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Scientific support for preparing an EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR)

European Food Safety Authority (EFSA)

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 50th session of the Codex Committee on Pesticide Residues (CCPR). In 2017, Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluated 15 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (bicyclopyrone, chlormequat, cyclaniliprole, fenazaquin, fenpropimorph, fenpyrazamine, fenpyroximate, fosetyl Al, isoprothiolane, natamycin, oxamyl, phosphonic acid, propylene oxide, thiophanate-methyl, triflumezopyrim) and 36 substances for deriving maximum residue limit (MRL) proposals (acetamiprid, azoxystrobin, bicyclopyrone, captan, chlormequat, cyclaniliprole, cyprodinil, 2,4-D, difenoconazole, fenazaquin, fenpropimorph, fenpyrazamine, fenpyroximate, flonicamid, fluensulfone, fluopyram, flupyradifurone, fosetyl Al, imazamox, imazapyr, imidacloprid, isoprothiolane, isopyrazam, natamycin, oxamyl, phosphonic acid, picoxystrobin, propiconazole, propylene oxide, prothioconazole, quinclorac, saflufenacil, spinetoram, tebuconazole, trifloxystrobin, triflumezopyrim); 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, relevant findings are summarised in this report.

Keywords: consumer risk assessment, toxicological evaluation, residue definitions, MRL setting, CCPR meeting 2018

Requestor: European Commission

Question numbers: EFSA-Q-2017-00763, EFSA-Q-2017-00764, EFSA-Q-2017-00765, EFSA-Q-2017-00766, EFSA-Q-2017-00767, EFSA-Q-2017-00768, EFSA-Q-2017-00769, EFSA-Q-2017-00770, EFSA-Q-2017-00771, EFSA-Q-2017-00772, EFSA-Q-2017-00773, EFSA-Q-2017-00774, EFSA-Q-2017-00775, EFSA-Q-2017-00776, EFSA-Q-2017-00777, EFSA-Q-2017-00778, EFSA-Q-2017-00779, EFSA-Q-2017-00780, EFSA-Q-2017-00781, EFSA-Q-2017-00782, EFSA-Q-2017-00783, EFSA-Q-2017-00784, EFSA-Q-2017-00785, EFSA-Q-2017-00786, EFSA-Q-2017-00787, EFSA-Q-2017-00788, EFSA-Q-2017-00789, EFSA-Q-2017-00790, EFSA-Q-2017-00791, EFSA-Q-2017-00792, EFSA-Q-2017-00793, EFSA-Q-2017-00794, EFSA-Q-2017-00795, EFSA-Q-2017-00796, EFSA-Q-2017-00797, EFSA-Q-2017-00798, EFSA-Q-2017-00799, EFSA-Q-2017-00800, EFSA-Q-2017-00804

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Summary

For the preparation of the 50th session of the Codex Committee on Pesticide Residues (CCPR meeting), the European Commission asked EFSA to provide comments on the individual active substances assessed in the 2017 Joint FAO/WHO Meeting on Pesticide Residues (JMPR), in particular on the recommended toxicological reference values and the proposed maximum residue limits (MRLs) at steps 3 and 6 of the Codex procedure.

In 2017, JMPR evaluated 15 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (bicyclopyrone, chlormequat, cyclaniliprole, fenazaquin, fenpropimorph, fenpyrazamine, fenpyroximate, fosetyl Al, isoprothiolane, natamycin, oxamyl, phosphonic acid, propylene oxide, thiophanate-methyl, triflumezopyrim). 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, European Food Safety Authority (EFSA) provided further explanations for the reasons of the differences.

Regarding the setting of MRLs, JMPR assessed 36 substances for deriving MRL proposals (acetamiprid, azoxystrobin, bicyclopyrone, captan, chlormequat, cyclaniliprole, cyprodinil, 2,4-D, difenoconazole, fenazaquin, fenpropimorph, fenpyrazamine, fenpyroximate, flonicamid, fluensulfone, fluopyram, flupyradifurone, fosetyl Al, imazamox, imazapyr, imidacloprid, isoprothiolane, isopyrazam, natamycin, oxamyl, phosphonic acid, picoxystrobin, propiconazole, propylene oxide, prothioconazole, quinclorac, saflufenacil, spinetoram, tebuconazole, trifloxystrobin, triflumezopyrim). EFSA provided comments on the proposed Codex MRLs as well as on active substances that were reassessed by JMPR following specific concerns raised in the previous years (quinclorac, abamectin, acetamiprid) and on general issues discussed in the 2017 JMPR meeting.

