental (skeletal variations) toxicity.
EFSA approach regarding both reference values were supported by European Commission

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.22.3. Residue definitions – isofetamid

In the following Table 105 the residue definitions for enforcement and risk assessment purpose are compared:

Table 105: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Isofetamid	Isofetamid
	Animal commodities	Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl]phenoxy] propanoic acid (PPA), expressed as isofetamid The residue is fat soluble	Isofetamid
RD-RA	Plant commodities	Isofetamid	Sum isofetamid and *N*-{1-[4-(b-D-glucopyranosyloxy)-2- methylphenyl]-2-methyl-1-oxopropan-2-yl}-3-methylthiophene-2-carboxamide (GPTC), expressed as isofetamid
	Animal commodities	Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl]phenoxy] propanoic acid (PPA), expressed as isofetamid The residue is fat soluble	Provisional (not required): Sum isofetamid and PPA expressed as isofetamid Open (pending confirmation by livestock feeding study, not required at this stage)

Comments:
Residue definitions derived by JMPR and those applicable in the EU are different: in the enforcement residue definition for animal commodities, JMPR included the metabolite PPA while the risk assessment residue definitions for commodities of plant origin are wider in the EU, covering also the metabolite GPTC.
For this new active substance, EU MRLs have been recently established in Commission Regulation (EU) No 2017/171). EU MRLs set above the LOQ exist for grapes (table and wine), strawberries, lettuces, spinaches and similar leaves, and herbs and edible flowers. The EU peer review also assessed uses in apricots, cherries and oilseed rape (extrapolated to linseed, poppy seeds, mustard seed and gold of pleasure), for which an MRL of 0.01* mg/kg was deemed adequate

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.22.4. Codex MRL proposals – isofetamid

In the Table 106, the Codex MRL proposals are compared with the EU MRLs.

Table 106: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Almonds	0.01*	0.01*	The proposed MRL is based on 5 trials reflecting the US GAP. The proposal is acceptable
Almond hulls	0.8 (dw)	–	–
Dried grapes (= Currants, Raisins and Sultanas)	7	–	–
Edible offal (Mammalian)	**0.07**	0.01*	The proposed MRL was derived from the livestock metabolism study. Considering that at the highest estimated maximum dietary burden significant residues in ruminants are expected, taking into account the results of the goat metabolism study, a feeding study in ruminants should be provided It is noted that the HR/STMR/MRL derived by JMPR are wrong, as they were calculated using an incorrect level of isofetamid in liver (0.10 mg/kg) (see JMPR report p. 246). The correct residue concentration in liver found in the goat metabolism study is 0.01 mg/kg (see also JMPR report p. 236). Using the correct value for liver, the STMR/HR derived for liver according to the JMPR residue definition would be 0.026 mg/kg ((0.010+0.062) × 0.36) instead of 0.058 mg/kg. STMR/HR derived for kidney using JMPR approach is 0.0076 mg/kg Considering the re-calculated results, a lower MRL for edible offal would be appropriate (i.e. 0.03 mg/kg)
Eggs	0.01*	0.01*	The proposed MRL is acceptable
Lettuce, Head	5	20	The proposed MRL was derived from 11 trials reflecting the US/CA GAP. The proposal is acceptable The intended (representative) EU uses are more critical. However, EU supervised residue trial data provided to JMPR have apparently not been considered due to the fact that authorisation labels from EU countries were not yet available. Once the authorisations are granted, the applicant should be encouraged to provide the data to JMPR asking to amend the Codex MRL to avoid trade problems
Lettuce, Leaf	7	20	The proposed MRL was derived from 12 trials reflecting the US/CA GAP. The proposal is acceptable The intended (representative) EU uses are more critical. However, EU supervised residue trial data provided to JMPR have apparently not been considered due to the fact that authorisation labels from EU countries were not yet available. Once the authorisations are granted, the applicant should be encouraged to provide the data to JMPR asking to amend the Codex MRL to avoid trade problems
Low growing berries (includes all commodities in this subgroup)	**4**	0.01* (cranberries)/ 3 (strawberries)	The proposed Codex MRL was derived from 10 trials in strawberries matching the CA GAP (5 × 0.5 kg ai/ha, 0-day PHI). The applied extrapolation by the JMPR is not in line with the acceptable EU extrapolations, but in line with JMPR general agreements The intended EU uses for strawberries are less critical
Mammalian fats (except milk fats)	**0.02**	0.01*	See comment on edible offal (mammalians)

Commodity	Codex MRL proposal	EU MRL	Comment
Meat (from mammals other than marine mammals)	**0.02 (fat)**	0.01*	See comment on edible offal (mammalians). In general, in addition to the MRL for fat, an MRL for muscle would be established in the EU
Milks	0.01*	0.01*	See comment on edible offal (Mammalians)
Poultry, Edible offal of	0.01*	0.01*	The proposed MRL is acceptable
Poultry fats	0.01*	0.01*	The proposed MRL is acceptable
Poultry meat	0.01*	0.01*	The proposed MRL is acceptable
Rape seed	**0.015**	0.01*	The proposed MRL is based on 17 trials reflecting the Canadian GAP. The proposed MRL is acceptable
Rape seed oil, edible	0.03		
Small fruit vine climbing (includes all commodities in this subgroup)	3	4 (table and wine grapes)	The proposed Codex MRL was derived from 15 trials in grapes matching the US and CA GAP. The proposal is acceptable The EU MRL derived in the peer review for NEU and SEU uses is slightly higher (4 mg/kg, HR_{Mo} 3.11 mg/kg). The EU supervised residue trial data provided to JMPR have apparently not been considered due to the fact that authorisation labels from EU countries were not yet available Once the authorisations are granted, the applicant should be encouraged to ask JMPR to evaluate the already provided EU data and to amend the Codex MRL accordingly to avoid trade problems
Grape juice	–	–	–
Red wine	–	–	–
White wine	–	–	–
General comment: –			

MRL: maximum residue limit; dw: dry weight; GAP: Good Agricultural Practice; HR: highest residue; STMR: supervised trials median residue; ai: active ingredient; PHI: preharvest interval.
*: Indicates that the MRL is set at the limit of quantification.

6.22.5. Consumer risk assessment – isofetamid

The result for the consumer risk assessment is presented in Table 107.

Table 107: Summary of the consumer risk assessment for isofetamid

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR as derived by JMPR. Where appropriate, the HR values were multiplied with the conversion factors derived during the peer review to accommodate for the wider EU residue definition (for commodities of plant origin) that comprises an additional metabolite For animal products, no final decision has been taken so far on the residue definition. However, as the provisional EU RD for RA is comparable with the JMPR RD-RA, the risk assessment values of JMPR (including the corrected value for edible offal) were used in the calculations The EU ARfD was used **Results:** No short-term exposure concern was identified (highest short-term exposure for strawberries (5%) For the remaining crops for which JMPR proposed MRLs, the EU risk assessment is still valid (EFSA, 2015)	**RA assumptions:** A tentative long-term risk assessment was performed, including the STMR values derived during the EU peer review for plant commodities and the STMR values for plant commodities for which STMR values were higher than the EU STMR values Where available, conversion factors were included to accommodate for the wider EU residue definition The EU ADI was used For animal products, no final decision has been taken so far on the residue definition. However, as the provisional EU RD for RA is comparable with the JMPR RD-RA, the risk assessment values of JMPR (including the corrected value for edible offal) were used in the calculations **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 15% of the ADI Among the commodities under consideration, the highest contribution to the exposure was related to wine grapes (14% of the ADI)	–

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.23. Oxathiapiprolin (291) (T/R)

6.23.1. Background information

Oxathiapiprolin was assessed by JMPR for the first time. In the Table 108 some background information on oxathiapiprolin is presented.

Table 108: Background information on oxathiapiprolin

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved	Commission Implementing Regulation (EU) 2017/239[(a)]	IE	EFSA conclusion	Yes	EFSA (2016f)
			MRL review	No	–
			MRL applications	No	–

(a): 2017/239: Commission Implementing Regulation (EU) 2017/239 of 10 February 2017 approving the active substance oxathiapiprolin 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 39–42.

6.23.2. Toxicological reference values – oxathiapiprolin

The following toxicological reference values derived at EU level and by JMPR are presented in Table 109.

Table 109: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	4 mg/kg bw per day	Rat; multigeneration	0.14 mg/kg bw per day	Dog, 1-year, with uncertainty factor of 100
ARfD	Unnecessary	–	Not necessary	–

Conclusion:
The EU peer review has concluded that the effect on the liver in dogs was triggering a NOAEL of 13.6 mg/kg bw per day. The JMPR evaluation has concluded that no adverse findings were observed up to the top dose levels in the dog studies (i.e. at least 1,242 mg/kg bw per day).
The EU peer review has concluded that in the multigeneration study with rats, the NOAEL for the offspring was 86.37 mg/kg bw per day based on delayed preputial separation at the two high doses, whereas the JMPR evaluation has concluded on the adversity of this effect at the high dose only, triggering a higher NOAEL of 430 mg/kg bw per day.
For the two metabolites identified in rotational crop studies, an ADI which was significantly higher than the ADI for the parent compound was derived (ADI for IN-E8S72 and IN-SXS67: 1.157 mg/kg bw per day)

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.23.3. Residue definitions – oxathiapiprolin

In the following Table 110, the residue definitions for enforcement and risk assessment purpose are compared:

Table 110: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities Animal commodities	Oxathiapiprolin The residue is not fat soluble	Reg. 396/2005: no specific MRLs set in Annex II or III Peer review proposal: Oxathiapiprolin Residue is not fat soluble
RD-RA	Plant commodities Animal commodities	Sum of oxathiapiprolin, 5-(trifluoromethyl)-1*H*-pyrazole-3-carboxylic acid (IN-SXS67) and 1-β-D-glucopyranosyl-3-(-(trifluoromethyl)-1*H*-pyrazole-5-carboxylic acid (IN-ES8S72), expressed as parent	Peer review proposal: Oxathiapiprolin

Comments:
No specific MRLs are established in Annex II or III of Reg. 396/2005. Thus, currently the default residue definition covering the parent compound only is applicable.
It is noted that the risk assessment residue definitions for plant and animal products derived b JMPR are wider, covering two additional metabolites, i.e. IN-SXS67 and IN-ES8S72; the metabolites were found to be main contributors to the long-term exposure through residues in rotational crops, mainly in legumes, pulses, leafy vegetables and cereals.
In the EU assessment, residues of IN-E8S72 and IN-SxS67 in succeeding crops were scaled to 90 g ai/ha, the representative use assessed.

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.23.4. Codex MRL proposals – oxathiapiprolin

In the Table 111 the Codex MRL proposals are compared with the EU MRLs.

Table 111: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs/peer review)	Comment
Broccoli	**1.5**	0.01*	The proposed MRL is based on 5 residue trials reflecting the US GAP (4 × 35 g ai/ha, PHI 0 day). No information on the residue concentration of the metabolites included in the RD for RA (IN-SXS67 and IN-ES8S72) is provided
Cabbages, Head	**0.7**	0.01*	The proposed MRL is based on 10 residue trials reflecting the US GAP (4 × 35 g ai/ha, PHI 0 day). No information on the residue concentration of the metabolites included in the RD for RA (IN-SXS67 and IN-ES8S72) is provided
Cauliflower	**0.3**	0.01*	The proposed MRL is based on 5 residue trials reflecting the US GAP (4 × 35 g ai/ha, PHI 0 days). The number of trials would not be sufficient in the EU but is in line with the JMPR rules. No information on the residue concentration of the metabolites included in the RD for RA (IN-SXS67 and IN-ES8S72) is provided
Dried grapes	**1.3**	–	
Edible offal (Mammalian)	0.01*	0.01*	Since no feeding studies are available, the MRL proposal was derived from the metabolism study in lactating goats performed with 25× the highest estimated cattle dietary burden calculated for oxathiapiprolin. The contribution of the metabolites was not included in the dietary burden calculation. Instead, a separate dietary burden calculation was performed for IN-SXS67 taking into account the residues in rotational crops. This calculation is not presented in a transparent way. JMPR concluded that the MRL for all animal products can be set at the level of 0.01* mg/kg. Overall, the presentation of the assessment does not allow verifying the conclusion of JMPR
Eggs	0.01*	0.01*	According the conclusion of JMPR, no poultry feed items were identified. Thus, JMPR proposed to set the MRL for all poultry products at the level of 0.01 mg/kg. However, it is noted that cabbage head is indeed part of the poultry diet leading to a low livestock exposure. Overall, the presentation of the assessment of animal products in not clear and does not allow to verify if the conclusions are valid
Fruiting vegetables, Cucurbits	**0.2**	0.01*/0.1 cucumber, courgette 0.15 melon	JMPR received 11 outdoor residue trials in cucumbers, 4 trials on protected cucumbers, 10 trials in summer squash and 11 trials in melons matching the US GAP for foliar application (4 × 35 g ai/ha, 0-day PHI). The data were merged to derive the MRL proposal since the median residues were within a fivefold range. At EU level, separate MRLs would be derived for cucurbits with and without edible peel In addition, trials reflecting the soil drench/drip irrigation (2–4 applications of 280 g ai/ha up to 0 days with a seasonal rate of 560 g ai/ha) (10 trials on cucumber, 14 trials in summer squash and 11 trials in melons). In none of the trials, the metabolites that were included in the RD for RA were analysed. The MRL proposal was derived from the trials with foliar application, because the trials with soil treatment showed in general lower residues of the a.s. The STMR value derived from the trials is questionable since the concentration of metabolites was not measured

Commodity	Codex MRL proposal	EU MRL (default MRLs/peer review)	Comment
Fruiting vegetables, other than Cucurbits (except sweetcorn and mushrooms)	**0.4**	0.01*/0.2 tomato	JMPR received 10 outdoor residue trials in peppers, 2 trials on protected peppers, 5 trials on non-bell peppers, 19 trials in field tomatoes and 4 trials in protected tomatoes matching the US GAP for foliar application (4 × 35 g ai/ha, 0-day PHI). The data were merged to derive the MRL proposal since the median residues were within a fivefold range In addition, trials reflecting the soil drench/drip irrigation (2–4 applications of 280 g ai/ha up to 0 days with a seasonal rate of 560 g ai/ha) (11 trials on peppers and 21 trials in tomatoes) In none of the trials, the metabolites that were included in the RD for RA were analysed. The MRL proposal was derived from the trials with foliar application, because the trials with soil treatment showed in general lower residues of the a.s. The STMR value derived from the trials is questionable since the concentration of metabolites was not measured In the EU, separate MRLs would be derived for tomatoes (with the possible extrapolation to aubergines) and peppers
Garlic	**0.04**	0.01*	The MRL proposal was derived by extrapolation from onion bulbs (see comments on onions)
Garlic, Great-headed	**0.04**	–	
Ginseng, dried including red ginseng	**0.15**	0.01*	4 residue trials matching the US GAP (4 × 35–280 g ai/ha, PHI 14 days, maximum rate of 560 g ai/ha per year) were used to derive the MRL proposal. The samples were analysed only for parent compound; no information is available on the metabolites included in the RA-RD
Grapes	**0.9**	0.01*/0.7 table grape	The proposed Codex MRL is based on a data set of 4 Chinese trials and 5 European trials matching the Chinese GAP (global data set approach); only residues of parent compound were measured with no information on the two metabolites included in the residue definition for RA. The approach is questionable because the climatic and viticultural conditions in the EU and in China may not be comparable and therefore the use of trials form the EU (no indication if NEU or SEU trials were used) is not acceptable It is noted that the EU MRL is based on 9 SEU and 9 NEU trials (combined data set)
Leek	**2.0**	0.01*	The proposed MRL was derived by extrapolation from spring onions (4 trials) At EU level, the number of trials would not be sufficient, according to the guidance document on facilitating the setting of MRLs for minor crops, 5 trials would be required for leek. See general comments on onions and spring onions

Commodity	Codex MRL proposal	EU MRL (default MRLs/peer review)	Comment
Lettuce, Head	**3.0**	0.01*/0.3	The proposed MRL was derived from 10 trials matching the US GAP for foliar application (4 × 35 g ai/ha, PHI 0 days, seasonal rate 140 g) In addition, data from trials with soil treatment (4 soil drench or drip irrigation up to 280 g ai/h up to 0 days PHI, max. seasonal rate 560 g ai/ha). In these trials the residues were lower In none of the trials the samples were analysed for IN-SXS67 and IN-ES8S72 To derive the STMR, JMPR added the mean residues of IN-SXS67 and IN-ES8S72 calculated from the rotational crop studies in leafy crops (0.33 mg/kg) to the median residue concentration derived from the primary crop trials. This approach is not consistent with the approach used for the other crops assessed
Lettuce, Leaf	**5.0**	0.01*/0.3	The proposed MRL was derived from 10 trials matching the US GAP for foliar application (4 × 35 g ai/ha, PHI 0 days, seasonal rate 140 g) In addition, data from trials with soil treatment (4 soil drench or drip irrigation up to 280 g ai/h up to 0 days PHI, max. seasonal rate 560 g ai/ha). In these trials the residues were lower In none of the trials, the samples were analysed for IN-SXS67 and IN-ES8S72 To derive the STMR, JMPR added the mean residues of IN-SXS67 and IN-ES8S72 calculated from the rotational crop studies in leafy crops (0.33 mg/kg) to the median residue concentration derived from the primary crop trials. This approach is not consistent with the approach used for the other crops assessed
Mammalian fats (except milk fats)	0.01*	0.01*	See comments on edible offals (mammalians)
Meat (from mammals other than marine mammals)	0.01*	0.01*	See comments on edible offals (mammalians)
Milks	0.01*	0.01*	See comments on edible offals (mammalians)
Onion, Bulb	**0.04**	0.01*	The proposed MRL and the STMR was calculated from the residue concentration of oxathiapiprolin from 10 residue trials matching the US GAP. Apparently, the STMR proposed by JMPR does not take into account the residues of metabolites included in the residue definition for risk assessment (IN-SXS67 and IN-ES8S72). Although these metabolites were included in the residue definition mainly due to the occurrence in rotational crops and after soil application, they may be of relevance in crops like onions, receiving repeated applications, because these residues are expected to be taken up via soil
Onion, Welsh	**2.0**	0.01*	The proposed MRL was derived by extrapolation from spring onions (4 trials). See general comments on onions and spring onions
Peas (pods and succulent =immature seeds)	**1.0**	0.01*	The proposed MRL was derived from 5 residue trials matching the US GAP. To derive the STMR, JMPR added the mean residues of IN-SXS67 and IN-ES8S72 calculated from the rotational crop studies to the median residue concentration derived from the primary crop trials. This approach is not consistent with the approach used for the other crops assessed

Commodity	Codex MRL proposal	EU MRL (default MRLs/peer review)	Comment
Peas, shelled	**0.05**	0.01*	The proposed MRL was derived from 5 residue trials matching the US GAP. At EU level, peas are considered a major crop and at least 8 trials would be required. To derive the STMR, JMPR added the mean residues of IN-SXS67 and IN-ES8S72 calculated from the rotational crop studies to the median residue concentration derived from the primary crop trials. This approach is not consistent with the approach used for the other crops assessed
Peppers Chilli, dried	4		The MRL proposal was derived from the residue data assessed for fruiting vegetables, other than Cucurbits (except sweetcorn and mushrooms) by applying a default dehydration factor of 10. It is noted that the MRL proposal for chilli peppers should be derived only from trials on bell peppers (using the dehydration factor of 10) or from non-bell peppers (using a dehydration factor of 7); the residue trials on tomatoes should not be used for this extrapolation
Potato	0.01*	0.01*/0.01*	The proposed MRL was derived from 18 overdosed trials (cGAP; 4 × 35 g ai/ha, PHI 5 days). In all trials, the residues of parent compound were < 0.01 mg/kg. Since the samples were not analysed for the metabolites included in the RD for RA, the STMR value is questionable
Poultry fats	0.01*	0.01*	See comments on edible offals (mammalians)
Poultry meat	0.01*	0.01*	See comments on edible offals (mammalians)
Poultry, Edible offal of	0.01*	0.01*	See comments on edible offals (mammalians)
Pulses		0.01*	
Shallots	**0.04**	0.01*	The MRL proposal was derived by extrapolation from onion bulbs (see comments on onions)
Spring onion	**2.0**	0.01*	4 trials matching the US GAP were provided. Since according to the guidance document to facilitate the establishment of MRLs for minor crops, spring onions fall in category 3, at least 5 trials will be required for this crop. General comments presented for onions are also valid for spring onions
Spinach	**15**	0.01*	The proposed MRL was derived from 10 trials matching the US GAP for foliar application (4 × 35 g ai/ha, PHI 0 days, seasonal rate 140 g) In addition, data from trials with soil treatment (4 soil drench or drip irrigation up to 280 g ai/h up to 0-day PHI, max. seasonal rate 560 g ai/ha). In these trials the residues were lower In none of the trials, the samples were analysed for IN-SXS67 and IN-ES8S72 To derive the STMR, JMPR added the mean residues of IN-SXS67 and IN-ES8S72 calculated from the rotational crop studies in leafy crops (0.33 mg/kg) to the median residue concentration derived from the primary crop trials. This approach is not consistent with the approach used for the other crops assessed
Sweet potato	0.01*	0.01*	The MRL proposal was derived by extrapolation from potatoes
Tomato, dried	3.0	–	–
Tomato, canned (and pealed)	–	–	–

Commodity	Codex MRL proposal	EU MRL (default MRLs/peer review)	Comment
Tomato paste	–	–	–
Tomato puree	–	–	–
Tomato juice	–	–	–
Grape juice	–	–	–
Wine	–	–	–
General comment: In general, it would be desirable to derive clear guidance for a.s. that are leading to residues in rotational crops due to their persistence in soil			

MRL: maximum residue limit; GAP: Good Agricultural Practice; ai: active ingredient; PHI: preharvest interval; RD: residue definition; RA: risk assessment; a.s.: active substance; STMR: supervised trials median residue.
*: Indicates that the MRL is set at the limit of quantification.

6.23.5. Consumer risk assessment – oxathiapiprolin

The result for the consumer risk assessment is presented in Table 112.

Table 112: Summary of the consumer risk assessment for oxathiapiprolin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant	**RA assumptions:** EFSA calculated a tentative long-term risk assessment, including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL. In addition, the input values derived in the EFSA conclusion for vine leaves and tomatoes were included. For the remaining crops, the existing EU MRL was used as input value Although the JMPR residue definition for risk assessment comprises two additional metabolites that were not included in the EU residue definition, the STMR values derived by JMPR do not cover the contribution of these metabolites. Thus, the risk assessment is rather reflecting the EU residue definition The EU ADI was used **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 2.8% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to spinach (1.3% of the ADI) and lettuce (0.7% of the ADI)	–

RA: risk assessment; MRL: maximum residue limit; STMR: supervised trials median residue; ADI: acceptable daily intake.