It is highlighted that the JMPR report summarising the recommendations of the 2017 JMPR meeting was published on 8 January 2018. The full evaluations were published on 6 March 2018. 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. 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 in accordance with the procedures established in the Codex Alimentarius (Codex Alimentarius, 2016). The most recent Joint FAO/WHO meeting on pesticide residues (JMPR) evaluations of the toxicological data and the residue studies are summarised in the JMPR Report 2017 (FAO, 2017). It comprises in total 38 active substances: 16 of them were assessed for both toxicological reference values and residues, 21 active substances were assessed in view of setting new CXLs and 3 active substances were assessed for specific concerns raised in previous Codex Committee on Pesticide Residues (CCPR) meetings by delegations.

On 14 November 2017, the European Commission requested European Food Safety Authority (EFSA) to provide support for the preparation of the European Union (EU)-coordinated position for the 50th session of the CCPR in April 2018 in China. In particular, EFSA was asked to give advice and to provide comments on the recommendations of the 2017 JMPR and on the proposed Codex maximum residue limits (MRLs) in support of the CCPR in April 2018. Additionally, the European Commission requested EFSA to give its comments on other proposed Codex MRLs that were retained in the step procedure in previous years and may not have been covered by the 2017 JMPR report but by (an) earlier JMPR report(s).

Furthermore, the European Commission asked for comments on the general chapters of the JMPR 2017 report, where relevant for risk assessment as well as on the proposed crop groupings, the JMPR priority list and documents related to the revision of the IESTI equation, if any.

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
1.	EFSA-Q-2017-00763	Abamectin – EFSA comments on the toxicological reference values evaluated by JMPR in 2017
2.	EFSA-Q-2017-00764	Acetamiprid – EFSA comments on the toxicological reference values evaluated by JMPR in 2017
3.	EFSA-Q-2017-00765	Azoxystrobin – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
4.	EFSA-Q-2017-00766	Bicyclopyrone – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
5.	EFSA-Q-2017-00767	Captan – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
6.	EFSA-Q-2017-00768	Chlormequat – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
7.	EFSA-Q-2017-00769	Cyclaniliprole – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
8.	EFSA-Q-2017-00770	Cyprodinil – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
9.	EFSA-Q-2017-00771	2,4-D – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
10.	EFSA-Q-2017-00772	Difenoconazole – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
11.	EFSA-Q-2017-00773	Fenazaquin – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
12.	EFSA-Q-2017-00774	Fenpropimorph – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
13.	EFSA-Q-2017-00775	Fenpyrazamine – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
14.	EFSA-Q-2017-00776	Fenpyroximate – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
15.	EFSA-Q-2017-00777	Flonicamid – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017

	Question number	Subject
16.	EFSA-Q-2017-00778	Fluensulfone – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
17.	EFSA-Q-2017-00779	Fluopyram – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
18.	EFSA-Q-2017-00780	Flupyradifurone – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
19.	EFSA-Q-2017-00781	Fosetyl Al – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
20.	EFSA-Q-2017-00782	Imazamox – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
21.	EFSA-Q-2017-00783	Imazapyr – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
22.	EFSA-Q-2017-00784	Imidacloprid – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
23.	EFSA-Q-2017-00785	Isoprothiolane – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
24.	EFSA-Q-2017-00786	Isopyrazam – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
25.	EFSA-Q-2017-00787	Natamycin – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
26.	EFSA-Q-2017-00788	Oxamyl – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
27.	EFSA-Q-2017-00789	Phosphonic acid – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
28.	EFSA-Q-2017-00790	Picoxystrobin – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
29.	EFSA-Q-2017-00791	Propiconazole – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
30.	EFSA-Q-2017-00792	Propylene oxide – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
31.	EFSA-Q-2017-00793	Prothioconazole – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
32.	EFSA-Q-2017-00794	Quinclorac – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
33.	EFSA-Q-2017-00795	Saflufenacil – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
34.	EFSA-Q-2017-00796	Spinetoram – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
35.	EFSA-Q-2017-00797	Tebuconazole – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
36.	EFSA-Q-2017-00798	Thiophanate-methyl – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
37.	EFSA-Q-2017-00799	Trifloxystrobin – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2017
38.	EFSA-Q-2017-00800	Triflumezopyrim – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2017
39.	EFSA-Q-2017-00804	EFSA comments on the general considerations provided by JMPR in 2017

1.2. Terms of Reference

The requested advice and comments on the recommendations of the 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 are 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 regards the proposed draft Codex MRLs for discussion in CCPR 2018, 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 draft Codex 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 2017 report, where relevant for risk assessment, as well as comments on the proposed crop groupings and the JMPR priority list can be provided as contributions to the EU-coordinated positions when these are discussed with the Member States and do not need to be covered by a scientific report.

(Terms of reference as provided by the European Commission in the Mandate of 14 November 2017)

EFSA agreed with the European Commission to respond to this request with a scientific report and to share the first draft of the scientific report containing comments on the active substances with all Member States and the European Commission by end of February 2018, inviting Member States to provide comments. Considering the short timelines, the first draft report did not cover yet all active substances (the detailed assessment was missing for three a.s.).

The final draft report addressing the Member State comments was completed on 9 March 2018; this document was intended to be used for discussions in the first Council Working Party scheduled for 16 March 2018.

It was agreed with the requestor to publish the final report before 31 July 2018.

The comments provided by Member States during the commenting period were addressed either directly in the final EFSA scientific report or though discussion during the Council Working Party meetings for the preparation of the 50th Session of the CCPRs.

2. Assessment

For each of the substances under consideration, EFSA provided the requested background information (first bullet point); in addition, the toxicological reference values (second bullet point of the Terms of Reference) derived by JMPR and at EU level were reported, comparing the assessments performed by JMPR and in the EU 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 (DAR) prepared by the Rapporteur Member States and other sources of information if available.

For deriving the comments on the Codex MRL proposals (third bullet point in the Terms of Reference), 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 DAR. The comparison of the existing EU MRLs and the proposed Codex MRLs is 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

[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

are indicated by adding an asterisk ('*') after the value. A detailed assessment of the analytical methods to be used for enforcement purpose was not performed.

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, 2010a, 2017a; OECD, 2011, 2013). It is noted that due to the different data requirements and policies in JMPR (FAO, 2017), 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, 2007a). 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 quite unlikely 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 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 the JMPR report summarising the recommendations of the 2017 JMPR meeting was published on 8 January 2018. The full evaluations were published on 6 March 2018. 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. EFSA Comments on JMPR report chapter 2 (General considerations), 3.1 (Concerns raised by the Codex Committee on Pesticide Residues) and 3.2 (Other matters of interest)

3.1. Harmonisation of the dietary exposure methodologies for compounds used both as pesticides and veterinary drugs – Special studies on microbiological effects of pesticide residues in foods

EFSA welcomes the initiative of JMPR to carry out microbiological assessments of pesticides residues' adverse chronic and acute effects on the microorganisms in the human gastrointestinal tract similarly to the assessments already routinely done by JECFA for veterinary drug residues.

For chemical active substances used as pesticides, specific studies investigating the potential adverse effects of pesticide residues on the microorganisms in the human gastrointestinal tract (human microbiome are not part of the EU data requirements). In the literature reviews which have to be submitted since 1 January 2014 in addition to the studies defined in the data requirements, adverse effects of pesticide residues on the microorganisms in the human gastrointestinal tract have not been reported so far.

3.2. Historical control data

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

3.3. Further consideration of the process for establishing group MRLs, update on use of the revised commodity classification for vegetables

EFSA shares the observation of JMPR that the shape/size or surface/weight ratio of a crop is an important parameter that influences the magnitude of residues. It may be less important for systemic substances or soil applications, but for foliar uses of pesticides close to harvest residue an extrapolation to crops with different morphological features may lead to inappropriate MRLs.