6.24. Pendimethalin (292) (T/R)

6.24.1. Background information

Pendimethalin has not previously assessed by JMPR. In the Table 113, some background information on pendimethalin is presented.

Table 113: Background information on pendimethalin

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Directive 91/414/EC and renewed	Commission Directive 2003/31/EC[(a)]	NL	EFSA conclusion	Yes	EFSA (2016b)
			MRL review	Yes	EFSA (2012f)
			MRL applications	Yes	In lettuce: EFSA (2015l) in various crops: EFSA (2014d) in various crop: EFSA, 2013c, eafy brassica, kohlrabi and herbs: EFSA (2011f)

(a): 2003/31/EC: Commission Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances. OJ L 101, 23.4.2003, p. 3–9.

6.24.2. Toxicological reference values – pendimethalin

The following toxicological reference values derived at EU level and by JMPR are presented in Table 114.

Table 114: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2016b)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.1 mg/kg bw per day	Dog, 2-year study, UF 100	0.125 mg/kg bw per day	Dog, 2-year study, UF 100
ARfD	1 mg/kg bw	Rat, acute neurotoxicity study, UF 100	0.3 mg/kg bw	Rabbit, developmental toxicity study, UF 100

Conclusion:
Both the JMPR and the EU evaluations agreed that the ADI should be based on the NOAEL of 12.5 mg/kg bw per day for hepatotoxicity observed in the 2-year toxicity study in dogs and applying a standard uncertainty factor (UF) of 100. The different values are due to rounding.
Regarding the ARfD, the JMPR derived an ARfD of 1 mg/kg bw, based on a NOAEL of 100 mg/kg bw for a number of clinical signs observed in both sexes in an acute neurotoxicity study in rats.
In the EU evaluation, the ARfD is 0.3 mg/kg bw, based on the NOAEL of 30 mg/kg bw per day for developmental toxicity (increased incidence of less than 12 pairs of ribs and missing/incomplete vertebrae in the absence of maternal toxicity) observed in developmental toxicity study in rabbits, 100 UF applied.
The difference in ARfD setting is due to a diverging interpretation of the results of the developmental toxicity study in rats.
EFSA supports the interpretation given by the EU evaluation

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.24.3. Residue definitions – pendimethalin

In the following Table 115, the residue definitions for enforcement and risk assessment purpose are compared:

Table 115: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2016b)
RD-enf	Plant commodities	Pendimethalin	Pendimethalin
	Animal commodities		
RD-RA	Plant commodities	The residue is fat soluble	The residue is fat soluble
	Animal commodities		

Comments:
The residue definitions derived by JMPR and EU are identical

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.24.4. Codex MRL proposals – pendimethalin

In the Table 116, the Codex MRL proposals are compared with the EU MRLs.

Table 116: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Alfalfa, fodder	4 (dw)	–	–
Almond hulls	7 (dw)	–	–
Asparagus	**0.1**	0.05*	The CXL proposal is based on four residue trials matching the cGAP from USA (4.4 kg ai/ha, PHI 14 days). The proposal is acceptable
Bean fodder	0.3 (dw)		
Beans, dry	0.05	0.15	The CXL proposal is based on nine trials reflecting the German GAP ((2 kg ai/ha before emergence of the crop); all results were below 0.05 mg/kg. It is noted that the MRL proposal should be labelled with '*', to be consistent with the recommendation of JMPR (see p. 318 of the 2016 JMPR Report) At EU level, a comparable GAP was reported during the MRL review resulting in a higher MRL. The applicant should be encouraged to submit the complete data set that was also provided for the EU MRL application to JMPR
Beans, except broad bean and soya bean (green pods and immature seeds)	0.05	0.05*	The CXL proposal is based on nine trials reflecting the German GAP ((2 kg ai/ha before emergence of the crop); all results were below 0.05 mg/kg. A comparable data set was evaluated at EU level. The CXL proposal is acceptable. The MRL proposal should be labelled with *, to be consistent with the recommendation of JMPR (see p. 318 of the 2016 JMPR Report)
Brassica leafy vegetables, except kale	**0.3**	0.05* (land cress) 0.5 (Chinese cabbage) 0.6 (rucola)	The proposed MRL is based on six trials on mustard greens reflecting US GAP (1.1 kg ai/ha, 21 days PHI). Although the number of the residue trials is sufficient to derive MRL for mustard green the extrapolation to the whole group of brassicas would not be acceptable in the EU It is noted that in the EU residue trials for Chinese cabbage and rucola were provided which lead to a higher MRL. The applicant should be encouraged to submit the complete data set to JMPR to avoid trade disruptions due to different MRLs
Onion, Bulb	0.05*	0.05* (ft)	The CXL proposal is based on 6 residue trials, with residues all below the LOQ. Several trials (9 onion bulb in EU, 6 onion, bulb in USA and 4 fennel bulb in EU) have been performed at exaggerated doses compared to the cGAP, not leading to quantifiable residues, indicating that the MRL set at LOQ is justified even without further data on the trials. Extrapolation to shallots is based on these data
Carrot	0.5	0.7	The MRL proposal is based on 16 residue trials matching the CZ GAP (1.7 kg ai/ha). The CXL proposal is sufficiently supported by data. However, it is noted that at EU level the MRL is based on a more critical GAP (in terms of application time (BBCH up to 13). The applicant should be encouraged to submit the complete data set to JMPR to avoid trade disruptions due to different MRLs
Celery	0.09	0.1	The CXL proposal is based on eight residue trials conducted according to the Austrian GAP (1 × 1.6 kg ai/ha, PHI 60 days). At EU level, a different GAP (1 × 1.37 kg ai/ha, PHI 42 days) was assessed during the MRL review, resulting in a slightly higher MRL. The applicant should be encouraged to submit information on the EU GAP and the supporting data set to JMPR to avoid trade disruptions due to different MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus fruits	0.03	0.05*	In total, 19 GAP-compliant trials were submitted (6 on grapefruits, 4 on lemons and 9 oranges). The trials were pooled since the median residues were within a fivefold range; because of a high level of censored data, no statistical tests were performed. Although according to EU guidance document, 8 residue trials on orange or grapefruits and 8 on lemons/mandarins would be necessary to derive a group MRL, the data set is considered sufficient to set the group MRL at 0.03 mg/kg
Edible offal (Mammalian)	**0.05**	0.01*	The proposed Codex MRL is based on the residue level at max DB (Japan diet) including residue in hay (1,030 mg/kg) unrealistically high, since a PHI of 0 days is not likely to be relevant in practice. EFSA is of the opinion that the DB intakes and the proposed MRL should be reconsidered. The RMS was of the opinion that the approach used by JMPR may be acceptable, if no data for longer PHI are available. In the JMPR evaluation the assessment of pendimethalin was missing
Eggs	0.01*	0.01*	The CXL proposal is acceptable
Fennel Bulb	0.05*	0.05*	The CXL proposal is based on six residue trials conducted on onions. The information provided in the JMPR report does not allow to verify if the available residue trials were representative for the critical US GAP (3 × 2.1 kg ai/ha, 45-day PHI). Furthermore, EU level the extrapolation from onions to fennel would not be acceptable
Garlic	0.05*	0.05* (ft)	The CXL proposal is based on six residue trials conducted on onions. The information provided in the JMPR report does not allow to verify if the available residue trials were representative for the critical US GAP (2 × 1.7 kg ai/ha, 45-day PHI)
Hay or fodder (dry) of grasses	2,500 (dw)	–	The CXL proposal is based on 12 residue trials conducted on grass reflecting the US GAP (4.5 kg ai/ha, without grazing or preharvest interval); the results were recalculated to hay with an average dry matter content of 88% It is noted that results are unrealistically high, since a PHI of 0 days is not likely to be relevant in practice. For the assessment of residues in grass (same GAP), JMPR decided not to use the residue data derived at 0-day PHI, since this was expected to result in unrealistic higher dietary burden. Instead, the residues at a PHI of 15 days for grass (to derive STMR and HR for dietary burden) were used. To be consistent, a similar approach should be applied for hay. The RMS was of the opinion that the approach used by JMPR may be acceptable, if no data for longer PHI are available. This point needs to be checked in the JMPR evaluation
Hops, dry	0.05	0.05*	The CXL proposal is based on 4 trials reflecting the US GAP (4.5 kg ai/ha, PHI 90 days); all results were below 0.05 mg/kg. The CXL proposal is acceptable. However, it is noted that the MRL should be labelled with*
Kale	0.5	0.5	The CXL proposal is based on 4 residue trials matching the German GAP (1.6 kg ai/ha, 60-day PHI). The CXL proposal is sufficiently supported by data
Lettuce, Leaf	**4**	0.1	The CXL proposal is based on 9 residue trials matching the US GAP (1.1 kg ai/ha, 20-day PHI). The CXL proposal is sufficiently supported by data

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats	**0.2**	0.01*	See comment on Edible offal (mammalian)
Meat (from mammals other than marine mammals)	**0.2 (fat)**	0.01*	See comment on Edible offal (mammalian). In addition to the MRL for fat, an MRL for muscle would be set in the EU
Milks	**0.02**	0.01*	See comment on Edible offal (mammalian)
Milk fats	0.5	–	–
Onion, Welsh	**0.4**	0.05* (ft) (spring onions)	The CXL is based on three residue trials in green onions matching the US GAP (2 × 1.1 kg ai/ha, PHI 30 days). At EU level, at least 4 trials would be required. According to the guidance document to facilitate the establishment of MRLs for pesticides for minor crops, at least 5 trials would be required for this crop
Peas (dry)	0.05	0.15	The MRL proposal was extrapolated from beans (dry). See the comment from beans (dry). The MRL should be labelled with*
Peas (pods and succulent = immature seeds)	0.05	0.05*	The CXL proposal is based on 15 trials reflecting the Greek GAP (2 kg ai/ha); all results were below 0.05 mg/kg. The CXL proposal is acceptable. The MRL should be labelled with*
Peas, shelled (succulent seeds)	0.05	0.05*	The CXL proposal is based on 15 trials reflecting the Greek GAP (2 kg ai/ha); all results were below 0.05 mg/kg. The CXL proposal is acceptable. The MRL should be labelled with*
Poultry, Edible offal of	0.01*	0.01*	The CXL proposal is acceptable
Poultry fats	0.01*	0.01*	The CXL proposal is acceptable
Poultry meat	0.01*	0.01*	The CXL proposal is acceptable
Shallots	0.05*	0.05* (ft)	The CXL proposal is based on three residue trials conducted on onions. See comments on onion, bulb
Spring onions	**0.4**	0.05*	The CXL is based on three residue trials in green onions matching the US GAP (2 × 1.1 kg ai/ha, PHI 30 days). At EU level, at least 4 trials would be required. According to the guidance document to facilitate the establishment of MRLs for pesticides for minor crops, at least 5 trials would be required for this crop
Tree nuts	0.05	0.05*	The CXL proposal is acceptable (7 trials n almonds and pecan, respectively, 2 trials in pistachio and 1 trial in walnuts, all results below the LOQ). The MRL should be labelled with*
Carrots, cooked	–	–	No PF can be derived based on submitted data
Carrot, canned	–	–	No PF can be derived based on submitted data
Carrot juice	–	–	A PF of 0.38 was derived based on 3 submitted studies

MRL: maximum residue limit; GAP: Good Agricultural Practice; cGAP: critical GAP; ai: active ingredient; PHI: preharvest interval; LOQ: limit of quantification; BBCH: growth stages of mono- and dicotyledonous plants; CXL: Codex Maximum Residue Limit; PF: processing factor.
*: Indicates that the MRL is set at the limit of quantification.

6.24.5. Consumer risk assessment – pendimethalin

The result for the consumer risk assessment is presented in Table 117.

Table 117: Summary of the consumer risk assessment for pendimethalin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An exposure was calculated with the EFSA PRIMo rev. 2 for the crops assessed by JMPR, where higher MRLs were proposed The EU ARfD was used **Results:** No short-term exposure concern was identified for any of the crops; the maximum short-term intake accounted for 20% of the ARfD for lettuce For the remaining crops, the calculated exposure was lower than 2.5% of the ARfD	**RA assumptions**: The most recent long-term exposure assessment performed by EFSA (EFSA, 2016) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL The EU ADI was used **EU ADI, Result:** The expected long-term exposure is below 1.4% the ADI	JMPR did not identify any dietary risk for pendimethalin

RA: risk assessment; MRL: maximum residue limit; ARfD: acute reference dose; ADI: acceptable daily intake.

6.25. Pinoxaden (293) (T/R)

6.25.1. Background information

Pinoxaden was assessed by JMPR for the first time. In the Table 118, some background information on pinoxaden is presented.

Table 118: Background information on pinoxaden

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009	Commission Implementing Regulation (EU) 2016/370[(a)]	UK	EFSA conclusion	Yes	EFSA (2013f)
			MRL review	No	–
			MRL applications	No	–

(a): 2016/370: Commission Implementing Regulation (EU) 2016/370 of 15 March 2016 approving the active substance pinoxaden, 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, amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and allowing the Member States to extend provisional authorisations granted for that active substance. OJ L 70, 16.3.2016, p. 7–11.

6.25.2. Toxicological reference values – pinoxaden

The following toxicological reference values derived at EU level and by JMPR are presented in Table 119.

Table 119: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	0.1 mg/kg bw per day		0.1 mg/kg bw per day	EFSA (2013f) (2-year rat study supported by rabbit teratology, with safety factor 100)
ARfD	0.3 mg/kg bw		0.1 mg/kg bw	EFSA (2013) (rabbit teratology, with safety factor 100)
Conclusion: –				

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.25.3. Residue definitions – pinoxaden

In the following Table 120, the residue definitions for enforcement and risk assessment purpose are compared:

Table 120: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD-enf	Plant commodities	Sum of free and conjugated M4 (SYN 505164; 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-9-hydroxy-1,2,4,5-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-7-one), expressed as pinoxaden	Reg. 396/2005: Pinoxaden Peer review: Sum of M4 and M6 expressed as parent pinoxaden (to include free and conjugated residues of M4 and M6) (provisional RD) A simpler proposal for M6 (3,5-diethyl-4-(9-hydroxy-7-oxo1,2,4,5-tetrahydro-7*H*-pyrazolo[1,2-d][1,4,5]oxadiazepin-8-yl)-benzoic acid, SYN 502836) (free metabolite) has been proposed as an enforcement residue definition for plant products (cereals) However, the peer review did not reach final agreement on the optional proposal of M6 (free)
	Animal commodities	M4 (SYN 505164; 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-9-hydroxy-1,2,4,5-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-7-one), expressed as pinoxaden	Reg. 396/2005: Pinoxaden Peer review: not necessary as a result of the representative use; however M4 would be the most suitable component for ruminant matrices based on exposure resulting from the representative use in cereals
RD-RA	Plant commodities	Sum of free and conjugated M4 (SYN 505164; 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-9-hydroxy-1,2,4,5-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-7-one), expressed as pinoxaden	Sum of M4 and M6 expressed as parent pinoxaden (to include free and conjugated residues of M4 and M6)
	Animal commodities	M4 (SYN 505164; 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-9-hydroxy-1,2,4,5-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-7-one), expressed as pinoxaden The residue is not fat soluble	Not necessary as a result of the representative use; however M4 would be the most suitable component for ruminant matrices based on exposure resulting from the representative use in cereals Not fat soluble

Comments:
The enforcement residue definitions are not fully compatible. Thus, the Codex MRLs cannot be taken over in EU legislation without adaptation. A modification of the existing EU residue definition could be considered.

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.25.4. Codex MRL proposals – pinoxaden

In the Table 121 the Codex MRL proposals are compared with the EU MRLs.

Table 121: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	0.7	1	JMPR received 21 US/CA trials and 17 European trials on wheat (results are reported as the total M4 (free and conjugated, expressed as parent equivalents). The Codex MRL proposal is sufficiently supported by data. However, no appropriate feeding studies in ruminants are available reflecting the critical dietary burden calculated for Australia. (In the peer review the lower EU dietary burden was used as a basis for the MRL setting in livestock.)
Wheat	0.7	1	JMPR received 30 US/CA trials and 26 European trials on wheat (results are reported as the total M4 (free and conjugated, expressed as parent equivalents)). The Codex MRL proposal is sufficiently supported by data. However, no appropriate feeding studies in ruminants are available reflecting the critical dietary burden calculated for Australia. (It is noted that in the peer review the lower EU dietary burden was used as a basis for the MRL setting in livestock.)

Commodity	Codex MRL proposal	EU MRL	Comment
Barley straw and fodder, dry	3 (dw)	–	–
Wheat straw and fodder, dry	3 (dw)	–	–
Poultry meat	**0.02***	0.01* (default MRL)	The proposed Codex MRLs reflect the critical dietary burden for the EU. The proposal is acceptable
Poultry fats	**0.02***	0.01* (default MRL)	The proposed Codex MRLs reflect the critical dietary burden for the EU. The proposal is acceptable
Poultry, Edible offal of	**0.02***	0.01* (default MRL)	The proposed Codex MRLs reflect the critical dietary burden for the EU. The proposal is acceptable
Eggs	**0.02***	0.01* (default MRL)	The proposed Codex MRLs reflect the critical dietary burden for the EU. The proposal is acceptable
General comment: The calculated dietary burden for Australian ruminants exceeded the highest feeding level of the feeding study in dairy cows. Thus, no MRL proposals could be derived			

MRL: maximum residue limit: dw: dry weight.

6.25.5. Consumer risk assessment – pinoxaden

The result for the consumer risk assessment is presented in Table 122.

Table 122: Summary of the consumer risk assessment for pinoxaden

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed including only those commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR as derived by JMPR The EU ARfD was used The risk assessment is tentative since the EU and JMPR residue definitions for risk assessment are different Since the EU residue definition comprises an additional metabolite, the result of the risk assessment may underestimate the acute exposure according to the EU residue definition **Results:** No short-term exposure concern was identified (0.2% of the ARfD for eggs and poultry meat) For the remaining commodities, the proposed Codex MRL does not have an impact on the EU risk assessment (the existing EU MRL for the crop concerned is higher than the proposed Codex MRL)	**RA assumptions:** The long-term risk assessment was calculated based on the existing EU MRLs, including the STMR values derived by JMPR for animal commodities The risk assessment is tentative, since for the EU uses no detailed information on the STMRs reflecting the EU residue definitions is available In addition, the STMR values for animal products are not complete since JMPR was not able to derive MRL proposals for all animal products due to deficiencies in the feeding studies in ruminants **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 10.5% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to wheat (EU MRL) (8.5% of the ADI)	–

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

6.26. Spiromesifen (294) (T/R)

6.26.1. Background information

Spiromesifen was assessed by JMPR for the first time. In the Table 123 some background information on spiromesifen is presented.

Table 123: Background information on spiromesifen

Approval status	Legislation	RMS	EFSA assessment		Reference and comments
Approved under Regulation 1107/2009	Commission Implementing Regulation (EU) No 375/2013[(a)]	UK	EFSA conclusion	Yes	EFSA (2012k)
			MRL review	No	–
			MRL applications	Yes	Tea: EFSA (2012o)

(a): 2005/53/EC: Commission Decision of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances, *OJ L 241, 17.9.2005*, p. 51–56.

6.26.2. Toxicological reference values – spiromesifen

The following toxicological reference values derived at EU level and by JMPR are presented in Table 124.

Table 124: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation		EU evaluation (EFSA, 2012k)	
	Value	**Comments**	**Value**	**Comments**
ADI	0.03 mg/kg bw per day	18-month mouse study supported by other toxicity studies, with uncertainty factor of 100	0.03 mg/kg bw per day	18-month mouse study supported by other toxicity studies, with safety factor of 100
ARfD	Unnecessary	–	2 mg/kg bw	Acute neurotoxicity study, with uncertainty factor 100)

Conclusion:
The ADI set at EU and JMPR level used the same point of departure and uncertainty factor.
At EU level, the setting of the ARfD was considered necessary whereas JMPR considered unnecessary because of low acute toxicity of spiromesifen.
EFSA and JMPR set a different NOAEL in the acute neurotoxicity study. As concluded in the Draft Assessment Report, a NO(A)EL of 200 mg/kg bw per day was based on urine stain observed at 700 mg/kg bw per day and above. This dose relationship could be regarded as conservative (given the numbers of animals affected) but was based on the conclusions study authors.
EFSA agreed with the JMPR conclusion that the toxicity of the rat metabolites M01, M02 and its glucoside and M07 could be considered to be covered by that of spiromesifen.

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

6.26.3. Residue definitions – spiromesifen

In the following Table 125, the residue definitions for enforcement and risk assessment purpose are compared:

Table 125: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2012k)
RD-enf	Plant commodities	Sum of spiromesifen and 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one (=Sp-enol), expressed as spiromesifen	Regulation 396/2005: Spiromesifen; Peer review: Parent spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen equivalents A molecular weight conversion factor of 1.36 has to be applied to convert the enol-metabolite to parent equivalents
	Animal commodities	Residue is fat soluble	Reg. 396/2005: Spiromesifen Peer review: No proposal (due to deficiencies in the studies) Residue is expected to be fat soluble (EFSA, 2012k)
RD-RA	Plant commodities	Sum of spiromesifen, 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro [4.4]non-3-en-2-one (Sp-enol), and 4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4] non-3-en-2-one (free and conjugated) (4-hydroxymethyl-Sp-enol), all expressed as spiromesifen	Peer review: Parent spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen equivalents (factor of 1.36 is applied to convert the enol to parent equivalents)
	Animal commodities	Sum of spiromesifen and 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one, expressed as spiromesifen	Peer review: No proposal (due to deficiencies in the studies)

Comments:
The current residue definitions for enforcement established in Regulation (EC) No 396/2005 are not directly comparable with the residue definition proposed by JMPR which comprises also the enol-metabolite. The legal residue definitions may be revised in the framework of the MRL review, following the advice of the peer review where the inclusion of the enol-metabolite was also proposed.
As regards the risk assessment residue definition, JMPR proposed to include not only the enol-metabolite but also 4-hydroxymethyl-Sp-enol, free and conjugated; the latter was not proposed by the peer review to be included in the RD. In the MRL review, the need to include the 4-hydroxymethyl-Sp-enol in the RA residue definition should be further discussed; this metabolite was found a major metabolite in leafy crops.
JMPR used a correction factor of 1.25 to derive the risk assessment values for leafy vegetables and *Brassica* leafy vegetables since the samples were analysed only for the parent compound and the Sp-enol

RD-enf: residue definition for enforcement practice; RD-RA: residue definition for risk assessment.

6.26.4. Codex MRL proposals – spiromesifen

In the Table 126, the Codex MRL proposals are compared with the EU MRLs.

Table 126: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Common bean (pods and/or immature seeds)	1	1	The proposed MRL is based on 8 residue trials matching the Greek GAP. The proposed MRL is acceptable
Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead Brassicas	**3**	0.02*(broccoli, cauliflowers, head cabbage and Brussels sprouts)	The proposed MRL is based on a combined data set (6 trials in broccoli and 5 trials in head cabbage) matching the US GAP (3 × 0,144 kg ai/ha, 7-day PHI). The pooling of data on broccoli and head cabbage would not be acceptable in the EU but is in line with JMPR practice. Head cabbage is a major crop not only in the EU, but also in Codex. Thus, the number of trials would not be sufficient in the EU

Commodity	Codex MRL proposal	EU MRL	Comment
Brassica leafy vegetables	**15**	0.02* (Chinese cabbage, kales)	The proposed MRL is based on a combined data set (6 trials in head lettuce, 6 trials in leaf lettuce, 6 trials in spinach and 8 trials in mustard greens) matching the US GAP (3 × 0.144 kg ai/ha, 7-day PHI). The pooling of residue data for these crops is not acceptable in the EU The group of *Brassica* leafy vegetables is a sub group of leafy vegetables. Thus, this proposed MRL is overlapping with the MRL proposal for Leafy vegetables (see below)
Cassava	0.02*	0.02*	The proposed MRL is acceptable
Coffee beans	0.05	0.02*	The MRL proposal is based on 5 residue trials. Since coffee is a major crop the number of trials is not sufficient
Cotton seed	**0.7**	0.02*	The proposed MRL is based on 12-GAP compliant trials; the proposal is acceptable
Cucumbers	0.15	0.3	The proposed MRL is based on 7 residue trials matching the Greek GAP. It is noted that the EU MRL is higher. Once the EU MRL review is completed and the existing EU MRL has been confirmed, there might be the need to request the modification of the Codex MRL
Edible offal (Mammalian)	**0.3**	0.01*	The proposed MRL is acceptable
Eggplants	**0.7**	0.5	The proposed MRL was derived by extrapolation from tomatoes
Eggs	**0.02**	0.01*	The proposed MRL was derived from the poultry metabolism study performed at an exaggerated dose rate (35N). In the metabolism study, the residues in eggs accounted for 0.018 mg/kg. This result would suggest under 1N condition no quantifiable residues would occur. Thus, a MRL of 0.01*mg/kg would be sufficient
Fruiting vegetables, Cucurbits, except melon and cucumber	0.09	0.3	The proposed MRL is based on a combined data set (5 US trials in summer squash, 6 trials in melons and 6 trials in cucumbers) matching the US GAP (3 × 0.144 kg ai/ha, 7-day PHI). The applied extrapolation is not in line with the EU acceptable extrapolations, but common practice for Codex. Furthermore, the EU MRL is higher than the proposed Codex MRL. The proposal may be acceptable
Leafy vegetables	**15**	0.02*	The proposed MRL is based on a combined data set (6 trials in head lettuce, 6 trials in leaf lettuce, 6 trials in spinach and 8 trials in mustard greens) matching the US GAP (3 × 0.144 kg ai/ha, 7-day PHI). The pooling of residue data for these crops is not acceptable in the EU The group of leafy vegetables comprises the sub group of *Brassica* leafy vegetables. Thus, this proposed MRL is overlapping with the MRL proposal for leafy vegetables (see below) (See also comments for *Brassica* leafy vegetables)
Low-growing berries	**3**	1 (cranberries, strawberries, muntries, cloudberries)	The MRL proposal is based on 8 residue trials in strawberries matching the US GAP (3 × 0.28 kg ai/ha, PHI 3 days) This extrapolation would not be acceptable in the EU, but is in line with the JMPR rules

Commodity	Codex MRL proposal	EU MRL	Comment
Maize	0.02*	0.02*	The proposed MRL is sufficiently supported by data
Maize fodder (dry)	6		
Mammalian fats (except milk fats)	**0.15**	0.01*	The proposed MRL is acceptable
Meat (from mammals other than marine mammals)	**0.15 (F)**	0.01*	The proposed MRL is acceptable. In addition to the MRL for fat, at EU level an MRL for muscle would be established
Melon, except watermelon	0.3	0.3	The proposed MRL is based on 8 EU indoor residue trials that were scaled up to match the Greek GAP (4 × 0.216 kg ai/ha, 7-day PHI). The proposal is acceptable
Milks	**0.015**	0.01*	The proposed MRL for milk is acceptable Considering that spiromesifen residues are classified as fat soluble, a separate MRL for milk fat should be derived
Okra	**0.5**	0.02*	The proposed MRL was derived by extrapolation from peppers
Pepino	0.5	0.5 (aubergines)	Pepinos are classified as eggplants at EU level The proposed MRL was derived by extrapolation from peppers
Peppers	0.5	0.5	The proposed MRL is based on 20 field trials matching the Canadian/Mexican GAP (3 × 0.144 kg ai/ha, 1-day PHI). The proposal is acceptable
Peppers chilli, dried	5		The proposed MRL was derived from peppers by using the default dehydration factor of 10
Popcorn	0.02*		The proposed MRL is acceptable
Potato	0.02*	0.02*	The proposed MRL is acceptable
Poultry fats	**0.02**	0.01*	The proposed MRL was derived from the poultry metabolism study performed at an exaggerated dose rate (35N). In the metabolism study, the residues in fat accounted for 0.049 mg/kg. This result would suggest under 1N condition no quantifiable residues would occur. Thus, a MRL of 0.01*mg/kg would be sufficient
Poultry meat	**0.02**	0.01*	The proposed MRL was derived from the poultry metabolism study performed at an exaggerated dose rate (35N). In the metabolism study, the residues in muscle accounted for 0.028 mg/kg. This result would suggest under 1N condition no quantifiable residues would occur. Thus, a MRL of 0.01*mg/kg would be sufficient. In the EU, a MRL for muscle would be established
Poultry, Edible offal of	**0.05**	0.01*	The proposed MRL was derived from the poultry metabolism study performed at an exaggerated dose rate (35N). In the metabolism study, the residues in liver accounted for 0.3 mg/kg. This result would suggest under 1N condition no quantifiable residues would occur. Thus, a MRL of 0.01 or 0.02 mg/kg would be sufficient
Sweet corn (corn-on-the-cob)	0.02*	0.02*	The proposed MRL is acceptable
Sweet potato	0.02*	0.02*	The proposed MRL was derived by extrapolation from potatoes

Commodity	Codex MRL proposal	EU MRL	Comment
Tea, Green, Black (black, fermented and dried)	**70**	50	The proposed MRL is based on 6 residue trials approximating the Japanese GAP. The residue concentration measured in fresh tea leaves were recalculated to dried tea leaves using results of one processing studies (PF for black tea 3.2). Since tea is a major crop, at least 8 trials would be required
Tomato	0.7	1	The proposed MRL is based on 16 EU greenhouse residue trials matching the FR/IT GAP (4 × 0.216 kg ai/ha, 3-day PHI). The proposal is acceptable
Tomato paste	2	–	–
Tomato, dried	4	–	–
Tomato purée	–	–	–
Tea (green and black infusion)	–	–	A processing factor based on only 1 processing factor was derived by JMPR which is not sufficient according to the EU rules

General comment:
JMPR multiplied the HR/STMR values derived for leafy vegetables and *Brassica* leafy vegetables with a correction factor of 1.25 since the samples were analysed only for the parent compound and the Sp-enol, but not for the 4-hydroxymethyl-Sp-enol. The correction factor was derived from the metabolism study in lettuce. For other crops no correction factor was considered necessary. Metabolism studies were available only for three crops (lettuce, tomatoes and cotton). It is questionable whether this limited information is representative for all crops for which MRL proposals were derived

MRL: maximum residue limit; GAP: Good Agricultural Practice; PHI: preharvest interval; ai: active ingredient.
*: Indicates that the MRL is set at the limit of quantification.

6.26.5. Consumer risk assessment – spiromesifen

The result for the consumer risk assessment is presented in Table 127.

Table 127: Summary of the consumer risk assessment for spiromesifen

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed as outlined in Section 'Assessment' for all commodities where JMPR proposed higher MRLs compared to the EU MRLs, using the HR/STMR reported in the JMPR report (JMPR did not derive HR values since in Codex no ARfD was considered necessary) The EU ARfD was used The risk assessment is tentative since the MRL review is not yet completed and thus a final decision on the residue definitions for risk assessment has not been taken **Results:** No short-term exposure concern was identified (55% of the ARfD for scarole, 42% for kale, 29% for Chinese cabbage, 17% for lettuce)	**RA assumptions:** A tentative long-term risk assessment was performed, including the STMR values derived by JMPR for crops where the proposed MRLs are higher than the existing EU MRL. For the remaining crops the existing EU MRL was used The EU ADI was used The risk assessment is tentative, since the MRL review is not yet completed; no final EU residue definition and STMR values for the EU uses are available **Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 24% of the ADI Among the crops under consideration, the highest contribution to the exposure was related to tea (8% of the ADI), spinach (5%) and lettuce (4%)	–

RA: risk assessment; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

7. Conclusions and recommendations

Deltamethrin (135)

The proposed Codex MRL is acceptable. It is compatible with the EU enforcement residue definition and does not lead to a short-term or long-term dietary exposure exceeding the EU toxicological reference values.

Methoprene (147)

At EU level, no risk assessment residue definitions have been set since methoprene was never assessed for its residue behaviour. Considering the log P_{OW}, the modification of the residue definition, including the label (F) for fat-soluble substances should be considered in the EU MRL legislation.

No metabolism studies available that are representative for the post-harvest use in oilseeds.

The number of trials in oilseed is considered insufficient to derive a group MRL for the whole group of oilseed, except peanuts.

In the tentative long-term risk assessment, using the existing EU MRLs and the ADI derived by JMPR for S-methoprene, a potential risk for consumers could not be excluded (126%). The contribution of the oilseeds (expressed as percentage of the ADI) was approximately 10%.

The main contributor to the overall exposure is the EU MRL for wheat (5 mg/kg) (up to 85%) and rye (44%). Further refinements could not be performed as no detailed information is available for these uses.

Buprofezin (173)

The proposed MRLs are sufficiently supported by data, except the MRL for basil (3 trials instead of 4 trials). Only a tentative risk assessment could be performed due to different residue definitions and lack of information on the STMR values related to existing EU MRLs. The chronic risk assessment based on the existing EU MRLs and the STMR for avocado derived by JMPR exceeded the ADI (650% of the ADI). Avocado was a minor contributor to the total exposure.

Penconazole (182)

The proposed Codex MRLs are sufficiently supported by data, except the MRL for globe artichoke where the lack of a specific metabolism study for leafy crops was noted. Since the JMPR residue definitions for risk assessment are not fully compatible with the EU enforcement residue definition, only a tentative risk assessment could be performed which did not raise short-term or long-term consumer health concerns.

Fenpropimorph (188)

In 2016, JMPR performed the toxicological assessment of the active substance, proposing a slightly higher ADI than the EU ADI. For the ARfD, JMPR proposed two different values, one for women of child-bearing age (0.1 mg/kg bw) and one for the general population (0.4 mg/kg bw). The EU ARfD that is applicable to the whole population is lower (0.03 mg/kg).

Clarifications should be provided by JMPR whether the toxicological reference values derived for the active substance are also applicable to the metabolite included in the residue definition for animal commodities (i.e. BF-421-2). It is noted that the EU residue definition for plant commodities covers two metabolites that were not considered relevant by JMPR (i.e. BF-421-2 and BF-421-10).

Teflubenzuron (190)

Using the BMD approach, JMPR derived an ADI value that was lower than the current EU ADI. The proposed MRLs are acceptable except for cauliflower, where the lack of a metabolism study representative for leafy crops was noted; for apples, the residue trials were found to be not fully representative for the GAP. Minor deficiencies were noted as regards the MRL proposal for papaya (4 residue trials instead of 5 trials); for melons, it should be verified once the JMPR evaluation is published, whether the residue concentration measured in pulp reflect the most critical residue trials (highest residues in the fruit including the peel). The result for pulp was used in the risk assessment.

Fipronil (202)

JMPR should clarify the residue definition for plant commodities: According to page 91 of the 2016 JMPR report, the residue definition is fipronil, fipronil-desulfinyl, fipronil-sulfone and fipronil-thioether

expressed as fipronil (for plant and animal products) while in the MRL database on the website of Codex Alimentarius the with residue definition comprises only the parent compound. Since the EU residue definition is different from the two before mentioned residue definitions, the proposed MRL for basil is not compatible with the EU legislation.

Dimethomorph (225)

At EU level, the renewal process for the approval of dimethomorph is ongoing; according to the RMS, the current toxicological reference values and the residue definitions for risk assessment may change. The proposed MRL for leaf lettuce which is lower than the existing EU MRL is sufficiently supported by data.

Chlorantraniliprole (230)

The proposed MRLs are sufficiently supported by data. Since the EU and JMPR risk assessment residue definition for animal product is not identical, the risk assessment is tentative. In the tentative risk assessment, no intake concern was identified.

Saflufenacil (251)

Due to different residue definitions established in the EU and by JMPR, the proposed Codex MRLs cannot be taken over in the EU legislation. In addition, it is noted that the available metabolism studies are not sufficient to derive a conclusion on the metabolic pattern in cereals following preharvest treatment. Thus, the proposed MRL for barley, wheat and triticale is considered not sufficiently supported.

The proposed MRL for edible offal (mammalians) (60 mg/kg) was derived from the residue concentration found in the ruminant feeding study in liver at dietary burden (DB for Australia). For bovine liver and swine liver acute intake concerns were identified. It is noted that JMPR did not derive an ARfD while in the EU a reference value was derived from the developmental toxicity study in rats.

Sulfoxaflor (252)

JMPR did not derive MRL proposals.

Benzovindiflupyr (261)

The proposed MRL for fruiting vegetables, Cucurbits was found not appropriate: for cucurbits with edible peel (cucumbers and courgette) an MRL of 0.08 mg/kg would be the alternative value; for cucurbits with inedible peel, the data provided to JMPR would suggest a MRL of 0.3 mg/kg.

Similar for fruiting vegetables other than cucurbits, the setting of separate MRLs for tomatoes and aubergines and for peppers should be considered (0.07 and 1 mg/kg, respectively), instead of setting a group MRL.

The proposed MRL for coffee beans is not sufficiently supported by data (at least 8 trials would be required in the EU, while only 6 trials were available).

For animal products, slightly lower MRLs than the proposed MRLs derived by JMPR would be sufficient.

Since the residue definitions for risk assessment are not fully compatible, the risk assessment is affected by some uncertainties. Overall, the short-term exposure for the crops assessed are not likely to pose a consumer health risk. For the long-term exposure, the exposure is well below the ADI.

Bixafen (262)

The proposed MRLs are acceptable; however, it is noted that for meat (from mammals other than marine mammals) and milk a slightly lower MRL would be sufficient. No consumer health concerns were identified.

Fluensulfone (265)

Fluensulfone has not been assessed in the EU.

In 2015, the EU raised concerns regarding the genotoxic potential of metabolite MeS; these concerns are still valid. Further genotoxicity tests would be needed to follow-up positive results *in vitro*.

The metabolism studies seem to be not fully representative for the residue behaviour observed in field condition, since in the residue trials metabolites were detected that were not found in significant levels in the metabolism study. The information currently available is considered insufficient to derive sound residue definitions.

JMPR derived an MRL proposal of 3 mg/kg for the food code VR 0075 (group of root and tuber vegetables (not specified elsewhere)), based on residues in rotational crops; for specific crops belonging to this crop group specific MRLs were established where a specific GAP was reported (e.g. MRL proposal of 4 mg/kg for carrots, radish, beetroots, celeriac, horseradish, Japanese radish, parsnip, swede, turnip rooted chervil and turnips. For potatoes and sweet potatoes, a lower MRL of 0.8 mg/kg was considered sufficient, based on primary crop residue trials. Overall, the approach used to derive MRL proposals on the basis of rotational crop studies is not very clear.

A similar observation is made for leafy vegetables (not specified elsewhere): a MRL of 1 mg/kg was proposed on the basis of rotational crop studies, while for lettuce, head (primary crop treatment) lower MRLs were set (e.g. 0.8 mg/kg for lettuce, head).

JMPR derived an MRL proposal for *Brassica* (cole or cabbage) vegetables, head cabbage, but assigned the wrong commodity code (VB 0400 which refers to broccoli instead of VB 0400).

Tolfenpyrad (269)

This active substance has never been assessed in the EU. The proposed MRLs are sufficiently supported by data. Using the JMPR toxicological reference values, no dietary exposure risk was identified.

Metrafenone (278)

The proposed MRLs are acceptable; however, it is noted that using the OECD calculator a slightly higher MRL for hops would be derived. No consumer health concerns were identified.

Flonicamid (282)

The proposed MRLs are acceptable; no consumer health concerns were identified.

Fluazifop-P-butyl (283)

The residue definition proposed by JMPR covers only of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid. Since the analytical methods do not allow to discriminate between fluazifop-P and fluazifop-S (and the related metabolites), it would seem more appropriate to include the S-enantiomer in the JMPR residue definition, considering that the residue trials were also analysed for the total fluazifop residues (R- and S-isomer).

Acute intake concerns were identified for the following crops: swedes (1,460% of the ARfD), head cabbage (1,145% of the ARfD, turnips (1,014%), potatoes (904%), yams (512%), turnips (422%) peas (without pods) (390%), beans with pods (327%), beans (258%), carrots (257%), sweet potatoes (240%), beans (without pods) (200%) of the ARfD).

In addition, for cabbage, head, the number of residue trials was found to be insufficient to derive an MRL proposal; at least eight trials would be required.

For tomatoes, it is noted that in the EU MRL review additional trials were submitted for a similar GAP; on the basis of these trials, an exceedance of the ARfD was identified. As a consequence, the European GAPs for tomatoes had to be withdrawn. The basis for the Codex MRL proposal (French GAP) is therefore no longer valid.

For beans, except broad bean and soya bean, peas, shelled (succulent seeds), carrots and swedes the MRL derived in the EU was based on a comparable GAP; however, the residue trials assessed by JMPR which showed the highest residues were not made available to EFSA. Thus, the appropriateness of the EU MRLs should be reconsidered. In addition, the consequences on the consumer health risk should be checked, considering that apparently significantly higher residues may be expected for the European GAP.

To derive the MRL proposal for potatoes, JMPR used residue trials from Brazil and Germany. The representativeness of the German trials for Brazil should be further investigated.

For sunflower seeds, while half of the trials had no quantifiable residues, in four trials significant residues up to 3.7 mg/kg were found. It is noted that for the EU GAP (1 × 0.38 kg/ha, PHI 90 days) residues were all at or below 0.06 mg/kg. The reason for the extremely high residues found in the residue trials used by JMPR to derive the MRL proposal should be examined.

The MRL proposals for meat (mammals other than marine mammals), mammalian fat, and edible offal (mammalian) were derived from a feeding study where the highest dosing level was lower than the calculated maximum dietary burden. In addition, it is noted that for the dietary burden calculation the contribution of metabolite X was not taken into account. Thus, the STMR/HR values derived for

total fluazifop-P were not multiplied by the adjustment factors. Thus, the calculated dietary burden may underestimate the livestock exposure.

Flupyradifurone (285)

Due to the discrepancies regarding the enforcement residue definition for animal products, the Codex MRLs for animal products are not compatible with the EU MRL legislation. For plant products specific MRLs for DFA need to be set in the EU. No corresponding MRLs are proposed by JMPR.

The risk assessment identified potential consumer risks for mustard greens (equivalent to Chinese cabbage) (620% of the ARfD), spinach (290%), celery (220%), oranges (195%), lettuce leaves (140%), cauliflower (130%), melons (110%); slight exceedances were also noted for table grapes and peppers (100.4% and 100.3%, respectively).

For deriving the STMR and HR values for a number of crops, JMPR added the mean and highest residue found in representative rotational crop studies to the STMR and HR for of the primary crop. However, the application rate tested in rotational crop studies is not clearly reported. From the available documentation, it seems that the worst case GAP in primary crops is higher than the application rate of the rotational crop study (cucurbits: 409 g ai/ha).

The MRL proposal for bus berries is based on eight residue trials in blueberries which were extrapolated to the whole group which also covers blueberries, currants, gooseberries, rosehips and related minor crops. At EU level this extrapolation is not foreseen.

The MRL proposal for cereal grains is based on a combined data set with trials in barley, wheat and sorghum. Although the statistical test demonstrated that the data sets are statistically different, they were pooled to derive a MRL for the whole group of cereals, because the mean resides differed less than fivefold. It would be more appropriate to set separate MRLs for wheat, barley and sorghum.

For cucumbers, JMPR proposed an MRL of 0.4 mg/kg but did not derive an HR and STMR because in decline studies the residues did not reach a maximum. Trials with sampling at longer PHIs would be required. Without having the possibility to perform a sound risk assessment, the MRL proposal is not acceptable. It is also noted that for cucumbers residues in primary crops following soil application were lower than the results of rotational crops studies.

Decline studies in tomatoes gave an indication that the residues may increase with longer PHIs. Thus, considering that for other crops with short PHI (e.g. tomatoes, strawberries, summer squash) a similar residue behaviour may be expected, decline studies should be checked to ensure that the MRL proposal and the STMR/HR reflect the worst case situation.

The number of trials in peas, shelled would not be sufficient for setting an EU MRL.

For apples, a lower MRL of 0.5 mg/kg would be sufficient.

JMPR did not propose MRLs for broccoli due to insufficient residue trials. However, since residues may occur in broccoli grown in crop rotation, an STMR and HR should be derived to perform the risk assessment.

Acibenzolar-S-methyl (288)

EFSA identified a short-term dietary exposure risk related to the proposed MRLs for melons, watermelons, broccoli, cauliflower, head cabbage and kale. For citrus fruit and kiwi, no appropriate metabolism studies are available representative for soil treatment. For cucurbits (edible peel) a slightly lower MRL would be sufficient. The remaining MRL proposals are sufficiently supported by data and no health concern was noted.

Imazethapyr (289)

The active substance was never assessed at EU level. For all commodities assessed JMPR proposed to set the MRL at the LOQ, except for soya beans. The residue trials in rape seed were not analysed for all components of the residue definition; thus, the proposed MRL is not fully justified. No consumer health concerns were identified for any of the proposed MRLs.