JMPR decided that based on residue trial in tomatoes, maximum residue levels will be derived only for cherry tomatoes (VO 2700) and tomatoes (VO 0448), but not for other crops listed in the subgroup 12A Tomatoes, e.g. to currant tomatoes, goji berries, tomatillos. Similarly, when data are available for Bell and non-bell peppers, JMPR decided to present maximum residue levels only for subgroup of peppers, exempting okra, martynia and roselle.

In the EU, MRLs established for tomatoes are also applicable to cherry tomatoes and to a number of minor crops, such as Cape gooseberries, tomatillos, goji berries, tomatillos and some other minor crops.

As regards peppers, the MRLs established for bell peppers would be equally applied to chili peppers, but not automatically to okra (okra are classified separately from peppers). However, an extrapolation from peppers to okra is allowed in the EU, provided that the same good agricultural practice (GAP) applies. Roselle and martynia are not explicitly listed in the EU food classification.

The MRLs derived with the OECD calculator usually accommodate for variations, but in certain cases, the MRLs might not be sufficient for small-sized crops listed in the crop classification in the same category as a comparably larger crop.

The uncertainty resulting from the application of MRLs that were established for major crops like tomatoes or peppers to the related minor crops was considered acceptable by risk managers, taking into account that these commodities are usually consumed in lower amounts, and usually no specific residue trials are available that would allow to establish separate MRLs.

3.4. Field use pattern anticipated residue comparison model

JMPR developed a model/tool that estimates residues at harvest resulting for a certain GAP based on residue trials that are not exactly matching with the critical GAP, but differ in application rates, retreatment intervals (RTI) and preharvest intervals (PHI). Crop-specific half-lives were estimated from a limited number of decline studies. This tool was used for deriving MRL proposals for cyclaniliprole.

Such a model/tool can be useful to decide if the results of supervised trials differing in one or several parameters are representative for the GAPs for which MRLs are requested. It might allow a more harmonised and objective evaluation of such GAPs by different assessment bodies.

However, before using this approach in a regulatory decision-making process, it is necessary that the model is validated to ensure that the derived MRL proposals are appropriate. The EU, therefore, requests that (1) a full description of the algorithms implemented in the model should be provided in the JMPR report and (2) a model validation is performed, comparing the outcome of an assessment based on trials matching the GAP with assessments based on residue trials that deviate in different parameters from the GAP to be assessed. Based on the results of the validation, a decision can be taken on the cases/scenarios where the tool can be used and the limitations of the tool (e.g. for residues with a complex degradation behaviour). Given these uncertainties resulting from the lack of a model validation, the EU will reserve its position for MRL proposals that were derived with this tool for the time being. The EU is ready to provide further detailed technical comments on its analysis of the model.

3.5. Update of the IESTI Model used for the calculation of dietary exposure: New Large Portion data

The update of the IESTI model to be used for dietary exposure calculations is welcome and regular updates should be further promoted. In future revisions, the recommendations of the international workshop on the IESTI equation should be incorporated as regards the consumption data.

EFSA would like to inform the participants of the CCPR meeting that a new revision of the European model for pesticide risk assessment (EFSA PRIMo) has been recently published, including new diets.

3.6. Quinclorac (287)

Following the 49th CCPR Meeting, the EU submitted a concern form asking JMPR to reconsider the residue definition for enforcement, since the more toxic metabolite (i.e. quinclorac methyl ester) was included in the residue definitions for compliance established by the US EPA and Health Canada, while it was not included in the residue definition for enforcement derived by JMPR.

JMPR confirmed that quinclorac is a suitable marker for compliance in all commodities and did not revise the previously derived residue definition. It was noted by JMPR that quinclorac methyl ester is included only in the residue definition for enforcement for specific crops/crop groups, i.e. in the USA for rapeseed and in Canada for pulses and oilseeds.

Further details on the new MRL proposals derived by JMPR in 2017 are presented in Section 4.29.

The concern of the EU is not fully addressed. Considering that, in 2017, JMPR assessed the setting of MRLs for rape seed, a crop where the methyl ester occurred in higher concentrations than expected from the metabolism studies, i.e. up to 400% of the parent compound, it would be more appropriate to include the more toxic metabolite as additional marker substance in the residue definition for enforcement. Further discussions with risk managers are recommended to decide on the EU position on the residue definition for quinclorac.

3.7. Abamectin (177)

JMPR received information on some new studies and published papers on abamectin. However, JMPR did not find it appropriate to re-evaluate abamectin. Since no detailed information is reported in the JMPR report, EFSA is not in a position to provide any comments.

3.8. Acetamiprid (246)

Following a request from CCPR, JMPR should perform a follow-up evaluation for toxicology. Since no relevant data were provided, JMPR did not find it appropriate to re-evaluate acetamiprid.

At EU level, acetamiprid was recently re-evaluated and the toxicological reference values have been lowered. The table below gives a comparison of the toxicological reference values established by JMPR and at EU level (Table 1).

Table 1: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.07 mg/kg bw per day	JMPR 2011	0.025 mg/kg bw per day	EFSA (2016q)	No
ARfD	0.1 mg/kg bw	JMPR 2011	0.025 mg/kg bw	European Commission (2017d)	No
Conclusion/ comment	The new EU toxicological reference values were taken note recently				

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

Following the lowering of the toxicological reference values, the existing EU MRLs and the previously accepted Codex MRLs are reconsidered. The assessment by EFSA will be finalised in April 2018.

It is recommended that an efficient procedure should be developed to share new toxicological data with JMPR to ensure that JMPR toxicological reference values are based on the same database.

3.9. Update from the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

No comments from EFSA side.

3.10. Harmonisation of the dietary exposure methodologies for compounds used both as pesticides and veterinary drugs – Harmonising/combining exposure from veterinary drug and pesticide use

The activities to harmonise/combine dietary exposure methodologies for pesticides and veterinary drugs are welcome.

3.11. Pesticides for vector control – New Pesticide Ingredients Developed Initially for Vector Control: Use of JMPR WHO Core Assessment Group for Pesticides

No comments.

3.12. Other Matters of Interest: Update from the International Programme on Chemical Safety (IPCS)

No comments.

3.13. Harmonisation of residue definition – determining the level of interest in a pilot project to achieve more harmonised residue definitions

A representative of Bayer CropScience proposed a procedure aiming to develop residue definitions that are acceptable by national regulators which would foster the acceptance of Codex MRLs. He proposed a pilot project.

Such an initiative is supported. It is noted that recently an EFSA guidance document on the establishment of the residue definition for dietary risk assessment was published (EFSA, 2016m). The discussions with risk managers on the details regarding the implementation of this guidance document are currently ongoing. The new EFSA guidance document could be used in the framework of the proposed pilot project to get experience on the use of the EFSA guidance at international level.

4. EFSA 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, 2017, 2018). 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.

4.1. Captan (007) R

4.1.1. Background information (Table 2)

Table 2: Background information on captan

		Comments, references
Type of JMPR evaluation	New use	
RMS	AT	Original RMS was IT
Approval status	Renewal of the approval	Commission Directive 2007/5/EC[(a)]
EFSA conclusion	Yes, see comments	EFSA (2009c) • Ongoing conclusion (AIR III)
MRL review	Yes, see comments	EFSA (2014d)
MRL applications	No	• Ongoing in hops

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2007/5/EU: Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances. OJ L 35, 8.2.2007, p. 11–17.

4.1.2. Toxicological reference values – captan (Table 3)

Table 3: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.1 mg/kg bw per day	JMPR, 1984 confirmed by JMPR, 1995 (reproductive toxicity studies in rats and monkeys)	0.1 mg/kg bw per day	European Commission (2008) confirmed in the EFSA (2009c) (teratogenicity study in rabbits, with safety factor of 100)	Yes
ARfD	0.3 mg/kg bw	WHO, 2009 established for women of childbearing age and unnecessary for the general population (based on NOAEL of 30 mg/kg bw per day for increased incidences of intrauterine deaths and malformations at 100 mg/kg bw per day in rabbits and a safety factor of 100)	0.3 mg/kg bw	European Commission (2008) confirmed in the EFSA (2009c) (teratogenicity study in rabbits, with safety factor of 100)	Yes
Conclusion/ comment	In the framework of AIR III, the RMS proposed a new ADI (0.25 mg/kg bw per day) and a new ARfD (0.9 mg/kg bw) for **captan**. According to the RMS, the rabbit is considered to be not the appropriate species for derivation of TRV for human risk assessment. The strong antimicrobial activity of captan is associated with secondary effects unique to the physiology of the rabbit digestive system (ingestion of caecotrophs/coprophagy). The toxicity of the metabolite **THPI** may need to be reconsidered during the renewal under AIR 3 as proposed by the RMS AT since recent studies indicate the acute oral toxicity of THPI to be higher than that of the parent captan and significantly higher than reported in the original DAR of 2003.				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; TRV: toxicological reference values; DAR:draft assesment report.