Isofetamid (290)

The JMPR residue definition for products of animal origin is not compatible with the EU residue definition. Thus, the proposed MRLs cannot be taken over in the EU legislation.

It is noted that the HR/STMR/MRL derived by JMPR for edible offal (mammalian) are wrong, as they were calculated using an incorrect level of isofetamid in liver (0.10 mg/kg) (see JMPR report p. 246). The correct residue concentration in liver found in the goat metabolism study is 0.01 mg/kg (see also JMPR report p. 236). Using the correct value for liver, the STMR/HR derived for liver

according to the JMPR residue definition would be 0.026 mg/kg ((0.010 + 0.062) × 0.36) instead of 0.07 mg/kg. STMR/HR derived for kidney using JMPR approach is 0.0076 mg/kg.

Considering the recalculated results, a lower MRL for edible offal would be appropriate (i.e. 0.03 mg/kg).

Oxathiapiprolin (291)

JMPR proposed to include two metabolites in the residue definition for risk assessment (IN-SXS67 and IN-ES8S72). These metabolites were found in primary crops following soil applications and in rotational crops (studies were performed in leafy vegetables, pulses and legume vegetables). In general, the residue trials for primary crops were not analysed for these metabolites. For crops with soil application, a constant residue concentration for IN-SXS67 and IN-ES8S72 derived from rotational crop studies was added to the STMR value. According to EFSA, the residue trials should provide information on the full residue definition.

The MRL proposal for fruiting vegetables, other than cucurbits is based on a mixed data set of outdoor and indoor residue trials in peppers and tomatoes. This practice of merging this kind of trials would not be acceptable in the EU.

The MRL proposal for grapes was based on a mixed data set of Chinese and European residue trials, matching the Chinese GAP. Since the climatic and viticultural conditions in the EU and in China may not be comparable, the use of trials form the EU (no indication if NEU or SEU trials were used) is not appropriate.

The presentation of the data in the JMPR report does not allow verifying the validity of the proposed MRLs for animal products.

Pendimethalin (292)

The EU and JMPR residue definitions for enforcement are compatible.

The Codex MRL proposal for *Brassica* leafy vegetables, except kale was derived from residue trials mustard green by extrapolation. This extrapolation would not be acceptable in the EU.

The number of trials is not sufficient to derive an MRL proposal for spring onions.

The proposed Codex MRL for edible offal (Mammalian) is based on unrealistically high dietary burden calculation, including residues in hay derived at a PHI of 0 days. It is recommended to reconsider the calculation of the dietary burden and to revise the MRL proposal.

It is noted that the Codex MRLs proposed for beans, dry; beans, except broad beans and soya beans, hops, dry; peas, dry; peas (pods and succulent seeds); peas, shelled) and tree nuts should be labelled with '*', indicating that it is an MRL at the LOQ.

Pinoxaden (293)

The current residue definition for enforcement established in Regulation (EC) No 396/2005 is not directly comparable with the residue definition proposed by JMPR which comprises only the metabolite M4 (free and conjugated). Thus, at the moment the Codex MRL proposals are not compatible with the EU legislation. The legal residue definitions in the EU may be revised in the framework of the MRL review, following the advice of the peer review where the inclusion of the enol-metabolite was also proposed.

The proposed MRLs for wheat and barley are supported by the required number of residue trials. However, since no appropriate feeding studies were available that take into account the contribution of cereals to the dietary burden in livestock, the proposed MRL for cereals is considered not sufficiently supported by data.

Spiromesifen (294)

The current residue definition for enforcement established in Regulation (EC) No 396/2005 is not directly comparable with the residue definition proposed by JMPR which comprises also the enol-metabolite. Thus, at the moment, the Codex MRL proposals are not compatible with the EU legislation. The legal residue definitions in the EU may be revised in the framework of the MRL review, following the advice of the peer review where the inclusion of the enol-metabolite was also proposed.

The proposed Codex MRLs are acceptable, except for *Brassica* (cole or cabbage) vegetables, head cabbages, flowerhead *Brassica* and tea where the number of trials was not sufficient to derive an MRL.

For some animal products (eggs, poultry fat, poultry meat and poultry edible offal), a lower MRL would be sufficient.

The proposed group MRL for leafy vegetables (VL 0053) was derived by pooling residue trials in different crops (head lettuce, leaf lettuce, spinach and mustard greens). The pooling and setting of a group MRL for this wide crop group would not be acceptable in the EU. It is noted that JMPR also proposed a MRL at the same level leafy vegetables for *Brassica* leafy vegetables (VL 0054) which is a subgroup of the group of leafy vegetables. Thus, the MRL proposal for *Brassica* leafy vegetables is redundant with the MRL proposal for leafy vegetables.

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Abbreviations

ADI	acceptable daily intake
ai	active ingredient
ARfD	acute reference dose
a.s.	active substance
BMD	benchmark dose
BMR	benchmark response
bw	body weight
BBCH	growth stages of mono- and dicotyledonous plants
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
cGAP	critical GAP
CSAF	chemical-specific adjustment factor
CXL	Codex Maximum Residue Limit (Codex MRL)
DALA	days after last application
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DB	dietary burden
DM	dry matter
DMS	document management system
dw	dry weight
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
IESTI	International estimated of short-term intake
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification (determination)
LP	large portion
MRL	maximum residue limit
MS	Member States
MW	Molecular weight
NEU	northern European Union
NOAEL	no observed adverse effect level
n.a	not applicable
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RD-RA	residue definition for risk assessment

RD-enf	residue definition for enforcement practice
RMS	rapporteur Member State
RAR	renewal assessment report
SEU	southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TTC	threshold of toxicological concern
TRR	total radioactive residues
VF	variation factor
WHO	World Health Organization
UF	uncertainty factor

Appendix A – Calculations of Consumer exposure with Pesticide Residue Intake Model (Primo)

Deltamethrin			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.05	Proposed LOQ:	0.02
Toxicological end points			
ADI (mg/kg bw per day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2002**	Year of evaluation:	**2002**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	3 51
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
50.7	IE adult	20.1	Maize	10.9	Barley	3.6	Tea (dried leaves and stalks)	4.6
48.9	DK child	38.7	Rye	2.5	Oats	2.1	Milk and cream	6.8
47.7	WHO Cluster diet B	21.6	Maize	5.0	Olives for oil production	2.9	Rice	7.0
29.6	UK Infant	9.0	Maize	6.6	Milk and cream	3.5	Rice	12.5
27.8	WHO cluster diet E	7.1	Barley	4.9	Maize	3.8	Rye	4.2
26.4	DE child	6.9	Rye	4.5	Apples	2.4	Milk and cream	11.4
23.4	WHO cluster diet D	4.6	Maize	3.5	Rye	3.1	Rice	5.1
22.9	WHO Cluster diet F	6.7	Rye	5.3	Barley	1.2	Rice	3.8
22.5	NL child	5.0	Milk and cream	2.4	Apples	2.0	Rice	12.3
20.1	UK Toddler	5.7	Sugar beet (root)	3.5	Milk and cream	3.2	Rice	12.9
18.4	ES child	2.7	Rice	2.5	Maize	2.1	Milk and cream	5.7
17.5	PT General population	4.4	Rice	4.2	Maize	1.9	Wine grapes	3.7
17.3	LT adult	9.4	Rye	1.3	Buckwheat	1.2	Rice	3.1
15.8	FR toddler	6.7	Milk and cream	2.0	Rice	1.2	Potatoes	12.1
15.7	WHO regional European diet	2.9	Barley	1.3	Maize	1.1	Rice	4.5
14.6	ES adult	4.3	Barley	1.3	Rice	1.1	Olives for oil production	3.2
11.9	NL general	3.3	Barley	1.1	Milk and cream	0.9	Rice	3.9
11.7	DK adult	6.0	Rye	1.0	Wine grapes	0.9	Milk and cream	2.8
11.4	SE general population 90th percentile	2.6	Rye	2.2	Rice	2.1	Milk and cream	6.1
10.9	FI adult	6.0	Rye	1.0	Milk and cream	0.6	Rice	2.2
10.0	UK vegetarian	2.1	Rice	1.4	Tea (dried leaves and stalks)	0.9	Sugar beet (root)	3.4
9.7	FR infant	4.4	Milk and cream	1.0	Potatoes	0.9	Apples	8.4
8.7	UK Adult	2.0	Rice	1.5	Tea (dried leaves and stalks)	1.0	Sugar beet (root)	3.0
8.2	FR all population	3.0	Wine grapes	0.8	Wheat	0.6	Rice	2.6
6.1	IT kids/toddler	1.7	Wheat	1.1	Rice	0.5	Lettuce	3.3
5.1	IT adult	1.0	Wheat	1.0	Rice	0.7	Lettuce	2.4
3.1	PL general population	0.8	Potatoes	0.8	Apples	0.2	Table grapes	2.5

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Deltamethrin is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**			**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**			**---**
	IESTI 1	*)	**)		**IESTI 2**	*)	**)		**IESTI 1**	*)	**)		**IESTI 2**	*)	**)	
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	
	0.8	Rape seed	0.07/-		0.8	Rape seed	0.07/-									
	No of critical MRLs (IESTI 1)			---					**No of critical MRLs (IESTI 2)**			---				
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**			**---**					**No of commodities for which ARfD/ADI is exceeded:**			**---**				
			***)								***)					
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)						Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)					
	60.1	Elderberry juice	0.375/-						6.6	Apple juice	0.1/-					
	59.1	Maize flour	1.375/-						5.3	Wine	0.1375/-					
	51.0	Apple juice	0.1/-						5.1	Maize flour	1.375/-					
	45.2	Grape juice	0.1375/-						2.5	Orange juice	0.025/-					
	37.9	Cuurant juice	0.375/-						2.0	Peach preserved with	0.1/-					
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.																
Conclusion: For Deltamethrin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.																

Methoprene			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.05**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2001**	Year of evaluation:	**2001**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	126
No of diets exceeding ADI:	2

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
126.2	WHO Cluster diet B	85.4	Wheat	24.7	Maize	5.3	Rice	
106.1	DK child	55.0	Wheat	44.2	Rye	4.0	Oats	
88.7	WHO cluster diet D	65.0	Wheat	5.5	Rice	5.3	Maize	
84.4	IT kids/toddler	66.5	Wheat	15.0	Other cereal	1.9	Rice	
69.1	IE adult	23.0	Maize	23.0	Maize	12.4	Barley	
68.1	WHO cluster diet E	39.4	Wheat	8.1	Barley	5.6	Maize	
60.9	NL child	47.4	Wheat	3.5	Rice	2.9	Milk and cream	
60.1	WHO Cluster diet F	36.0	Wheat	7.6	Rye	6.0	Barley	
59.3	DE child	41.1	Wheat	7.9	Rye	2.7	Rice	
56.8	PT General population	39.2	Wheat	7.9	Rice	4.8	Maize	
54.7	ES child	44.4	Wheat	4.8	Rice	2.9	Maize	
51.0	IT adult	41.4	Wheat	7.1	Other cereal	1.8	Rice	
50.3	UK Infant	26.2	Wheat	10.3	Maize	6.3	Rice	
49.5	UK Toddler	39.2	Wheat	5.8	Rice	2.1	Milk and cream	
41.0	SE general population 90th percentile	32.0	Wheat	4.0	Rice	3.0	Rye	
39.8	WHO regional European diet	29.7	Wheat	3.3	Barley	2.0	Rice	
36.7	FR all population	32.9	Wheat	1.3	Sunflower seed	1.1	Rice	
35.4	FR toddler	26.2	Wheat	4.0	Milk and cream	3.6	Rice	
33.1	ES adult	23.5	Wheat	4.9	Barley	2.4	Rice	
29.9	DK adult	20.1	Wheat	6.8	Rye	1.1	Oats	
29.1	NL general	20.7	Wheat	3.7	Barley	1.6	Rice	
28.1	LT adult	10.8	Rye	10.5	Wheat	2.1	Rice	
26.1	UK vegetarian	20.5	Wheat	3.8	Rice	0.5	Oats	
21.8	UK Adult	16.8	Wheat	3.7	Rice	0.3	Milk and cream	
20.0	FI adult	9.8	Wheat	6.8	Rye	1.1	Rice	
12.8	FR infant	8.4	Wheat	2.6	Milk and cream	0.9	Rice	
0.5	PL general population	0.1	Potatoes	0.1	Apples	0.0	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 0.5–126 % of the ADI.
For 2 diets, the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

	Acute risk assessment /children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *) **)			**IESTI 2** *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.					
	Conclusion: As no ARfD was considered necessary, it is concluded that the short-term intake of Methoprene residues is unlikely to present a pulbic health concern.					

Buprofezin

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.01**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	73 652
No of diets exceeding ADI:	21

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
651.6	DE child	398.2	Apples	50.5	Citrus fruit	41.9	Oranges	
441.5	NL child	209.0	Apples	44.7	Citrus fruit	34.3	Oranges	
354.5	WHO Cluster diet B	105.4	Olives for oil production	33.9	Tomatoes	33.3	Apples	
269.4	FR toddler	86.5	Apples	25.7	Citrus fruit	23.8	PRODUCTS OF ANIMAL ORIGIN	
214.5	ES child	40.3	Olives for oil production	37.7	Apples	25.8	Citrus fruit	
213.1	IE adult	29.4	Citrus fruit	27.1	Apples	13.8	Wine grapes	
208.4	FR infant	82.5	Apples	16.1	Strawberries	15.1	PRODUCTS OF ANIMAL ORIGIN	
204.4	UK Toddler	56.3	Apples	25.4	Citrus fruit	21.8	Oranges	
180.6	UK Infant	51.6	Apples	23.1	PRODUCTS OF ANIMAL ORIGIN	21.3	Milk and cream,	
174.7	DK child	76.7	Apples	18.0	Cucumbers	12.0	PRODUCTS OF ANIMAL ORIGIN	
170.9	PT General population	34.7	Apples	30.4	Table and wine grapes	27.4	Wine grapes	
169.8	FR all population	45.2	Table and wine grapes	44.0	Wine grapes	15.7	Apples	
159.0	WHO cluster diet E	27.9	Apples	19.7	Table and wine grapes	17.7	Wine grapes	
158.3	SE general population 90th percentile	34.7	Apples	15.3	Citrus fruit	9.9	Bananas	
148.2	ES adult	25.4	Apples	23.2	Olives for oil production	15.9	Citrus fruit	
145.5	NL general	39.0	Apples	20.4	Citrus fruit	16.4	Oranges	
132.0	WHO regional European diet	22.0	Apples	12.1	Tomatoes	9.0	Citrus fruit	
114.3	WHO Cluster diet F	21.7	Apples	12.4	Citrus fruit	9.6	Oranges	
113.7	WHO cluster diet D	21.9	Apples	11.1	Tomatoes	6.1	Table and wine grapes	
107.3	PL general population	67.4	Apples	9.7	Tomatoes	3.8	Plums	
101.5	IT kids/toddler	29.3	Apples	15.7	Tomatoes	8.1	Citrus fruit	
99.7	UK vegetarian	19.5	Apples	11.5	Citrus fruit	9.8	Table and wine grapes	
99.0	LT adult	61.6	Apples	6.8	Tomatoes	4.3	Cucumbers	
97.6	DK adult	25.9	Apples	16.2	Table and wine grapes	15.3	Wine grapes	
89.4	IT adult	26.2	Apples	12.8	Tomatoes	6.4	Citrus fruit	
84.9	UK Adult	13.5	Apples	12.5	Table and wine grapes	11.9	Wine grapes	
73.1	FI adult	13.3	Apples	12.4	Citrus fruit	10.7	Oranges	

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 73.1–652 % of the ADI.

For 21 diets, the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	The acute risk assessment is based on the ARfD.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.					
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.					
	In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.					
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---	
	IESTI 1 *) **)		**IESTI 2** *) **)		**IESTI 1** *) **)		**IESTI 2** *) **)	
	Highest % of ARfD/ADI	Commodities / pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities / pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities / pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities / pTMRL/ threshold MRL (mg/kg)
	0.4	Avocados 0.055/-	0.3	Avocados 0.055/-	0.2	Avocados 0.055/-	0.2	Avocados 0.055/-
	No of critical MRLs (IESTI 1) ---				**No of critical MRLs (IESTI 2)** ---			
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
	***)				***)			
	Highest % of ARfD/ADI	Processed commodities / pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI	Processed commodities / pTMRL/ threshold MRL (mg/kg)		
	30.6	Apple juice 3/-			3.9	Apple juice 3/-		
	9.9	Orange juice 1/-			2.0	Orange juice 1/-		
	6.6	Grape juice 1/-			0.8	Wine 1/-		
	5.6	Plums juice 2/-			0.4	Tomato (preserved- 1/-		
	3.5	Tomato juice 1/-			0.3	Peach preserved with 0.7/-		
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.							
	**) pTMRL: provisional temporary MRL.							
	***) pTMRL: provisional temporary MRL for unprocessed commodity.							
	Conclusion:							
	For Buprofezin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.							
	No exceedance of the ARfD/ADI was identified for any unprocessed commodity.							
	For processed commodities, no exceedance of the ARfD/ADI was identified.							

Penconazole

Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):	0.05	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.03**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	5 63
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
62.9	DE child	48.3	Apples	2.5	Pears	1.9	Tomatoes	4.0
37.1	NL child	25.3	Apples	1.7	Pears	1.2	Tomatoes	5.6
25.3	WHO Cluster diet B	6.2	Tomatoes	4.0	Apples	2.0	Peppers	5.4
22.1	DK child	9.3	Apples	3.3	Cucumbers	2.7	Pears	4.0
20.4	FR toddler	10.5	Apples	1.5	Tomatoes	1.3	Milk and cream	5.1
17.7	UK Toddler	6.8	Apples	3.8	Sugar beet (root)	1.2	Tomatoes	7.1
17.4	IE adult	3.3	Apples	2.7	Pears	1.1	Peaches	4.8
17.3	FR infant	10.0	Apples	1.3	Courgettes	1.3	Pears	3.3
14.9	UK Infant	6.3	Apples	1.7	Sugar beet (root)	1.3	Milk and cream	5.7
13.9	ES child	4.6	Apples	2.0	Tomatoes	1.8	Pears	3.5
13.5	SE general population 90th percentile	4.2	Apples	1.5	Tomatoes	1.4	Pears	3.1
13.0	PT General population	4.2	Apples	1.8	Tomatoes	1.4	Pears	2.5
12.9	PL general population	8.2	Apples	1.8	Tomatoes	1.1	Pears	1.0
12.2	WHO cluster diet D	2.7	Apples	2.0	Tomatoes	1.1	Wheat	3.3
12.1	LT adult	7.5	Apples	1.2	Tomatoes	0.8	Cucumbers	1.6
12.1	IT kids/toddler	3.5	Apples	2.9	Tomatoes	1.4	Pears	2.1
11.9	WHO cluster diet E	3.4	Apples	1.1	Tomatoes	0.8	Wine grapes	3.7
11.7	WHO regional European diet	2.7	Apples	2.2	Tomatoes	0.8	Pears	3.2
10.3	NL general	4.7	Apples	0.9	Tomatoes	0.7	Pears	2.3
10.3	IT adult	3.2	Apples	2.3	Tomatoes	0.9	Pears	1.4
10.1	ES adult	3.1	Apples	1.6	Tomatoes	1.3	Pears	2.1
9.5	WHO Cluster diet F	2.6	Apples	1.4	Tomatoes	0.6	Wheat	3.1
8.5	DK adult	3.1	Apples	0.8	Tomatoes	0.8	Pears	1.6
8.5	FR all population	2.0	Wine grapes	1.9	Apples	0.9	Tomatoes	1.7
7.6	UK vegetarian	2.4	Apples	1.2	Tomatoes	0.6	Sugar beet (root)	2.1
6.0	UK Adult	1.6	Apples	0.9	Tomatoes	0.7	Sugar beet (root)	1.9
5.4	FI adult	1.6	Apples	0.9	Tomatoes	0.5	Cucumbers	1.3

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Penconazole is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1 *)		**)	**IESTI 2** *)		**)	**IESTI 1** *)		**)	**IESTI 2** *)		**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
21.0	Table grapes	1.6/-	21.0	Table grapes	1.6/-	10.2	Table grapes	1.6/-	10.2	Table grapes	1.6/-
9.1	Melons	0.3/-	9.1	Melons	0.3/-	7.6	Wine grapes	1.6/-	7.6	Wine grapes	1.6/-
8.2	Currants (red, black	4.4/-	8.2	Currants (red,	4.4/-	2.4	Melons	0.3/-	2.4	Melons	0.3/-
6.9	Strawberries	2.2/-	6.9	Strawberries	2.2/-	2.3	Currants (red, black	4.4/-	2.3	Currants (red, black and white)	4.4/-
2.5	Wine grapes	1.6/-	2.5	Wine grapes	1.6/-	2.3	Strawberries	2.2/-	2.3	Strawberries	2.2/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Penconazole, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Teflubenzuron			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.01**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
8	80
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
80.5	DE child	57.9	Apples	7.1	Milk and cream	4.2	Oranges	
60.6	NL child	30.4	Apples	14.7	Milk and cream	3.4	Oranges	
43.8	FR toddler	19.8	Milk and cream	12.6	Apples	2.5	Potatoes	
34.0	UK Infant	19.4	Milk and cream	7.5	Apples	1.6	Potatoes	
31.6	FR infant	12.9	Milk and cream	12.0	Apples	2.1	Potatoes	
28.0	WHO Cluster diet B	10.0	Tomatoes	4.8	Apples	1.8	Pears	
26.7	UK Toddler	10.3	Milk and cream	8.2	Apples	2.2	Oranges	
26.6	DK child	11.1	Apples	6.3	Milk and cream	3.3	Pears	
23.6	ES child	6.3	Milk and cream	5.5	Apples	3.2	Tomatoes	
23.3	SE general population 90th percentile	6.2	Milk and cream	5.0	Apples	3.1	Head cabbage	
18.9	LT adult	9.0	Apples	2.0	Tomatoes	2.0	Head cabbage	
18.1	PL general population	9.8	Apples	2.9	Tomatoes	1.8	Head cabbage	
17.7	WHO regional European diet	3.6	Tomatoes	3.2	Apples	2.4	Milk and cream	
17.7	NL general	5.7	Apples	3.3	Milk and cream	1.6	Oranges	
17.3	IE adult	3.9	Apples	3.2	Pears	1.4	Milk and cream	
16.0	WHO cluster diet E	4.1	Apples	1.9	Potatoes	1.7	Tomatoes	
15.8	PT General population	5.0	Apples	2.9	Tomatoes	2.7	Potatoes	
15.6	WHO cluster diet D	3.3	Tomatoes	3.2	Apples	2.5	Milk and cream	
14.9	WHO Cluster diet F	3.2	Apples	2.2	Tomatoes	2.0	Milk and cream	
14.5	ES adult	3.7	Apples	2.5	Tomatoes	2.5	Milk and cream	
12.2	IT kids/toddler	4.6	Tomatoes	4.3	Apples	1.7	Pears	
12.2	DK adult	3.8	Apples	2.7	Milk and cream	1.3	Tomatoes	
11.9	FR all population	3.8	Wine grapes	2.3	Apples	1.4	Tomatoes	
10.4	UK vegetarian	2.8	Apples	2.0	Tomatoes	1.6	Milk and cream	
10.3	IT adult	3.8	Apples	3.8	Tomatoes	1.1	Pears	
9.1	FI adult	2.8	Milk and cream	1.9	Apples	1.4	Tomatoes	
8.3	UK Adult	2.0	Apples	1.5	Milk and cream	1.4	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Teflubenzuron is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *) **)			**IESTI 2** *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1)	---		**No of critical MRLs (IESTI 2)**	---	
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.					
	Conclusion: As no ARfD was considered necessary, it is concluded that the short-term intake of Teflubenzuron residues is unlikely to present a pulbic health concern.					