4.1.3. Residue definitions – captan (Table 4)

Table 4: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Captan	Reg. 396/2005: Sum of captan and THPI, expressed as captan Wine grapes: captan	No
	Animal products	Captan The residue is not fat soluble	Reg. 396/2005: Animal matrices except honey: sum of THPI, 3-OH THPI and 5-OH THPI, expressed as captan Honey and other apiculture products: sum of captan and THPI, expressed as captan The residue is not fat soluble	No
RD RA	Plant products	Captan	EFSA (2014c): Sum of captan and THPI, expressed as captan	No
	Animal products	Captan	EFSA (2014c): Sum of THPI, 3-OH THPI and 5-OH THPI, expressed as captan	No
Conclusion/ comments	Footnote for EU residue definition: The EU reference laboratories identified the reference standard for 3-OH THPI and 5-OH THPI as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 30 March 2017, or, if that reference standard is not commercially available by that date, the unavailability of it			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.1.4. Codex MRL proposals – captan (Table 5)

Table 5: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Ginseng	No Codex proposal	0.1*	Critical GAP: USA critical GAP is 3.36 kg ai/ha with a maximum of 8 applications or 27 kg ai/ha per season and a PHI of 14 days. Four trials conducted at 26.88 kg ai/ha per season, in accordance with the USA critical GAP. The 2017 JMPR concluded that '*there were analytical issues in the supervised field trials that precluded sufficient confidence in the representativeness of the captan residues for estimating a maximum residue level*'. In addition, it should be highlighted that metabolism studies for root crops would be required. JMPR did not report the availability of metabolism studies in root crops neither in 2017 nor in previous assessments. The RMS informed EFSA, that in the AIR III process, a metabolism study on root crops was not provided.
General comments	–		

GAP: Good Agricultural Practice; RMS: rapporteur Member State; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; PHI: preharvest interval.
*: Indicates that the input value is proposed at the limit of quantification.

4.1.5. Consumer risk assessment – captan

Not relevant, since no Codex MRL proposal was derived.

4.2. Chlormequat (15) (R/T)

4.2.1. Background information (Table 6)

Table 6: Background information on chlormequat

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	UK	
Approval status	Renewal of the approval	Commission Directive 2010/2/EU[(a)]
EFSA conclusion	Yes, see comments	EFSA (2009a) • EFSA on-going conclusion (AIR IV)
MRL review	Yes, see comments	EFSA (2016d)
MRL applications	No	None on going

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2010/2/EU: Commission Directive 2010/2/EU of 27 January 2010 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance chlormequat. OJ L 24, 28.1.2010, p. 11–13.

4.2.2. Toxicological reference values – chlormequat (Table 7)

Table 7: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR 2017; Dog, 90-day and 1-year studies	0.04 mg/kg bw per day	EFSA (2009a)Dog, 1-year study (UF 100) Confirmed in European Commission (2015)	No
ARfD	0.05 mg/kg bw	JMPR 2017; Dog, 90-day and 1-year studies	0.09 mg/kg bw	EFSA (2009a)Dog, 4-week study (UF 100) Confirmed inEuropean Commission (2015)	No
Conclusion/ comment	**JMPR** confirmed the previous assessments of chlormequat, establishing the ADI and the ARfD on the basis of the overall NOAEL of 4.7 mg/kg bw per day in the 1-year and 90-day dog studies, and applying a safety factor of 100. During the **EU** peer review, the 1-year dog study was also considered for the derivation of the ADI, with an additional correction of the NOAEL (from 5 to 4 mg/kg bw per day) in order to take into account the analytical results during the study (the tested concentrations were 21% lower than the target values after 6 months). For the derivation of the ARfD, the acute effects observed during the 4-week dog study were considered as an appropriate basis. It is noted that the EU and JMPR ADI and ARfD are established for chlormequat chloride. JMPR has recalculated to TRV using the molecular weight correction factor to match with the residue definition that is expressed as chlormequat cation.				