Fipronil			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.0002	ARfD (mg/kg bw):	0.009
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Tox endpoints of EFSA, 2006 in agreement with EC 2013. RD RA for plant at EU is much more complex than JMPR level.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	85
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
85.5	FR toddler	59.4	Milk and cream	7.6	Potatoes	6.7	Bovine: Meat	
75.7	NL child	44.0	Milk and cream	8.8	Potatoes	7.8	Swine: Meat	
71.4	UK Infant	58.1	Milk and cream	4.9	Potatoes	4.7	Birds' eggs	
53.4	FR infant	38.6	Milk and cream	6.2	Potatoes	2.9	Bovine: Meat	
45.5	ES child	18.8	Milk and cream	7.1	Bovine: Meat	6.2	Swine: Meat	
40.4	UK Toddler	31.0	Milk and cream	5.2	Potatoes	3.1	Birds' eggs	
37.4	DE child	21.4	Milk and cream	3.9	Birds' eggs	3.8	Potatoes	
35.8	WHO regional European diet	7.2	Milk and cream	6.3	Swine: Meat	6.0	Potatoes	
34.7	WHO Cluster diet B	4.9	Maize	4.8	Milk and cream	4.1	Bovine: Meat	
30.0	WHO cluster diet E	5.8	Potatoes	4.5	Milk and cream	3.6	Poultry: Meat	
29.5	SE general population 90th percentile	18.6	Milk and cream	6.3	Potatoes	3.1	Birds' eggs	
27.5	IE adult	4.6	Maize	4.2	Milk and cream	3.8	Basil	
27.4	WHO Cluster diet F	5.9	Milk and cream	5.8	Swine: Meat	5.1	Potatoes	
26.9	DK child	18.9	Milk and cream	3.6	Potatoes	3.0	Birds' eggs	
26.8	NL general	9.8	Milk and cream	4.6	Swine: Meat	4.1	Potatoes	
25.7	WHO cluster diet D	7.6	Milk and cream	6.1	Potatoes	3.0	Bovine: Meat	
22.7	ES adult	7.4	Milk and cream	3.7	Bovine: Meat	3.6	Swine: Meat	
21.1	LT adult	5.9	Milk and cream	4.8	Swine: Meat	4.8	Potatoes	
15.0	DK adult	8.0	Milk and cream	2.8	Bovine: Meat	2.2	Potatoes	
14.3	FR all population	4.0	Milk and cream	2.5	Bovine: Meat	2.1	Poultry: Meat	
11.6	FI adult	8.5	Milk and cream	1.8	Potatoes	0.8	Birds' eggs	
10.3	PT General population	8.0	Potatoes	1.0	Maize	0.8	Onions	
9.3	UK vegetarian	4.9	Milk and cream	2.1	Potatoes	1.2	Birds' eggs	
8.4	UK Adult	4.5	Milk and cream	2.1	Potatoes	1.1	Birds' eggs	
6.2	PL general population	5.2	Potatoes	0.7	Onions	0.2	Cauliflower	
1.8	IT kids/toddler	1.3	Potatoes	0.3	Onions	0.1	Cauliflower	
1.3	IT adult	0.9	Potatoes	0.2	Onions	0.1	Cauliflower	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fipronil is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
4.4	Basil	0.57/-	4.4	Basil	0.57/-	0.2	Basil	0.57/-	0.2	Basil	0.57/-

No of critical MRLs (IESTI 1)	---	No of critical MRLs (IESTI 2)	---

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				No of commodities for which ARfD/ADI is exceeded: ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
0.9	Potato puree (flakes)	0.006/-		0.1	Potato uree (flakes)	0.006/-	
0.2	Maize flour	0.004/-		0.1	Fried potatoes	0.006/-	
0.1	Fried potatoes	0.006/-		0.0	Maize flour	0.004/-	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Fipronil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Dimethomorph

Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.05**	ARfD (mg/kg bw):	**0.6**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	2 – 16
No of diets exceeding ADI:	--- 0

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
16	FR toddler	11.7	Spinach	1.0	Broccoli	0.8	Oranges	0.0
13	NL child	6.2	Spinach	1.2	Oranges	0.9	Table grapes	0.0
11	WHO Cluster diet B	2.6	Lettuce	2.1	Wine grapes	1.7	Tomatoes	0.0
10	FR infant	7.4	Spinach	0.8	Broccoli	0.5	Milk and milk products: Cattle	0.0
9	DE child	3.4	Spinach	1.5	Table grapes	1.4	Oranges	0.0
8	IE adult	2.1	Spinach	1.5	Wine grapes	0.6	Celery	0.0
7	ES adult	3.9	Lettuce	1.2	Spinach	0.5	Wine grapes	0.0
7	WHO regional European diet	2.7	Lettuce	0.9	Head cabbage	0.6	Tomatoes	0.0
7	NL general	2.4	Spinach	0.9	Lettuce	0.7	Wine grapes	0.0
7	FR all population	4.7	Wine grapes	0.7	Lettuce	0.2	Tomatoes	0.0
7	ES child	3.0	Lettuce	1.3	Spinach	0.8	Oranges	0.0
6	WHO cluster diet E	1.9	Wine grapes	0.7	Spinach	0.7	Lettuce	0.0
6	IT adult	2.7	Lettuce	1.6	Spinach	0.6	Tomatoes	0.0
6	WHO Cluster diet F	2.2	Lettuce	0.7	Wine grapes	0.7	Head cabbage	0.0
5	SE general population 90th percentile	1.5	Head cabbage	1.1	Spinach	0.4	Potatoes	0.0
5	IT kids/toddler	2.1	Lettuce	1.0	Spinach	0.8	Tomatoes	0.0
5	PT General population	2.9	Wine grapes	0.5	Potatoes	0.5	Tomatoes	0.0
5	UK vegetarian	1.0	Lettuce	1.0	Wine grapes	0.6	Spinach	0.0
4	UK Adult	1.3	Wine grapes	0.8	Lettuce	0.3	HOPS (dried),	0.0
4	WHO cluster diet D	0.5	Tomatoes	0.4	Head cabbage	0.4	Wine grapes	0.0
3	UK Toddler	0.8	Oranges	0.5	Spinach	0.3	Potatoes	0.0
3	DK child	1.0	Lettuce	0.7	Cucumbers	0.3	Tomatoes	0.0
3	DK adult	1.6	Wine grapes	0.2	Tomatoes	0.1	Head cabbage	0.0
3	PL general population	0.9	Head cabbage	0.5	Tomatoes	0.4	Table grapes	0.0
2	LT adult	1.0	Head cabbage	0.5	Lettuce	0.3	Tomatoes	0.0
2	FI adult	0.6	Lettuce	0.4	Oranges	0.4	Wine grapes	0.0
2	UK Infant	0.5	Oranges	0.3	Potatoes	0.2	Head cabbage	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Dimethomorph is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
	The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *)		**)	**IESTI 2** *)		**)	**IESTI 1** *)		**)	**IESTI 2** *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	48	Lettuce	10.7/-	29	Lettuce	10.7/-	19.6	Lettuce	10.7/-	11.8	Lettuce	10.7/-
	No of critical MRLs (IESTI 1) 0 ---						**No of critical MRLs (IESTI 2)** 0 ---					
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
	***)						***)					
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.											
	Conclusion: For Dimethomorph, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.											

Chlorantraniliprole

Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**1.56**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

No exposre calculation was done for animal commodities since EU RA RD is different at EU level compare with JMPR.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	0 2
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
2.2	NL child	0.5	Spinach	0.3	Scarole (broad-leaf endive)	0.2	Witloof	0.0
1.7	WHO Cluster diet B	0.5	Lettuce	0.1	Tomatoes	0.1	Wine grapes	0.0
1.6	FR toddler	0.9	Spinach	0.1	Milk and cream	0.1	Oranges	0.0
1.5	DE child	0.4	Apples	0.3	Spinach	0.2	Oranges	0.0
1.3	IT adult	0.5	Lettuce	0.2	Other lettuce and other salad plants	0.1	Spinach	0.0
1.3	IE adult	0.3	Other leafy brassica	0.2	Spinach	0.1	Lettuce	0.0
1.2	ES adult	0.7	Lettuce	0.1	Beet leaves (chard)	0.1	Spinach	0.0
1.2	NL general	0.2	Witloof	0.2	Spinach	0.2	Lettuce	0.0
1.1	ES child	0.5	Lettuce	0.1	Spinach	0.1	Beet leaves (chard)	0.0
1.1	WHO regional European diet	0.5	Lettuce	0.0	Head cabbage	0.0	Scarole (broad-leaf endive)	0.0
1.1	FR all population	0.3	Wine grapes	0.2	Other lettuce and other salad plants	0.2	Witloof	0.0
1.1	FR infant	0.6	Spinach	0.1	Witloof	0.1	Milk and cream	0.0
1.1	IT kids/toddler	0.4	Lettuce	0.1	Other lettuce and other salad plants	0.1	Beet leaves (chard)	0.0
1.0	WHO cluster diet D	0.2	Chinese cabbage	0.1	Kale	0.1	Kale	0.0
0.9	WHO cluster diet E	0.1	Lettuce	0.1	Wine grapes	0.1	Rape seed	0.0
0.9	WHO Cluster diet F	0.4	Lettuce	0.1	Chinese cabbage	0.0	Kale	0.0
0.9	SE general population 90th percentile	0.3	Chinese cabbage	0.1	Spinach	0.1	Head cabbage	0.0
0.5	UK vegetarian	0.2	Lettuce	0.1	Wine grapes	0.0	Spinach	0.0
0.5	DK child	0.2	Lettuce	0.1	Apples	0.0	Milk and cream	0.0
0.5	UK Toddler	0.1	Oranges	0.1	Milk and cream	0.1	Apples	0.0
0.4	PT General population	0.2	Wine grapes	0.0	Sunflower seed	0.0	Tomatoes	0.0
0.4	UK Infant	0.1	Milk and cream	0.1	Oranges	0.1	Apples	0.0
0.4	UK Adult	0.2	Lettuce	0.1	Wine grapes	0.0	Oranges	0.0
0.3	FI adult	0.1	Lettuce	0.0	Chinese cabbage	0.0	Oranges	0.0
0.3	LT adult	0.1	Lettuce	0.1	Apples	0.1	Head cabbage	0.0
0.3	PL general population	0.1	Apples	0.0	Head cabbage	0.0	Tomatoes	0.0
0.3	DK adult	0.1	Wine grapes	0.0	Apples	0.0	Chinese cabbage	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Chlorantraniliprole is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.					
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.					
	In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.					
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---
	IESTI 1 *)	**)	**IESTI 2** *)	**IESTI 1** *)	**)	**IESTI 2** *)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1)		---	**No of critical MRLs (IESTI 2)**		---						
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
		***)			***)	
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.					
	**) pTMRL: provisional temporary MRL.					
	***) pTMRL: provisional temporary MRL for unprocessed commodity.					
	Conclusion:					
	As no ARfD was considered necessary, it is concluded that the short-term intake of Chlorantraniliprole residues is unlikely to present a pulbic health concern.					

Saflufenacil			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.03	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.046**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**UK, EFSA**	Source of ARfD:	**UK, EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

No ARfD was derived at JMPR level; therefore, both acute and chronic exposure calculation is performed by using the STMRs values

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	34
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
34.0	WHO Cluster diet B	9.9	Bovine: Edible offal	6.1	Wheat	4.9	Bovine: Liver	2.1
27.0	IE adult	15.2	Sheep: Liver	7.2	Sheep: Edible offal	1.6	Wheat	1.9
21.3	WHO cluster diet D	7.1	Bovine: Edible offal	4.7	Wheat	4.2	Swine: Edible offal	1.1
19.9	WHO cluster diet E	7.2	Swine: Edible offal	5.2	Bovine: Edible offal	2.8	Wheat	1.2
18.2	WHO regional European diet	6.7	Bovine: Edible offal	5.6	Swine: Edible offal	2.1	Wheat	1.1
16.7	NL child	5.1	Bovine: Liver	4.8	Swine: Liver	3.4	Wheat	2.6
14.4	WHO Cluster diet F	4.5	Bovine: Edible offal	3.5	Swine: Edible offal	2.6	Wheat	1.0
14.0	DK child	8.6	Bovine: Liver	3.9	Wheat	0.3	Rye	1.4
12.6	FR toddler	8.3	Bovine: Edible offal	1.9	Wheat	0.9	Milk and cream	2.3
12.1	UK Infant	6.2	Bovine: Liver	1.9	Wheat	1.5	Bovine: Kidney	2.5
11.2	ES child	4.3	Swine: Liver	3.2	Wheat	1.3	Bovine: Edible offal	1.2
7.5	UK Toddler	2.8	Wheat	1.5	Sugar beet (root)	1.4	Bovine: Liver	2.9
7.2	FR all population	3.9	Bovine: Edible offal	2.4	Wheat	0.3	Wine grapes	0.8
5.7	ES adult	1.7	Wheat	1.2	Swine: Liver	0.8	Bovine: Edible offal	0.8
5.7	DK adult	3.6	Bovine: Liver	1.4	Wheat	0.1	Milk and cream	0.6
5.7	NL general	1.7	Swine: Liver	1.5	Wheat	1.2	Bovine: Liver	1.0
5.5	DE child	2.9	Wheat	0.8	Apples	0.3	Milk and cream	2.5
5.4	IT kids/toddler	4.8	Wheat	0.1	Solanacea	0.1	Other cereal	0.6
4.6	FR infant	2.3	Bovine: Edible offal	0.6	Wheat	0.6	Milk and cream	1.7
4.1	LT adult	1.4	Swine: Liver	1.1	Bovine: Liver	0.8	Wheat	0.7
4.0	PT General population	2.8	Wheat	0.3	Potatoes	0.2	Wine grapes	1.1
3.7	SE general population 90th percentile	2.3	Wheat	0.3	Potatoes	0.3	Milk and cream	1.4
3.5	IT adult	3.0	Wheat	0.1	Solanacea	0.1	Leaf vegetables & fresh herbs	0.5
3.1	UK Adult	1.2	Wheat	0.9	Bovine: Liver	0.3	Sugar beet (root)	0.8
2.3	UK vegetarian	1.5	Wheat	0.2	Sugar beet (root)	0.1	Potatoes	0.9
1.3	FI adult	0.7	Wheat	0.1	Milk and cream	0.1	Potatoes	0.6
0.6	PL general population	0.2	Potatoes	0.1	Apples	0.1	Solanacea	0.6

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Saflufenacil is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
871.4	Bovine: Liver	54/6.19	871.4	Bovine: Liver	54/6.19	291.2	Bovine: Liver	54/18.54	291.2	Bovine: Liver	54/18.54
120.0	Swine: Liver	54/45	120.0	Swine: Liver	54/45	73.8	Sheep: Liver	54/-	73.8	Sheep: Liver	54/-
3.2	Bovine: Kidney	0.43/-	3.2	Bovine: Kidney	0.43/-	71.6	Swine: Liver	54/-	71.6	Swine: Liver	54/-
1.2	Barley	0.33/-	1.2	Barley	0.33/-	4.8	Barley	0.33/-	4.8	Barley	0.33/-
1.1	Swine: Kidney	0.43/-	1.1	Swine: Kidney	0.43/-	1.5	Bovine: Kidney	0.43/-	1.5	Bovine: Kidney	0.43/-
0.9	Wheat	0.03/-	0.9	Wheat	0.03/-	1.2	Swine: Kidney	0.43/-	1.2	Swine: Kidney	0.43/-
0.6	Bovine: Edible offal	0.044/-	0.6	Bovine: Edible offal	0.044/-	0.5	Wheat	0.03/-	0.5	Wheat	0.03/-
0.3	Sugar cane	0.02/-	0.3	Sugar cane	0.02/-	0.3	Bovine: Edible offal	0.044/-	0.3	Bovine: Edible offal	0.044/-
0.1	Horse: Meat	0.01/-	0.1	Horse: Meat	0.01/-	0.2	Sugar cane	0.02/-	0.2	Sugar cane	0.02/-
0.0	Coffee beans	0.03/-	0.0	Coffee beans	0.03/-	0.1	Coffee beans	0.03/-	0.1	Coffee beans	0.03/-
						0.1	Sheep: Edible offal	0.044/-	0.1	Sheep: Edible offal	0.044/-
						0.0	Other swine products	0.01/-	0.0	Other swine products	0.01/-
						0.0	Horse: Meat	0.01/-	0.0	Horse: Meat	0.01/-
No of critical MRLs (IESTI 1)		2				**No of critical MRLs (IESTI 2)**		2			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**				**No of commodities for which ARfD/ADI is exceeded:**		**---**			
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Saflufenacil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 2 commodities.

Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 2 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Scenario 2

Benzovidndiflupyr			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.05**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2015**	Year of evaluation:	**2015**

Consumer risk assessment with US MRLs of 0.06 mg/kg for ruminant and equine liver.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 3
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
2.9	NL child	1.2	Milk and cream	0.6	Apples	0.2	Wheat	
2.9	DE child	1.2	Apples	0.6	Milk and cream	0.2	Tomatoes	
2.6	FR toddler	1.6	Milk and cream	0.3	Apples	0.1	Tomatoes	
2.5	UK Infant	1.5	Milk and cream	0.2	Sugar beet (root)	0.2	Apples	
2.2	WHO Cluster diet B	0.5	Tomatoes	0.3	Wheat	0.1	Milk and cream	
2.1	UK Toddler	0.8	Milk and cream	0.5	Sugar beet (root)	0.2	Apples	
1.8	IE adult	0.5	Barley	0.1	Milk and cream	0.1	Wheat	
1.8	DK child	0.5	Milk and cream	0.2	Apples	0.2	Wheat	
1.7	FR infant	1.0	Milk and cream	0.3	Apples	0.1	Potatoes	
1.5	ES child	0.5	Milk and cream	0.2	Wheat	0.2	Tomatoes	
1.4	WHO cluster diet E	0.3	Barley	0.2	Wheat	0.1	Milk and cream	
1.3	SE general population 90th percentile	0.5	Milk and cream	0.1	Tomatoes	0.1	Wheat	
1.3	WHO Cluster diet F	0.2	Barley	0.2	Milk and cream	0.1	Wheat	
1.2	WHO cluster diet D	0.3	Wheat	0.2	Milk and cream	0.2	Tomatoes	
1.2	WHO regional European diet	0.2	Tomatoes	0.2	Milk and cream	0.1	Barley	
1.1	ES adult	0.2	Milk and cream	0.2	Barley	0.1	Tomatoes	
1.1	NL general	0.3	Milk and cream	0.1	Barley	0.1	Apples	
0.8	IT kids/toddler	0.3	Wheat	0.3	Tomatoes	0.1	Apples	
0.8	LT adult	0.2	Apples	0.2	Milk and cream	0.1	Tomatoes	
0.8	PT General population	0.2	Tomatoes	0.2	Wheat	0.1	Potatoes	
0.7	DK adult	0.2	Milk and cream	0.1	Wheat	0.1	Apples	
0.7	UK vegetarian	0.1	Milk and cream	0.1	Tomatoes	0.1	Wheat	
0.7	FR all population	0.1	Wheat	0.1	Milk and cream	0.1	Wine grapes	
0.6	IT adult	0.2	Tomatoes	0.2	Wheat	0.1	Apples	
0.6	FI adult	0.2	Milk and cream	0.1	Tomatoes	0.0	Apples	
0.6	UK Adult	0.1	Milk and cream	0.1	Sugar beet (root)	0.1	Tomatoes	
0.5	PL general population	0.2	Apples	0.2	Tomatoes	0.1	Potatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Benzovidndiflupyr is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	39.05	Peppers	0.62/-	27.89	Peppers	0.62/-	15.43	Aubergines (egg	0.62/-	15.43	Aubergines (egg plants)	0.62/-
	36.05	Tomatoes	0.62/-	26.12	Tomatoes	0.62/-	10.13	Peppers	0.62/-	8.47	Pumpkins	0.16/-
	24.27	Melons	0.16/-	24.27	Melons	0.16/-	9.44	Tomatoes	0.62/-	7.62	Tomatoes	0.62/-
	19.56	Watermelons	0.16/-	19.56	Watermelons	0.16/-	8.47	Pumpkins	0.16/-	7.24	Peppers	0.62/-
	15.50	Aubergines (egg	0.62/-	15.50	Aubergines (egg	0.62/-	6.50	Watermelons	0.16/-	6.50	Watermelons	0.16/-
	9.36	Cucumbers	0.16/-	9.36	Cucumbers	0.16/-	6.32	Melons	0.16/-	6.32	Melons	0.16/-
	7.44	Courgettes	0.16/-	5.46	Pumpkins	0.16/-	4.32	Courgettes	0.16/-	3.25	Courgettes	0.16/-
	5.46	Pumpkins	0.16/-	5.31	Courgettes	0.16/-	3.15	Cucumbers	0.16/-	3.15	Cucumbers	0.16/-
	2.61	Gherkins	0.16/-	1.89	Gherkins	0.16/-	0.80	Gherkins	0.16/-	0.61	Gherkins	0.16/-
	0.52	Bovine: Liver	0.064/-	0.52	Bovine: Liver	0.064/-	0.19	Bovine: Edible offal	0.064/-	0.19	Bovine: Edible offal	0.064/-
	0.47	Bovine: Edible offal	0.064/-	0.47	Bovine: Edible offal	0.064/-	0.17	Bovine: Liver	0.064/-	0.17	Bovine: Liver	0.064/-
	0.24	Bovine: Kidney	0.064/-	0.24	Bovine: Kidney	0.064/-	0.11	Bovine: Kidney	0.064/-	0.11	Bovine: Kidney	0.064/-
	0.15	Bovine: Meat	0.012/-	0.15	Bovine: Meat	0.012/-	0.09	Swine: Kidney	0.064/-	0.09	Swine: Kidney	0.064/-
	0.12	Sheep: Meat	0.012/-	0.12	Sheep: Meat	0.012/-	0.07	Bovine: Meat	0.012/-	0.07	Bovine: Meat	0.012/-
	0.10	Swine: Meat	0.0118/-	0.10	Swine: Meat	0.0118/-	0.06	Swine: Meat	0.0118/-	0.06	Swine: Meat	0.0118/-
	0.08	Swine: Kidney	0.064/-	0.08	Swine: Kidney	0.064/-	0.06	Sheep: Meat	0.012/-	0.06	Sheep: Meat	0.012/-
	0.07	Horse: Meat	0.012/-	0.07	Horse: Meat	0.012/-	0.04	Sheep: Edible offal	0.064/-	0.04	Sheep: Edible offal	0.064/-
	0.07	Swine: Liver	0.064/-	0.07	Swine: Liver	0.064/-	0.04	Sheep: Liver	0.064/-	0.04	Sheep: Liver	0.064/-
	0.06	Peanuts	0.01/-	0.06	Peanuts	0.01/-	0.04	Swine: Liver	0.064/-	0.04	Swine: Liver	0.064/-
	0.05	Peas	0.011/-	0.05	Peas	0.011/-	0.04	Peas	0.011/-	0.04	Peas	0.011/-
	0.04	Bovine: Fat	0.019/-	0.04	Bovine: Fat	0.019/-	0.03	Swine: Fat free of lean	0.019/-	0.03	Swine: Fat free of lean meat	0.019/-
	0.03	Rape seed	0.023/-	0.03	Rape seed	0.023/-	0.02	Peanuts	0.01/-	0.02	Peanuts	0.01/-
	0.02	Swine: Fat free of lean	0.019/-	0.02	Swine: Fat free of	0.019/-	0.02	Coffee beans	0.015/-	0.02	Coffee beans	0.015/-
	0.02	Soya bean	0.01/-	0.02	Soya bean	0.01/-	0.02	Goat: Meat	0.012/-	0.02	Goat: Meat	0.012/-
	0.01	Coffee beans	0.015/-	0.01	Coffee beans	0.015/-	0.01	Horse: Meat	0.012/-	0.01	Horse: Meat	0.012/-
							0.01	Bovine: Fat	0.019/-	0.01	Bovine: Fat	0.019/-
							0.01	Soya bean	0.01/-	0.01	Soya bean	0.01/-
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**						**No of commodities for which ARfD/ADI is exceeded:**					
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	0.41	Apple juice	0.008/-				0.05	Apple juice	0.008/-			
	0.11	Grape juice	0.0032/-				0.04	Raisins	0.0944/-			
	0.04	Grapes (raisins)	0.0944/-				0.01	Wine	0.0032/-			
	0.00	Wine	0.0032/-									
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.												
Conclusion: For Benzovidndiflupyr, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.												

Bixafen			
Status of the active substance:	**Pending**	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.02**	ARfD (mg/kg bw):	**0.2**
Source of ADI:	**RMS (UK)**	Source of ARfD:	**RMS (UK)**
Year of evaluation:	**2009**	Year of evaluation:	**2009**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	**19**
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
19.3	NL child	12.0	Milk and milk products: Cattle	2.1	Swine: Meat	1.6	Bovine: Meat	1.4
12.7	FR infant	10.6	Milk and milk products: Cattle	0.8	Bovine: Meat	0.3	Bovine: Edible offal	0.8
11.3	ES child	5.1	Milk and milk products: Cattle	1.9	Bovine: Meat	1.7	Swine: Meat	0.7
9.6	WHO Cluster diet B	1.2	Bovine: Edible offal	1.2	Milk and milk products: Cattle	1.1	Bovine: Meat	1.5
9.2	DE child	5.8	Milk and milk products: Cattle	0.6	Apples	0.6	Swine: Meat	1.6
8.9	WHO regional European diet	2.0	Milk and milk products: Cattle	1.7	Swine: Meat	1.4	Bovine: Meat	0.7
8.4	IE adult	1.9	Sheep: Liver	1.1	Milk and milk products: Cattle	0.9	Sheep: Edible offal	1.4
7.4	WHO Cluster diet F	1.6	Milk and milk products: Cattle	1.6	Swine: Meat	1.2	Bovine: Meat	0.6
7.4	WHO cluster diet E	1.2	Milk and milk products: Cattle	0.9	Bovine: Meat	0.9	Swine: Edible offal	0.8
6.9	WHO cluster diet D	1.9	Milk and milk products: Cattle	0.9	Bovine: Edible offal	0.8	Bovine: Meat	0.7
6.4	NL general	2.7	Milk and milk products: Cattle	1.2	Swine: Meat	0.9	Bovine: Meat	0.6
6.3	SE general population 90th percentile	5.1	Milk and milk products: Cattle	0.3	Wheat	0.2	Potatoes	0.8
5.8	ES adult	2.0	Milk and milk products: Cattle	1.0	Bovine: Meat	1.0	Swine: Meat	0.5
4.7	FR toddler	1.8	Bovine: Meat	1.0	Bovine: Edible offal	0.4	Swine: Meat	1.1
4.6	LT adult	1.6	Milk and milk products: Cattle	1.3	Swine: Meat	0.3	Bovine: Meat	0.4
3.6	FR all population	1.1	Milk and milk products: Cattle	0.7	Bovine: Meat	0.5	Bovine: Edible offal	0.5
3.0	DK child	1.1	Bovine: Liver	0.6	Wheat	0.4	Rye	0.6
2.6	UK Infant	0.8	Bovine: Liver	0.5	Sugar beet (root)	0.3	Wheat	1.2
2.5	UK Toddler	1.1	Sugar beet (root)	0.4	Wheat	0.2	Potatoes	1.8
1.9	DK adult	0.7	Bovine: Meat	0.5	Bovine: Liver	0.2	Wheat	0.3
1.3	PT General population	0.4	Wheat	0.3	Potatoes	0.1	Wine grapes	0.8
1.1	IT kids/toddler	0.7	Wheat	0.1	Tomatoes	0.0	Potatoes	0.4
0.9	UK vegetarian	0.2	Wheat	0.2	Sugar beet (root)	0.1	Potatoes	0.6
0.9	UK Adult	0.2	Sugar beet (root)	0.2	Wheat	0.1	Bovine: Liver	0.5
0.8	IT adult	0.4	Wheat	0.1	Tomatoes	0.0	Apples	0.4
0.5	FI adult	0.1	Wheat	0.1	Rye	0.1	Potatoes	0.3
0.5	PL general population	0.2	Potatoes	0.1	Apples	0.0	Tomatoes	0.5

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Bixafen is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	15.7	Bovine: Liver	3.9/-	15.734	Bovine: Liver	3.9/-	5.773	Bovine: Edible offal	3.9/-	5.773	Bovine: Edible offal	3.9/-
	14.2	Bovine: Edible offal	3.9/-	14.188	Bovine: Edible offal	3.9/-	5.257	Bovine: Liver	3.9/-	5.257	Bovine: Liver	3.9/-
	5.3	Bovine: Meat	0.828/-	5.291	Bovine: Meat	0.828/-	2.464	Bovine: Meat	0.828/-	2.464	Bovine: Meat	0.828/-
	5.1	Milk and milk products:	0.082/-	5.093	Milk and milk	0.082/-	2.1	Swine: Meat	0.828/-	2.1	Swine: Meat	0.828/-
	4.3	Sheep: Meat	0.828/-	4.3	Sheep: Meat	0.828/-	2.0	Sheep: Meat	0.828/-	2.0	Sheep: Meat	0.828/-
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**						**No of commodities for which ARfD/ADI is exceeded:**					
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	0.3	Apple juice	0.01/-				0.1	Orange juice	0.01/-			
	0.2	Orange juice	0.01/-				0.0	Bread/pizza	0.02/-			
	0.2	Carrot, juice	0.01/-				0.0	Apple juice	0.01/-			
	0.2	Grape juice	0.01/-				0.0	Wine	0.01/-			
	0.1	Wheat flour	0.02/-				0.0	Pineapples preserved	0.01/-			
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.												
Conclusion: For Bixafen, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.												

Fluensulfone

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.01**	ARfD (mg/kg bw):	**0.3**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2016**	Year of evaluation:	**2016**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum 1 – 10
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
9.9	FR toddler	4.0	Milk and cream	2.9	Carrots	0.5	Potatoes	
8.4	UK Infant	3.9	Milk and cream	1.6	Carrots	1.0	Sugar beet (root)	
7.7	FR infant	3.2	Carrots	2.6	Milk and cream	0.4	Potatoes	
7.5	NL child	2.9	Milk and cream	0.6	Apples	0.6	Carrots	
7.0	UK Toddler	2.3	Sugar beet (root)	2.1	Milk and cream	0.6	Carrots	
6.6	DE child	1.4	Milk and cream	1.2	Carrots	1.2	Apples	
5.8	WHO Cluster diet B	0.9	Wheat	0.8	Beetroot	0.3	Milk and cream	
5.6	IE adult	0.8	Parsnips	0.4	Carrots	0.4	Sweet potatoes	
5.6	DK child	1.6	Carrots	1.3	Milk and cream	0.6	Wheat	
4.6	SE general population 90th percentile	1.2	Milk and cream	1.0	Carrots	0.4	Potatoes	
3.7	ES child	1.3	Milk and cream	0.4	Wheat	0.2	Oranges	
3.6	WHO cluster diet E	0.5	Carrots	0.4	Wheat	0.4	Potatoes	
3.6	WHO Cluster diet F	0.6	Carrots	0.4	Milk and cream	0.4	Wheat	
3.3	WHO cluster diet D	0.7	Wheat	0.5	Milk and cream	0.4	Potatoes	
3.3	WHO regional European diet	0.5	Milk and cream	0.4	Carrots	0.4	Potatoes	
2.8	PT General population	0.8	Carrots	0.5	Potatoes	0.4	Wheat	
2.6	NL general	0.7	Milk and cream	0.3	Potatoes	0.3	Carrots	
2.3	FR all population	0.4	Wine grapes	0.4	Carrots	0.3	Wheat	
2.3	DK adult	0.5	Milk and cream	0.5	Carrots	0.2	Wheat	
2.2	ES adult	0.5	Milk and cream	0.2	Wheat	0.2	Carrots	
2.1	UK vegetarian	0.4	Sugar beet (root)	0.3	Milk and cream	0.3	Carrots	
1.9	LT adult	0.4	Milk and cream	0.3	Potatoes	0.2	Carrots	
1.9	UK Adult	0.4	Sugar beet (root)	0.3	Milk and cream	0.2	Carrots	
1.9	IT kids/toddler	0.7	Wheat	0.2	Carrots	0.2	Other cereal	
1.7	FI adult	0.6	Milk and cream	0.2	Carrots	0.1	Potatoes	
1.6	PL general population	0.4	Carrots	0.3	Potatoes	0.3	Beetroot	
1.4	IT adult	0.4	Wheat	0.2	Carrots	0.1	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fluensulfone is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
10.6	Carrots	0.5/-	9.2	Celeriac	0.5/-	4.2	Celery	0.55/-	4.0	Swedes	0.5/-
9.2	Celeriac	0.5/-	8.6	Swedes	0.5/-	4.0	Swedes	0.5/-	3.1	Celery	0.55/-
8.6	Swedes	0.5/-	8.4	Celery	0.55/-	2.8	Celeriac	0.5/-	2.8	Celeriac	0.5/-
8.4	Celery	0.55/-	7.5	Carrots	0.5/-	2.3	Parsnips	0.5/-	1.8	Beetroot	0.5/-
7.3	Beetroot	0.5/-	5.4	Beetroot	0.5/-	2.3	Beetroot	0.5/-	1.7	Parsnips	0.5/-
6.0	Parsnips	0.5/-	4.3	Parsnips	0.5/-	2.0	Carrots	0.5/-	1.6	Carrots	0.5/-
6.0	Turnips	0.5/-	4.3	Turnips	0.5/-	1.9	Radishes	0.5/-	1.3	Radishes	0.5/-
3.7	Radishes	0.5/-	2.6	Radishes	0.5/-	1.8	Turnips	0.5/-	1.3	Turnips	0.5/-
0.5	Potatoes	0.01/-	0.5	Melons	0.01/-	0.2	Courgettes	0.017/-	0.1	Watermelons	0.01/-
0.5	Melons	0.01/-	0.4	Watermelons	0.01/-	0.1	Horseradish	0.5/-	0.1	Melons	0.01/-
0.4	Watermelons	0.01/-	0.4	Potatoes	0.01/-	0.1	Watermelons	0.01/-	0.1	Chinese cabbage	0.01/-
0.3	Cucumbers	0.017/-	0.3	Cucumbers	0.017/-	0.1	Melons	0.01/-	0.1	Courgettes	0.017/-
0.3	Scarole (broad-leaf	0.01/-	0.2	Cauliflower	0.01/-	0.1	Chinese cabbage	0.01/-	0.1	Cucumbers	0.017/-
0.3	Courgettes	0.017/-	0.2	Chervil	0.5/-	0.1	Cucumbers	0.017/-	0.1	Cauliflower	0.01/-
0.2	Sweet corn	0.01/-	0.2	Courgettes	0.017/-	0.1	Cauliflower	0.01/-	0.1	Horseradish	0.5/-
0.2	Kale	0.01/-	0.2	Scarole (broad-leaf	0.01/-	0.1	Head cabbage	0.01/-	0.1	Aubergines (egg plants)	0.01/-
0.2	Cauliflower	0.01/-	0.2	Sweet corn	0.01/-	0.1	Potatoes	0.01/-	0.1	Potatoes	0.01/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Fluensulfone, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Tolfenpyrad

Status of the active substance:	**Not approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.006**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2016**	Year of evaluation:	**2016**

JMPR tox ref values were used for the exposure calculation. No codex proposal > EU MRL. Thereofre no values in bold for this substance. Current EU MRL for crops are reorted under the acute sheet, no other action on chronic.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
2	11
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
11.3	UK Infant	6.5	Milk and cream	1.7	Sugar beet (root)	0.5	Potatoes	
11.2	FR toddler	6.6	Milk and cream	0.8	Potatoes	0.4	Apples	
11.1	NL child	4.9	Milk and cream	1.1	Apples	1.0	Potatoes	
10.5	UK Toddler	3.8	Sugar beet (root)	3.4	Milk and cream	0.7	Wheat	
8.9	DE child	2.4	Milk and cream	2.0	Apples	0.7	Wheat	
7.8	WHO Cluster diet B	1.4	Wheat	0.5	Milk and cream	0.5	Tomatoes	
7.4	FR infant	4.3	Milk and cream	0.7	Potatoes	0.4	Carrots	
6.8	DK child	2.1	Milk and cream	0.9	Wheat	0.7	Rye	
6.3	IE adult	0.6	Sweet potatoes	0.5	Milk and cream	0.4	Maize	
5.9	ES child	2.1	Milk and cream	0.7	Wheat	0.4	Oranges	
5.4	SE general population 90th percentile	2.1	Milk and cream	0.7	Potatoes	0.5	Wheat	
4.9	WHO cluster diet E	0.7	Wheat	0.6	Potatoes	0.5	Milk and cream	
4.7	WHO cluster diet D	1.1	Wheat	0.8	Milk and cream	0.7	Potatoes	
4.6	WHO regional European diet	0.8	Milk and cream	0.7	Potatoes	0.5	Wheat	
4.3	WHO Cluster diet F	0.7	Milk and cream	0.6	Wheat	0.6	Potatoes	
3.8	NL general	1.1	Milk and cream	0.5	Potatoes	0.3	Wheat	
3.4	PT General population	0.9	Potatoes	0.7	Wheat	0.4	Wine grapes	
3.3	ES adult	0.8	Milk and cream	0.4	Wheat	0.2	Oranges	
3.1	FR all population	0.7	Wine grapes	0.5	Wheat	0.4	Milk and cream	
3.0	UK vegetarian	0.6	Sugar beet (root)	0.5	Milk and cream	0.3	Wheat	
2.9	DK adult	0.9	Milk and cream	0.3	Wheat	0.2	Potatoes	
2.7	IT kids/toddler	1.1	Wheat	0.3	Other cereal	0.2	Tomatoes	
2.7	UK Adult	0.7	Sugar beet (root)	0.5	Milk and cream	0.3	Wheat	
2.7	LT adult	0.7	Milk and cream	0.5	Potatoes	0.3	Apples	
2.4	FI adult	0.9	Milk and cream	0.2	Potatoes	0.2	Wheat	
2.0	IT adult	0.7	Wheat	0.2	Tomatoes	0.1	Apples	
1.6	PL general population	0.6	Potatoes	0.3	Apples	0.1	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Tolfenpyrad is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *) **)			**IESTI 2** *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	15.4	Potatoes	0.01/-	11.0	Potatoes	0.01/-
	0.2	Pecans	0.01/-	0.2	Pecans	0.01/-
	No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---		

Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
For Tolfenpyrad, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Metrafenone			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	0.01
Toxicological end points			
ADI (mg/kg bw per day):	**0.25**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2006**	Year of evaluation:	**2006**

EFSA, 2015 and EFSA, 2013 confirmed by EC 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
0	3
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
2.6	DE child	1.1	Apples	0.5	Table grapes	0.3	Milk and cream	
2.2	NL child	0.6	Milk and cream	0.6	Apples	0.3	Table grapes	
1.7	FR toddler	0.8	Milk and cream	0.2	Apples	0.1	Potatoes	
1.5	UK Infant	0.8	Milk and cream	0.2	Sugar beet (root)	0.1	Apples	
1.5	UK Toddler	0.5	Sugar beet (root)	0.4	Milk and cream	0.2	Apples	
1.4	WHO Cluster diet B	0.2	Wine grapes	0.2	Table grapes	0.1	Tomatoes	
1.2	FR infant	0.5	Milk and cream	0.2	Apples	0.1	Potatoes	
1.2	IE adult	0.1	Wine grapes	0.1	Table grapes	0.1	Apples	
1.0	DK child	0.3	Milk and cream	0.2	Apples	0.1	Cucumbers	
0.9	WHO cluster diet E	0.2	Wine grapes	0.1	Apples	0.1	Potatoes	
0.8	ES child	0.3	Milk and cream	0.1	Apples	0.0	Oranges	
0.8	PT General population	0.2	Wine grapes	0.1	Table grapes	0.1	Potatoes	
0.8	SE general population 90th percentile	0.2	Milk and cream	0.1	Apples	0.1	Potatoes	
0.8	FR all population	0.4	Wine grapes	0.1	Milk and cream	0.0	Table grapes	
0.7	WHO regional European diet	0.1	Milk and cream	0.1	Potatoes	0.1	Table grapes	
0.7	WHO cluster diet D	0.1	Milk and cream	0.1	Table grapes	0.1	Potatoes	
0.7	NL general	0.1	Milk and cream	0.1	Apples	0.1	Table grapes	
0.6	WHO Cluster diet F	0.1	Milk and cream	0.1	Potatoes	0.1	Apples	
0.6	ES adult	0.1	Milk and cream	0.1	Apples	0.0	Wine grapes	
0.5	DK adult	0.1	Wine grapes	0.1	Milk and cream	0.1	Apples	
0.5	PL general population	0.2	Apples	0.1	Table grapes	0.1	Potatoes	
0.5	UK vegetarian	0.1	Wine grapes	0.1	Sugar beet (root)	0.1	Milk and cream	
0.5	UK Adult	0.1	Wine grapes	0.1	Sugar beet (root)	0.1	Milk and cream	
0.5	LT adult	0.2	Apples	0.1	Milk and cream	0.1	Potatoes	
0.4	IT kids/toddler	0.1	Apples	0.1	Tomatoes	0.0	Table grapes	
0.4	IT adult	0.1	Apples	0.1	Table grapes	0.1	Tomatoes	
0.3	FI adult	0.1	Milk and cream	0.0	Apples	0.0	Wine grapes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Metrafenone is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.					
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.					
	In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.					
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---		**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---
	IESTI 1 *)	**)	**IESTI 2** *)	**)	**IESTI 1** *)	**)	**IESTI 2** *)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.					
	**) pTMRL: provisional temporary MRL.					
	***) pTMRL: provisional temporary MRL for unprocessed commodity.					
	Conclusion:					
	As no ARfD was considered necessary, it is concluded that the short-term intake of Metrafenone residues is unlikely to present a pulbic health concern.					

Flonicamid			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.025	ARfD (mg/kg bw):	0.025
Source of ADI:	EU	Source of ARfD:	EU
Year of evaluation:	2010	Year of evaluation:	2010

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
4	34
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
34	NL child	8.5	Spinach	6.6	Wheat	5.9	Milk and cream	
34	FR toddler	16.2	Spinach	7.9	Milk and cream	3.7	Wheat	
27	DE child	6.3	Apples	5.8	Wheat	4.7	Spinach	
26	WHO Cluster diet B	11.9	Wheat	3.8	Lettuce	1.9	Spinach	
22	DK child	7.7	Wheat	5.7	Rye	2.5	Milk and cream	
21	FR infant	10.1	Spinach	5.1	Milk and cream	1.3	Apples	
20	WHO cluster diet D	9.1	Wheat	3.4	Chinese cabbage	1.7	Kale	
19	ES child	6.2	Wheat	4.5	Lettuce	2.5	Milk and cream	
18	SE general population 90th percentile	4.5	Wheat	3.7	Chinese cabbage	2.5	Milk and cream	
16	IT kids/toddler	9.3	Wheat	3.1	Lettuce	1.3	Spinach	
15	WHO Cluster diet F	5.0	Wheat	3.2	Lettuce	1.2	Chinese cabbage	
15	WHO regional European diet	4.2	Wheat	4.0	Lettuce	1.0	Milk and cream	
15	UK Infant	7.7	Milk and cream	3.7	Wheat	0.8	Apples	
15	ES adult	5.7	Lettuce	3.3	Wheat	1.7	Spinach	
15	NL general	3.2	Spinach	2.9	Wheat	1.8	Kale	
14	IT adult	5.8	Wheat	4.0	Lettuce	2.2	Spinach	
14	UK Toddler	5.5	Wheat	4.1	Milk and cream	0.9	Apples	
14	IE adult	3.2	Wheat	2.9	Spinach	0.9	Lettuce	
13	WHO cluster diet E	5.5	Wheat	1.0	Spinach	1.0	Lettuce	
8	FR all population	4.6	Wheat	1.0	Lettuce	0.5	Milk and cream	
8	PT General population	5.5	Wheat	0.6	Potatoes	0.5	Apples	
8	UK vegetarian	2.9	Wheat	1.5	Lettuce	0.8	Spinach	
8	LT adult	1.5	Wheat	1.4	Rye	1.0	Apples	
7	DK adult	2.8	Wheat	1.1	Milk and cream	0.9	Rye	
6	FI adult	1.4	Wheat	1.1	Milk and cream	0.9	Rye	
6	UK Adult	2.3	Wheat	1.3	Lettuce	0.6	Milk and cream	
4	PL general population	1.1	Apples	0.5	Head cabbage	0.5	Tomatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Flonicamid is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
24.8	Milk and milk products:	0.05/-	24.8	Milk and milk	0.05/-	6.8	HOPS (dried),	9.33/-	6.8	HOPS (dried),	9.33/-
7.7	Bovine: Meat	0.15/-	7.7	Bovine: Meat	0.15/-	3.6	Bovine: Meat	0.15/-	3.6	Bovine: Meat	0.15/-
7.4	Birds' eggs	0.15/-	7.4	Birds' eggs	0.15/-	3.4	Milk and milk	0.05/-	3.4	Milk and milk products: Cattle	0.05/-
6.5	Bovine: Liver	0.2/-	6.5	Bovine: Liver	0.2/-	3.0	Swine: Meat	0.15/-	3.0	Swine: Meat	0.15/-
6.2	Sheep: Meat	0.15/-	6.2	Sheep: Meat	0.15/-	2.9	Sheep: Meat	0.15/-	2.9	Sheep: Meat	0.15/-
5.1	Swine: Meat	0.15/-	5.1	Swine: Meat	0.15/-	2.3	Birds' eggs	0.15/-	2.3	Birds' eggs	0.15/-
4.8	Milk and milk products:	0.05/-	4.8	Milk and milk	0.05/-	2.2	Bovine: Liver	0.2/-	2.2	Bovine: Liver	0.2/-
3.6	Horse: Meat	0.15/-	3.6	Horse: Meat	0.15/-	1.4	Bovine: Kidney	0.2/-	1.4	Bovine: Kidney	0.2/-
3.0	Bovine: Kidney	0.2/-	3.0	Bovine: Kidney	0.2/-	1.4	Milk and milk products: Goat	0.05/-	1.4	Milk and milk products: Goat	0.05/-
1.5	Bovine: Edible offal	0.05/-	1.5	Bovine: Edible offal	0.05/-	1.1	Swine: Kidney	0.2/-	1.1	Swine: Kidney	0.2/-
1.0	Swine: Kidney	0.2/-	1.0	Swine: Kidney	0.2/-	0.9	Goat: Meat	0.15/-	0.9	Goat: Meat	0.15/-
0.9	Swine: Liver	0.2/-	0.9	Swine: Liver	0.2/-	0.7	Horse: Meat	0.15/-	0.7	Horse: Meat	0.15/-
0.8	HOPS (dried),	9.33/-	0.8	HOPS (dried),	9.33/-	0.6	Bovine: Edible offal	0.05/-	0.6	Bovine: Edible offal	0.05/-
0.4	Bovine: Fat	0.05/-	0.4	Bovine: Fat	0.05/-	0.5	Sheep: Liver	0.2/-	0.5	Sheep: Liver	0.2/-
0.4	Milk and milk products:	0.05/-	0.4	Milk and milk	0.05/-	0.5	Swine: Liver	0.2/-	0.5	Swine: Liver	0.2/-
0.3	Swine: Fat free of lean	0.05/-	0.3	Swine: Fat free of	0.05/-	0.3	Milk and milk	0.05/-	0.3	Milk and milk products: Sheep	0.05/-
						0.3	Swine: Fat free of lean	0.05/-	0.3	Swine: Fat free of lean meat	0.05/-
						0.1	Sheep: Edible offal	0.05/-	0.1	Sheep: Edible offal	0.05/-
						0.1	Bovine: Fat	0.05/-	0.1	Bovine: Fat	0.05/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
53.0	Wheat flour	1.12/-		19.7	Bread/pizza	1.12/-	
37.7	Apple juice	0.185/-		4.9	Apple juice	0.185/-	
21.3	Peach juice	0.298/-		2.9	Orange juice	0.071/-	
16.7	Tomato juice	0.24/-		2.4	Peach preserved with	0.298/-	
14.1	Orange juice	0.071/-		1.8	Tomato (preserved-	0.24/-	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Flonicamid, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Fluazifop-P			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.01**	ARfD (mg/kg bw):	**0.017**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

RA RD to be careffully checked.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
5	72
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
71.5	UK Infant	38.7	Milk and cream	11.9	Beans	9.6	Sugar beet (root)	
69.5	UK Toddler	21.7	Sugar beet (root)	20.7	Milk and cream	18.6	Beans	
63.6	IE adult	35.5	Sweet potatoes	3.5	Linseed	3.3	Swedes	
62.2	FR toddler	39.6	Milk and cream	5.1	Potatoes	4.4	Carrots	
52.1	WHO cluster diet E	21.8	Soya bean	14.0	Rape seed	3.8	Potatoes	
51.9	WHO Cluster diet F	24.4	Soya bean	7.3	Rape seed	4.0	Milk and cream	
48.4	NL child	29.3	Milk and cream	5.9	Potatoes	1.8	Peas (without pods)	
44.5	WHO Cluster diet B	22.8	Soya bean	3.2	Milk and cream	2.7	Potatoes	
43.9	FR infant	25.7	Milk and cream	4.8	Carrots	4.1	Potatoes	
32.0	WHO cluster diet D	13.8	Soya bean	5.0	Milk and cream	4.1	Potatoes	
27.0	PT General population	11.4	Soya bean	5.3	Potatoes	4.0	Beans	
26.3	DE child	14.3	Milk and cream	2.6	Potatoes	1.9	Carrots	
25.8	WHO regional European diet	4.8	Milk and cream	4.0	Potatoes	2.9	Rape seed	
24.7	SE general population 90th percentile	12.4	Milk and cream	4.2	Potatoes	1.5	Carrots	
24.2	ES child	12.5	Milk and cream	3.0	Beans	1.8	Potatoes	
20.0	UK vegetarian	8.6	Beans	3.6	Sugar beet (root)	3.3	Milk and cream	
19.3	DK child	12.6	Milk and cream	2.5	Carrots	2.4	Potatoes	
16.0	UK Adult	5.3	Beans	3.8	Sugar beet (root)	3.0	Milk and cream	
15.8	NL general	6.6	Milk and cream	2.7	Potatoes	0.9	Beans	
11.9	ES adult	5.0	Milk and cream	1.2	Beans	0.9	Potatoes	
9.9	FI adult	5.7	Milk and cream	1.2	Potatoes	1.0	Beans	
9.8	LT adult	4.0	Milk and cream	3.2	Potatoes	0.8	Head cabbage	
9.4	DK adult	5.4	Milk and cream	1.5	Potatoes	0.8	Carrots	
8.5	FR all population	2.7	Milk and cream	1.1	Potatoes	1.0	Sunflower seed	
7.2	PL general population	3.4	Potatoes	0.8	Beans	0.7	Head cabbage	
6.1	IT kids/toddler	1.9	Beans	0.9	Potatoes	0.8	Tomatoes	
4.8	IT adult	1.4	Beans	0.6	Tomatoes	0.6	Potatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Fluazifop-P is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 10			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 10			No of commodities for which ARfD/ADI is exceeded (IESTI 1): 8			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 7		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
1460.4	Swedes	4.8/0.32	1460.4	Swedes	4.8/0.32	690.9	Head cabbage	3.7/0.53	674.5	Swedes	4.8/0.71
1145.5	Head cabbage	3.7/0.32	687.3	Head cabbage	3.7/0.53	674.5	Swedes	4.8/0.71	414.6	Head cabbage	3.7/0.89
904.5	Potatoes	1/0.11	646.0	Potatoes	1/0.15	256.0	Yams	2/0.78	206.5	Yams	2/0.96
512.3	Yams	2/0.39	390.5	Peas (without	8.1/2.07	181.5	Peas (without pods)	8.1/4.46	181.5	Peas (without pods)	8.1/4.46
422.6	Turnips	2/0.47	365.9	Yams	2/0.54	175.5	Potatoes	1/0.56	152.8	Beans (with pods)	4.9/3.2
390.5	Peas (without pods)	8.1/2.07	327.0	Beans (with pods)	4.9/1.49	152.8	Beans (with pods)	4.9/3.2	145.9	Beans (without pods)	4.9/3.35
327.0	Beans (with pods)	4.9/1.49	301.9	Turnips	2/0.66	145.9	Beans (without pods)	4.9/3.35	137.4	Potatoes	1/0.72
258.0	Beans	2.4/0.93	258.0	Beans	2.4/0.93	124.0	Turnips	2/1.61			
257.3	Carrots	0.69/0.26	200.6	Beans (without pods)	4.9/2.44						
200.6	Beans (without pods)	4.9/2.44	183.8	Carrots	0.69/0.37						
No of critical MRLs (IESTI 1) 10						**No of critical MRLs (IESTI 2)** 10					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
47.9	Carrot, juice	0.19/-				4.5	Tomato (preserved-	0.4/-			
41.0	Tomato juice	0.4/-				0.6	Orange juice	0.01/-			
22.5	Celeriac juice	0.29/-				0.5	Potato uree (flakes)	0.1/-			
8.0	Potato puree (flakes)	0.1/-				0.5	Fried potatoes	0.1/-			
5.7	Elderberry juice	0.06/-				0.4	Apple juice	0.01/-			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Fluazifop-P, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 10 commodities.

Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 10 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Flupyradifurone			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.064**	ARfD (mg/kg bw):	**0.15**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2015**	Year of evaluation:	**2015**

The risk assessment performed according to the risk assessment residue definition 'Sum of flupyradifurone and DFA, expressed as flupyradifurone'.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
6	45
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
45	WHO Cluster diet B	17.5	Wheat	3.4	Tomatoes	3.3	Soya bean	
42	NL child	9.7	Wheat	5.0	Milk and cream	4.9	Spinach	
40	FR toddler	9.4	Spinach	6.8	Milk and cream	5.4	Wheat	
37	DE child	8.5	Apples	8.4	Wheat	3.0	Oranges	
31	DK child	11.3	Wheat	9.1	Rye	2.2	Milk and cream	
29	UK Toddler	8.0	Wheat	4.3	Sugar beet (root)	3.9	Beans	
29	WHO cluster diet D	13.4	Wheat	3.4	Chinese cabbage	2.0	Soya bean	
28	IE adult	4.7	Wheat	2.5	Barley	1.8	Maize	
28	WHO cluster diet E	8.1	Wheat	3.1	Soya bean	1.7	Potatoes	
27	UK Infant	6.7	Milk and cream	5.4	Wheat	2.5	Peas (without pods)	
26	WHO Cluster diet F	7.4	Wheat	3.5	Soya bean	1.6	Rye	
25	FR infant	5.9	Spinach	4.4	Milk and cream	3.5	Beans (with pods)	
25	ES child	9.1	Wheat	2.2	Milk and cream	1.7	Oranges	
23	SE general population 90th percentile	6.6	Wheat	3.8	Chinese cabbage	2.1	Milk and cream	
22	IT kids/toddler	13.7	Wheat	1.6	Tomatoes	1.2	Lettuce	
22	PT General population	8.1	Wheat	2.4	Wine grapes	2.4	Potatoes	
22	WHO regional European diet	6.1	Wheat	1.8	Potatoes	1.5	Lettuce	
18	NL general	4.3	Wheat	1.9	Spinach	1.2	Potatoes	
18	ES adult	4.8	Wheat	2.2	Lettuce	1.0	Oranges	
17	IT adult	8.5	Wheat	1.5	Lettuce	1.3	Tomatoes	
16	FR all population	6.8	Wheat	3.9	Wine grapes	0.6	Beans (with pods)	
14	UK vegetarian	4.2	Wheat	1.8	Beans	0.8	Wine grapes	
12	DK adult	4.1	Wheat	1.4	Rye	1.4	Wine grapes	
12	LT adult	2.2	Rye	2.2	Wheat	1.4	Potatoes	
11	UK Adult	3.4	Wheat	1.1	Beans	1.1	Wine grapes	
9	FI adult	2.0	Wheat	1.4	Rye	1.0	Milk and cream	
6	PL general population	1.6	Potatoes	1.4	Apples	1.0	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Flupyradifurone is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
	The acute risk assessment is based on the ARfD.											
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.											
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.											
	In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.											
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**10**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**7**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**3**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**2**
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	619	Chinese cabbage	25/4.03	618.9	Chinese cabbage	25/4.03	595.2	Chinese cabbage	25/4.2	595.2	Chinese cabbage	25/4.2
	286	Spinach	19/6.63	286.3	Spinach	19/6.63	113.2	Spinach	19/16.78	113.2	Spinach	19/16.78
	220	Celery	7.19/3.26	220.0	Celery	7.19/3.26	110.4	Celery	7.19/6.51	81.6	Celery	7.19/-
	194.5	Oranges	2.2/1.13	140.6	Oranges	2.2/1.56	63.7	Cauliflower	3.01/-	63.7	Cauliflower	3.01/-
	143.5	Lettuce	8/5.57	132.6	Cauliflower	3.01/2.26	58.6	Lettuce	8/-	48.7	Table grapes	2.3/-
	132.6	Cauliflower	3.01/2.26	108.2	Melons	1.07/0.98	48.7	Table grapes	2.3/-			
	108.2	Melons	1.07/0.98	100.4	Table grapes	2.3/2.29	37.5	Oranges	2.2/-			
	108.2	Tomatoes	2.79/2.57				36.4	Wine grapes	2.3/-			
	100.4	Table grapes	2.3/2.29				36.2	Head cabbage	1.71/-			
	100.3	Peppers	2.39/2.38				28.3	Tomatoes	2.79/-			
	77.8	Sweet corn	1.59/-				28.2	Melons	1.07/-			
	60.0	Head cabbage	1.71/-				26.0	Peppers	2.39/-			
	58.4	Potatoes	0.57/-				23.1	Sweet corn	1.59/-			
	57.9	Carrots	1.37/-				21.8	Swedes	1.37/-			
	50.5	Celeriac	1.37/-				19.9	Yams	1.37/-			
	47.2	Swedes	1.37/-				18.0	Beans (with pods)	5.1/-			
	45.1	Apples	0.69/-				15.4	Celeriac	1.37/-			
	41.9	Pears	0.69/-				14.5	Peas (without pods)	5.7/-			
	40.0	Beetroot	1.37/-				13.5	Beans	3.22/-			
	39.8	Yams	1.37/-				12.8	Parsnips	1.37/-			
	39.7	Milk and milk products:	0.48/-				12.6	Beetroot	1.37/-			
	39.2	Beans	3.22/-				11.6	Peas (with pods)	5.5/-			
	38.6	Beans (with pods)	5.1/-				11.3	Potatoes	0.57/-			
	36.7	Mandarins	0.99/-				10.8	Carrots	1.37/-			
	35.9	Salsify	1.37/-				10.3	Apples	0.69/-			
	33.0	Parsnips	1.37/-				10.1	Radishes	1.37/-			
	32.8	Turnips	1.37/-				9.9	Pears	0.69/-			
	31.1	Peas (without pods)	5.7/-				9.8	Salsify	1.37/-			
	28.5	Strawberries	2.74/-				9.7	Strawberries	2.74/-			
	20.0	Radishes	1.37/-				9.6	Turnips	1.37/-			
	19.0	Grapefruit	0.32/-				9.4	Beans (without pods)	2.77/-			
	18.3	Persimmon	0.69/-				8.9	Mandarins	0.99/-			
	16.8	Lemons	0.73/-				8.0	Peas	3.605/-			
	16.1	Currants (red, black	2.6/-				6.9	Wheat	1.315/-			
	14.8	Bovine: Liver	2.75/-				6.5	Persimmon	0.69/-			
	12.9	Beans (without pods)	2.77/-				6.3	Barley	1.315/-			
	12.7	Wheat	1.315/-				5.5	Milk and milk	0.48/-			
	12.7	Peas (with pods)	5.5/-				5.2	Jerusalem artichokes	1.37/-			
	11.9	Wine grapes	2.3/-				4.9	Bovine: Liver	2.75/-			
	10.7	Gooseberries	2.6/-				4.7	Bovine: Meat	1.188/-			
	10.1	Bovine: Meat	1.188/-				4.7	Poultry: Meat	0.6/-			
							4.6	Currants (red, black	2.6/-			
	No of critical MRLs (IESTI 1)		10				**No of critical MRLs (IESTI 2)**		7			

Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		**1**		**No of commodities for which ARfD/ADI is exceeded:**		**---**
			***)				***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	132.1	Orange juice	4/3.02		26.8	Orange juice	4/-

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Flupyradifurone, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 10 commodities.
Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 7 commodities.
For processed commodities, the ARfD/ADI was exceeded in one or several cases.

Acibenzolar-S-methyl			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.03**	ARfD (mg/kg bw):	**0.03**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2016**	Year of evaluation:	**2016**

Comment:, Check for RD RA for garlic and onions, lettuce and spinach, brassica (haed , flower head and leafy) at EU level the 4-OH is not included in the RD.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	4
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
4.2	WHO Cluster diet B	1.3	Tomatoes	0.6	Wheat	0.4	Watermelons	
3.5	NL child	0.5	Cauliflower	0.4	Apples	0.4	Spinach	
3.0	DE child	0.8	Apples	0.4	Tomatoes	0.3	Cucumbers	
2.8	FR toddler	0.7	Spinach	0.4	Broccoli	0.4	Broccoli	
2.8	SE general population 90th percentile	0.7	Head cabbage	0.4	Chinese cabbage	0.3	Tomatoes	
2.7	WHO cluster diet D	0.4	Tomatoes	0.4	Wheat	0.4	Chinese cabbage	
2.4	IE adult	0.5	Melons	0.2	Broccoli	0.2	Brussels sprouts	
2.4	DK child	1.0	Cucumbers	0.4	Wheat	0.2	Tomatoes	
2.4	WHO regional European diet	0.5	Tomatoes	0.4	Head cabbage	0.2	Cauliflower	
1.8	IT kids/toddler	0.6	Tomatoes	0.4	Wheat	0.2	Lettuce	
1.8	NL general	0.2	Cauliflower	0.2	Head cabbage	0.2	Kale	
1.8	FR infant	0.4	Spinach	0.4	Courgettes	0.3	Broccoli	
1.7	WHO Cluster diet F	0.3	Tomatoes	0.3	Head cabbage	0.2	Wheat	
1.7	IT adult	0.5	Tomatoes	0.3	Wheat	0.2	Lettuce	
1.6	ES child	0.4	Tomatoes	0.3	Wheat	0.3	Lettuce	
1.5	WHO cluster diet E	0.3	Head cabbage	0.3	Wheat	0.2	Tomatoes	
1.4	ES adult	0.3	Tomatoes	0.3	Lettuce	0.2	Wheat	
1.3	UK Toddler	0.3	Wheat	0.3	Tomatoes	0.1	Cauliflower	
1.2	UK Infant	0.3	Cauliflower	0.2	Brussels sprouts	0.2	Wheat	
1.2	PL general population	0.4	Head cabbage	0.4	Tomatoes	0.1	Apples	
1.2	LT adult	0.4	Head cabbage	0.3	Tomatoes	0.2	Cucumbers	
1.2	UK vegetarian	0.3	Tomatoes	0.1	Wheat	0.1	Cauliflower	
1.0	FR all population	0.2	Wheat	0.2	Tomatoes	0.1	Melons	
0.9	PT General population	0.4	Tomatoes	0.3	Wheat	0.1	Apples	
0.9	DK adult	0.2	Tomatoes	0.2	Cucumbers	0.1	Wheat	
0.8	UK Adult	0.2	Tomatoes	0.1	Wheat	0.1	Broccoli	
0.7	FI adult	0.2	Tomatoes	0.2	Cucumbers	0.1	Head cabbage	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of acibenzolar-S-methyl is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		**6**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
237.6	Melons	0.47/0.19	142.6	Melons	0.47/0.32	94.6	Chinese cabbage	0.795/-	94.6	Chinese cabbage	0.795/-
191.6	Watermelons	0.47/0.24	114.9	Watermelons	0.47/0.4	82.9	Pumpkins	0.47/-	82.9	Pumpkins	0.47/-
179.1	Kale	0.795/0.44	98.4	Chinese cabbage	0.795/-	65.6	Cauliflower	0.62/-	65.6	Cauliflower	0.62/-
136.6	Cauliflower	0.62/0.45	91.6	Cucumbers	0.47/-	65.6	Head cabbage	0.62/-	63.6	Watermelons	0.47/-
120.4	Broccoli	0.62/0.51	81.9	Cauliflower	0.62/-	63.6	Watermelons	0.47/-	61.8	Melons	0.47/-
108.8	Head cabbage	0.62/0.57									
98.4	Chinese cabbage	0.795/-									
91.6	Cucumbers	0.47/-									
No of critical MRLs (IESTI 1)		6				**No of critical MRLs (IESTI 2)**		2			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**				**No of commodities for which ARfD/ADI is exceeded:**		**---**			
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
36.0	Tomato juice	0.62/-				3.9	Tomato (preserved-	0.62/-			
15.3	Apple juice	0.09/-				2.0	Apple juice	0.09/-			
5.4	Peach juice	0.09/-				0.6	Peach preserved with	0.09/-			
5.3	Pear juice	0.09/-				0.4	Bread/pizza	0.028/-			
1.5	Kiwi juice	0.03/-									

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For acibenzolar-S-methyl, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 6 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 2 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Imazethapyr			
Status of the active substance:	Not	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.6	ARfD (mg/kg bw):	n.n.
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2016	Year of evaluation:	2016

JMPR tox ref values were used for the exposure calculation; Please check maize, rice and soyabean comments.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
0.1	UK Infant	0.1	Milk and cream	0.0	Sugar beet (root)	0.0	Rice	
0.1	NL child	0.0	Milk and cream	0.0	Apples	0.0	Potatoes	
0.1	FR toddler	0.1	Milk and cream	0.0	Potatoes	0.0	Rice	
0.1	UK Toddler	0.0	Sugar beet (root)	0.0	Milk and cream	0.0	Rice	
0.1	DE child	0.0	Milk and cream	0.0	Apples	0.0	Wheat	
0.1	WHO Cluster diet B	0.0	Wheat	0.0	Rice	0.0	Milk and cream	
0.1	FR infant	0.0	Milk and cream	0.0	Potatoes	0.0	Carrots	
0.1	DK child	0.0	Milk and cream	0.0	Wheat	0.0	Rye	
0.1	IE adult	0.0	Sweet potatoes	0.0	Milk and cream	0.0	Maize	
0.1	ES child	0.0	Milk and cream	0.0	Wheat	0.0	Rice	
0.1	SE general population 90th percentile	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	
0.1	WHO cluster diet D	0.0	Wheat	0.0	Milk and cream	0.0	Rice	
0.1	WHO cluster diet E	0.0	Wheat	0.0	Potatoes	0.0	Milk and cream	
0.0	WHO Cluster diet F	0.0	Milk and cream	0.0	Wheat	0.0	Potatoes	
0.0	WHO regional European diet	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	
0.0	PT General population	0.0	Rice	0.0	Potatoes	0.0	Wheat	
0.0	NL general	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	
0.0	ES adult	0.0	Milk and cream	0.0	Wheat	0.0	Rice	
0.0	UK vegetarian	0.0	Sugar beet (root)	0.0	Milk and cream	0.0	Rice	
0.0	FR all population	0.0	Wine grapes	0.0	Wheat	0.0	Milk and cream	
0.0	UK Adult	0.0	Sugar beet (root)	0.0	Milk and cream	0.0	Rice	
0.0	IT kids/toddler	0.0	Wheat	0.0	Other cereal	0.0	Rice	
0.0	DK adult	0.0	Milk and cream	0.0	Wheat	0.0	Potatoes	
0.0	LT adult	0.0	Milk and cream	0.0	Potatoes	0.0	Apples	
0.0	FI adult	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	
0.0	IT adult	0.0	Wheat	0.0	Rice	0.0	Tomatoes	
0.0	PL general population	0.0	Potatoes	0.0	Apples	0.0	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Imazethapyr is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *) **)			**IESTI 2** *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.					
	Conclusion: As no ARfD was considered necessary, it is concluded that the short-term intake of Imazethapyr residues is unlikely to present a pulbic health concern.					

Isofetamid			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.02**	ARfD (mg/kg bw):	**1**
Source of ADI:	**EFSA 2015**	Source of ARfD:	**EFSA 2015**
Year of evaluation:		Year of evaluation:	

No Art 10/12, current MRL applied.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 16
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
15.7	FR all population	14.2	Wine grapes	0.4	Table grapes	0.2	Strawberries	
10.8	PT General population	8.8	Wine grapes	1.0	Table grapes	0.3	Potatoes	
10.8	WHO Cluster diet B	6.4	Wine grapes	1.2	Table grapes	0.7	Lettuce	
8.5	DE child	4.5	Table grapes	1.2	Strawberries	0.7	Milk and cream	
8.1	WHO cluster diet E	5.7	Wine grapes	0.5	Table grapes	0.2	Strawberries	
7.9	IE adult	4.4	Wine grapes	0.9	Table grapes	0.6	Strawberries	
6.8	NL child	2.7	Table grapes	1.5	Milk and cream	0.6	Strawberries	
6.1	DK adult	4.9	Wine grapes	0.3	Table grapes	0.3	Milk and cream	
5.8	FR toddler	2.0	Milk and cream	1.5	Strawberries	0.7	Table grapes	
5.1	UK Adult	3.8	Wine grapes	0.2	Lettuce	0.2	Sugar beet (root)	
4.6	UK Toddler	1.1	Sugar beet (root)	1.0	Milk and cream	0.9	Table grapes	
4.6	NL general	2.2	Wine grapes	0.8	Table grapes	0.3	Milk and cream	
4.6	WHO Cluster diet F	2.1	Wine grapes	0.6	Lettuce	0.4	Table grapes	
4.4	UK vegetarian	2.9	Wine grapes	0.3	Table grapes	0.3	Lettuce	
4.1	UK Infant	1.9	Milk and cream	0.5	Strawberries	0.5	Sugar beet (root)	
3.8	ES adult	1.5	Wine grapes	1.0	Lettuce	0.2	Milk and cream	
3.8	FR infant	1.3	Milk and cream	1.2	Strawberries	0.3	Table grapes	
3.7	WHO regional European diet	0.8	Wine grapes	0.7	Lettuce	0.5	Table grapes	
3.5	WHO cluster diet D	1.3	Wine grapes	0.7	Table grapes	0.3	Wheat	
3.0	DK child	0.6	Table grapes	0.6	Milk and cream	0.3	Wheat	
2.9	ES child	0.8	Lettuce	0.6	Milk and cream	0.2	Wheat	
2.1	FI adult	1.1	Wine grapes	0.3	Milk and cream	0.2	Strawberries	
2.1	SE general population 90th percentile	0.6	Milk and cream	0.4	Strawberries	0.2	Potatoes	
2.1	IT kids/toddler	0.5	Lettuce	0.4	Table grapes	0.3	Wheat	
1.9	IT adult	0.7	Lettuce	0.5	Table grapes	0.2	Wheat	
1.7	PL general population	1.1	Table grapes	0.2	Potatoes	0.1	Apples	
1.1	LT adult	0.2	Milk and cream	0.2	Potatoes	0.1	Lettuce	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Isofetamid is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations				Acute risk assessment/adults/general population – refined calculations			
	The acute risk assessment is based on the ARfD.							
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.							
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.							
	In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.							
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.							
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *)		**)	**IESTI 2** *)		**)	**IESTI 1** *)		**)	**IESTI 2** *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	4.8	Strawberries	3.1/-	4.8	Strawberries	3.1/-	1.6	Strawberries	3.1/-	1.6	Strawberries	3.1/-
	0.4	Cranberries	3.1/-	0.4	Cranberries	3.1/-	0.0	Bovine: Meat	0.010496/-	0.0	Bovine: Meat	0.010496/-
	0.0	Milk and milk products:	0.003/-	0.0	Milk and milk	0.003/-	0.0	Swine: Meat	0.010496/-	0.0	Swine: Meat	0.010496/-
	0.0	Bovine: Meat	0.010496/-	0.0	Bovine: Meat	0.010496/-	0.0	Milk and milk	0.003/-	0.0	Milk and milk products: Cattle	0.003/-
	0.0	Sheep: Meat	0.010496/-	0.0	Sheep: Meat	0.010496/-	0.0	Sheep: Meat	0.010496/-	0.0	Sheep: Meat	0.010496/-
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.											
	**) pTMRL: provisional temporary MRL.											
	***) pTMRL: provisional temporary MRL for unprocessed commodity.											
	Conclusion:											
	For Isofetamid, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.											
	No exceedance of the ARfD/ADI was identified for any unprocessed commodity.											
	For processed commodities, no exceedance of the ARfD/ADI was identified.											

Oxathiapiprolin			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.14**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2016**	Year of evaluation:	**2016**

No tox ref value defined for EU. Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
0	3
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
2.8	FR toddler	1.9	Spinach	0.3	Leek	0.3	Milk and cream	
1.9	NL child	1.0	Spinach	0.2	Milk and cream	0.2	Lettuce	
1.8	FR infant	1.2	Spinach	0.2	Milk and cream	0.2	Leek	
1.7	WHO Cluster diet B	0.6	Lettuce	0.3	Wine grapes	0.2	Spinach	
1.4	DE child	0.5	Spinach	0.2	Table grapes	0.1	Milk and cream	
1.3	ES adult	0.8	Lettuce	0.2	Spinach	0.1	Wine grapes	
1.2	IE adult	0.3	Spinach	0.2	Wine grapes	0.1	Leek	
1.2	ES child	0.7	Lettuce	0.2	Spinach	0.1	Milk and cream	
1.1	WHO regional European diet	0.6	Lettuce	0.1	Spinach	0.1	Peas (with pods)	
1.0	IT adult	0.6	Lettuce	0.3	Spinach	0.0	Tomatoes	
1.0	NL general	0.4	Spinach	0.2	Lettuce	0.1	Wine grapes	
1.0	FR all population	0.6	Wine grapes	0.1	Lettuce	0.1	Leek	
0.9	WHO Cluster diet F	0.5	Lettuce	0.1	Wine grapes	0.0	Milk and cream	
0.9	WHO cluster diet E	0.2	Wine grapes	0.1	Lettuce	0.1	Spinach	
0.8	IT kids/toddler	0.5	Lettuce	0.2	Spinach	0.1	Tomatoes	
0.7	UK Toddler	0.2	Sugar beet (root)	0.1	Milk and cream	0.1	Spinach	
0.6	UK vegetarian	0.2	Lettuce	0.1	Wine grapes	0.1	Spinach	
0.6	DK child	0.2	Lettuce	0.1	Milk and cream	0.0	Wheat	
0.6	UK Infant	0.3	Milk and cream	0.1	Sugar beet (root)	0.0	Peas (without pods)	
0.6	PT General population	0.4	Wine grapes	0.0	Table grapes	0.0	Potatoes	
0.6	SE general population 90th percentile	0.2	Spinach	0.1	Milk and cream	0.1	Head cabbage	
0.6	UK Adult	0.2	Lettuce	0.2	Wine grapes	0.0	Spinach	
0.4	DK adult	0.2	Wine grapes	0.0	Milk and cream	0.0	Tomatoes	
0.4	WHO cluster diet D	0.1	Wine grapes	0.0	Wheat	0.0	Tomatoes	
0.3	FI adult	0.1	Lettuce	0.0	Wine grapes	0.0	Milk and cream	
0.3	LT adult	0.1	Lettuce	0.0	Head cabbage	0.0	Milk and cream	
0.2	PL general population	0.0	Table grapes	0.0	Head cabbage	0.0	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of oxathiapiprolin is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		
	Acute risk assessment is not necessary.					
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1 *) **)			**IESTI 2** *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---			**No of commodities for which ARfD/ADI is exceeded:** ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.					
	Conclusion: As no ARfD was considered necessary, it is concluded that the short-term intake of oxathiapiprolin residues is unlikely to present a pulbic health concern.					

Pendimethalin

Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.125**	ARfD (mg/kg bw):	**0.3**
Source of ADI:	**EC**	Source of ARfD:	**EFSA**
Year of evaluation:	**2003**	Year of evaluation:	**2016**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
0	1
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
1.4	NL child	0.3	Apples	0.2	Potatoes	0.2	Milk and milk products: Cattle	
1.4	WHO Cluster diet B	0.3	Wheat	0.1	Tomatoes	0.1	Potatoes	
1.3	DE child	0.5	Apples	0.2	Wheat	0.1	Milk and milk products: Cattle	
1.0	WHO cluster diet D	0.3	Wheat	0.2	Potatoes	0.1	Chinese cabbage	
1.0	IE adult	0.1	Maize	0.1	Maize	0.1	Potatoes	
0.9	WHO cluster diet E	0.2	Wheat	0.2	Potatoes	0.1	Wine grapes	
0.9	FR toddler	0.2	Potatoes	0.1	Apples	0.1	Apples	
0.9	DK child	0.2	Wheat	0.2	Rye	0.1	Potatoes	
0.8	FR infant	0.2	Milk and milk products: Cattle	0.2	Potatoes	0.1	Carrots	
0.8	SE general population 90th percentile	0.2	Potatoes	0.1	Wheat	0.1	Milk and milk products: Cattle	
0.8	WHO Cluster diet F	0.1	Wheat	0.1	Potatoes	0.0	Milk and milk products: Cattle	
0.8	PT General population	0.2	Potatoes	0.2	Wheat	0.10	Wine grapes	
0.8	WHO regional European diet	0.2	Potatoes	0.1	Wheat	0.04	Tomatoes	
0.7	ES child	0.2	Wheat	0.1	Milk and milk products: Cattle	0.1	Potatoes	
0.6	NL general	0.1	Potatoes	0.1	Wheat	0.1	Milk and milk products: Cattle	
0.6	UK Toddler	0.2	Wheat	0.1	Potatoes	0.1	Apples	
0.6	UK Infant	0.1	Potatoes	0.1	Wheat	0.1	Apples	
0.5	FR all population	0.2	Wine grapes	0.1	Wheat	0.04	Potatoes	
0.5	IT kids/toddler	0.3	Wheat	0.1	Tomatoes	0.04	Potatoes	
0.5	ES adult	0.1	Wheat	0.0	Milk and milk products: Cattle	0.04	Potatoes	
0.5	LT adult	0.1	Potatoes	0.1	Apples	0.04	Rye	
0.4	IT adult	0.2	Wheat	0.05	Tomatoes	0.03	Apples	
0.4	DK adult	0.1	Wheat	0.1	Potatoes	0.1	Wine grapes	
0.4	PL general population	0.1	Potatoes	0.1	Apples	0.04	Tomatoes	
0.4	UK vegetarian	0.1	Wheat	0.1	Potatoes	0.03	Wine grapes	
0.3	UK Adult	0.1	Wheat	0.1	Potatoes	0.04	Wine grapes	
0.2	FI adult	0.05	Potatoes	0.0	Wheat	0.03	Rye	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Pendimethalin is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
	The acute risk assessment is based on the ARfD.											
	For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.											
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.											
	In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.											
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	19.7	Lettuce	2.2/-	11.8	Lettuce	2.2/-	8.1	Lettuce	2.2/-	4.8	Lettuce	2.2/-
	2.4	Cauliflower	0.11/-	2.4	Cauliflower	0.11/-	1.4	Lamb's lettuce	2.2/-	1.4	Lamb's lettuce	2.2/-
	2.1	Broccoli	0.11/-	2.1	Lamb's lettuce	2.2/-	1.3	Chinese cabbage	0.11/-	1.3	Chinese cabbage	0.11/-
	2.1	Lamb's lettuce	2.2/-	1.5	Broccoli	0.11/-	1.2	Cauliflower	0.11/-	1.2	Cauliflower	0.11/-
	1.4	Chinese cabbage	0.11/-	1.4	Chinese cabbage	0.11/-	0.8	Broccoli	0.11/-	0.8	Broccoli	0.11/-
		calculatred										
	No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	1.4	Carrot, juice	0.1/-				0.2	Orange juice	0.05/-			
	0.8	Apple juice	0.05/-				0.1	Apple juice	0.05/-			
	0.8	Orange juice	0.05/-				0.1	Bread/pizza	0.05/-			
	0.5	Grape juice	0.05/-				0.1	Wine	0.05/-			
	0.4	Celeriac juice	0.1/-				0.0	Peach preserved with	0.05/-			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.											
	**) pTMRL: provisional temporary MRL.											
	***) pTMRL: provisional temporary MRL for unprocessed commodity.											
	Conclusion:											
	For Pendimethalin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.											
	No exceedance of the ARfD/ADI was identified for any unprocessed commodity.											
	For processed commodities, no exceedance of the ARfD/ADI was identified.											

Pinoxaden			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.1**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

No codex proposal > EU MRL.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum 0 – 10
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
10.5	DK child	5.5	Wheat	4.4	Rye	0.3	Milk and cream	
9.6	WHO Cluster diet B	8.5	Wheat	0.3	Barley	0.1	Milk and cream	
7.5	WHO cluster diet D	6.5	Wheat	0.4	Rye	0.2	Barley	
6.9	IT kids/toddler	6.6	Wheat	0.0	Other cereal	0.0	Tomatoes	
6.1	NL child	4.7	Wheat	0.6	Milk and cream	0.2	Rye	
5.9	DE child	4.1	Wheat	0.8	Rye	0.3	Milk and cream	
5.6	WHO cluster diet E	3.9	Wheat	0.8	Barley	0.4	Rye	
5.3	WHO Cluster diet F	3.6	Wheat	0.8	Rye	0.6	Barley	
5.1	UK Toddler	3.9	Wheat	0.5	Sugar beet (root)	0.4	Milk and cream	
5.0	ES child	4.4	Wheat	0.3	Milk and cream	0.0	Oranges	
4.4	PT General population	3.9	Wheat	0.1	Rye	0.1	Potatoes	
4.3	IE adult	2.3	Wheat	1.2	Barley	0.1	Rye	
4.3	IT adult	4.1	Wheat	0.0	Tomatoes	0.0	Apples	
4.1	SE general population 90th percentile	3.2	Wheat	0.3	Rye	0.2	Milk and cream	
3.9	UK Infant	2.6	Wheat	0.8	Milk and cream	0.2	Sugar beet (root)	
3.9	FR toddler	2.6	Wheat	0.8	Milk and cream	0.1	Potatoes	
3.7	WHO regional European diet	3.0	Wheat	0.3	Barley	0.1	Milk and cream	
3.6	FR all population	3.3	Wheat	0.1	Wine grapes	0.1	Milk and cream	
3.1	ES adult	2.3	Wheat	0.5	Barley	0.1	Milk and cream	
2.9	DK adult	2.0	Wheat	0.7	Rye	0.1	Milk and cream	
2.9	NL general	2.1	Wheat	0.4	Barley	0.1	Milk and cream	
2.4	LT adult	1.1	Rye	1.1	Wheat	0.1	Milk and cream	
2.4	UK vegetarian	2.0	Wheat	0.1	Sugar beet (root)	0.1	Milk and cream	
2.0	UK Adult	1.7	Wheat	0.1	Sugar beet (root)	0.1	Milk and cream	
1.9	FI adult	1.0	Wheat	0.7	Rye	0.1	Milk and cream	
1.7	FR infant	0.8	Wheat	0.5	Milk and cream	0.1	Potatoes	
0.2	PL general population	0.1	Potatoes	0.0	Apples	0.0	Tomatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Pinoxaden is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations			Acute risk assessment/adults/general population – refined calculations		

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
1.4	Wheat	0.1/-	1.4	Wheat	0.1/-	0.8	Wheat	0.1/-	0.8	Wheat	0.1/-
0.2	Birds' eggs	0.02/-	0.2	Birds' eggs	0.02/-	0.7	Barley	0.09/-	0.7	Barley	0.09/-
0.2	Poultry: Meat	0.02/-	0.2	Poultry: Meat	0.02/-	0.2	Poultry: Meat	0.02/-	0.2	Poultry: Meat	0.02/-
0.2	Barley	0.09/-	0.2	Barley	0.09/-	0.1	Poultry: Liver	0.02/-	0.1	Poultry: Liver	0.02/-
						0.1	Birds' eggs	0.02/-	0.1	Birds' eggs	0.02/-
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Pinoxaden, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Spiromesifen			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.03**	ARfD (mg/kg bw):	**2**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

The risk assessment for tea is performed for a risk assessment residue definition 'the sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen'.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	4 24
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
23.9	WHO Cluster diet B	10.3	Tomatoes	2.5	Tea (dried leaves and stalks)	2.5	Lettuce	
18.3	IE adult	8.1	Tea (dried leaves and stalks)	1.4	Other leafy brassica	1.3	Tomatoes	
16.4	NL child	2.6	Spinach	2.1	Tomatoes	1.7	Beans (with pods)	
15.4	FR toddler	4.9	Spinach	3.7	Beans (with pods)	2.6	Tomatoes	
13.2	WHO regional European diet	3.7	Tomatoes	2.6	Lettuce	2.4	Tea (dried leaves and stalks,	
12.3	WHO cluster diet D	3.4	Tomatoes	2.2	Tea (dried leaves and stalks)	1.3	Chinese cabbage	
12.1	DE child	3.2	Tomatoes	1.4	Spinach	0.8	Strawberries	
11.6	IT adult	3.9	Tomatoes	2.6	Lettuce	1.1	Other lettuce and other salad	
11.1	IT kids/toddler	4.8	Tomatoes	2.0	Lettuce	0.8	Other lettuce and other salad	
10.2	ES child	3.3	Tomatoes	2.9	Lettuce	0.8	Beans (with pods)	
10.0	FR infant	3.0	Spinach	2.8	Beans (with pods)	0.8	Strawberries	
9.8	ES adult	3.7	Lettuce	2.6	Tomatoes	0.8	Beans (with pods)	
9.5	WHO cluster diet E	2.1	Tea (dried leaves and stalks)	1.8	Tomatoes	0.9	Beans (with pods)	
8.9	SE general population 90th percentile	2.6	Tomatoes	1.4	Chinese cabbage	0.5	Spinach	
8.6	NL general	1.4	Tomatoes	1.0	Witloof	1.0	Spinach	
8.3	UK vegetarian	3.1	Tea (dried leaves and stalks)	2.1	Tomatoes	1.0	Lettuce	
8.2	WHO Cluster diet F	2.3	Tomatoes	2.1	Lettuce	0.8	Tea (dried leaves and stalks,	
7.9	UK Infant	3.5	Tea (dried leaves and stalks)	1.2	Tomatoes	0.7	Sugar beet (root)	
7.8	UK Toddler	2.0	Tomatoes	1.7	Tea (dried leaves and stalks)	1.5	Sugar beet (root)	
7.2	FR all population	1.4	Tomatoes	1.3	Other lettuce and other salad plants	0.9	Witloof	
7.1	UK Adult	3.3	Tea (dried leaves and stalks)	1.5	Tomatoes	0.8	Lettuce	
6.9	DK child	1.8	Tomatoes	1.6	Cucumbers	1.0	Lettuce	
4.8	PT General population	3.0	Tomatoes	0.4	Potatoes	0.3	Peppers	
4.5	PL general population	2.9	Tomatoes	0.3	Head cabbage	0.2	Potatoes	
4.4	FI adult	1.4	Tomatoes	0.9	Tea (dried leaves and stalks)	0.5	Lettuce	
4.0	LT adult	2.1	Tomatoes	0.4	Lettuce	0.4	Cucumbers	
3.6	DK adult	1.4	Tomatoes	0.6	Tea (dried leaves and stalks)	0.3	Cucumbers	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Spiromesifen is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1 *)		**)	**IESTI 2** *)		**)	**IESTI 1** *)		**)	**IESTI 2** *)		**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
54.6	Scarole (broad-leaf	12.5/-	32.8	Scarole (broad-leaf	12.5/-	22.3	Chinese cabbage	12.5/-	22.3	Chinese cabbage	12.5/-
42.3	Kale	12.5/-	30.2	Kale	12.5/-	12.7	Kale	12.5/-	9.5	Kale	12.5/-
29.0	Witloof	12.5/-	23.2	Chinese cabbage	12.5/-	10.3	Witloof	12.5/-	8.5	Witloof	12.5/-
23.2	Chinese cabbage	12.5/-	22.1	Witloof	12.5/-	6.9	Lettuce	12.5/-	5.9	Purslane	12.5/-
16.8	Lettuce	12.5/-	14.1	Spinach	12.5/-	6.5	Purslane	12.5/-	5.6	Spinach	12.5/-
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---		
		***)			***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Spiromesifen, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.