EU: European Union; ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; NOAEL: no observed adverse effect level; TRV: toxicological reference values.

4.2.3. Residue definitions – chlormequat (Table 8)

Table 8: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2016d)	RDs comparable
RD enf	Plant products	Chlormequat cation	EU Reg. 396/2005: Chlormequat (Sum of chlormequat and its salts, expressed as chlormequat chloride) Art 12: Sum of chlormequat and its salts, expressed as chlormequat chloride (only for cereals, pears and cultivated fungi)	Yes (see comment below)
	Animal products	Chlormequat cation The residue is not fat soluble	EU Reg. 396/2005: Chlormequat (Sum of chlormequat and its salts, expressed as chlormequat chloride) Art 12: Sum of chlormequat and its salts, expressed as chlormequat chloride The residue is not fat soluble	Yes (see comment below)
RD RA	Plant products	Chlormequat cation	Sum of chlormequat and its salts, expressed as chlormequat chloride (only for cereals, pears and cultivated fungi)	Yes (see comment below)
	Animal products	Chlormequat cation	Sum of chlormequat and its salts, expressed as chlormequat chloride	Yes (see comment below)
Conclusion/ comments	Residue definitions for enforcement derived by JMPR and by EU evaluation are comparable. However, if CXLs defined for chlormequat cation are taken over in the EU, they need to be multiplied by a correction factor of 1.29 to be expressed as chlormequat chloride (molecular weight correction factor). NB: the JMPR residue definition also applies to fruit crops as an additional metabolism study performed on grapes was assessed in the JMPR report. This study was not assessed in the EU evaluation			

CXL: Codex Maximum Residue Limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice.

4.2.4. Codex MRL proposals – chlormequat (Table 9)

Table 9: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	2	3	Critical GAP: 1 x 1,650 g a.s./ha at BBCH 25-30 (no PHI needed) (UK) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: minor deviation on the timing of applications seems acceptable to support the UK GAP. MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL. Conclusion: The proposed Codex MRL is acceptable. See general comment below
Barley straw and fodder, dry	50 (dw)		Critical GAP: 1 × 1650 g a.s./ha at BBCH 25-30 (no PHI needed) [the most critical GAP authorised Ireland is not supported by data] Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: same as for barley grain. Conclusion: Currently, no MRLs are established in the EU for feed items

Commodity	Codex MRL proposal	EU MRL	Comment
Pearl (pot) barley	2		PF of 0.9 is derived by JMPR. A similar PF of 0.9 was derived in the context of the MRL review
Barley, malt	2		PF of 0.9 was derived by JMPR from one processing study. A similar PF of 0.9 was derived in the context of the MRL review
Barley, spent grain	2		PF of 0.02 was derived by JMPR from 4 processing studies
Barley, beer	2		A PF of 0.2 was derived by JMPR from 4 processing studies. A similar PF of 0.2 was derived in the context of the MRL review.
Oats	4	15	Critical GAP: 1 × 1650 g a.s./ha at BBCH 33 (UK) Number of trials: 7 Sufficiently supported by data: No, 1 trial is missing. Specific comments/observations: MRL proposal needs to be converted into chlormequat chloride before being implemented in the EU Regulation. Conclusion: The proposed Codex MRL is acceptable. See general comment below
Oat straw and fodder, dry	7 (dw)		Critical GAP: 1 × 1,650 g a.s./ha at BBCH 33 (UK) Number of trials: 7 Sufficiently supported by data: Yes, although 1 trial is missing. Specific comments/observations: same as oat grain. Conclusion: Currently, no MRLs are established in the EU for feed items
Oat kernels	4		PF of 1 was derived by JMPR from 1 trial. No PF derived for this commodity in the MRL review.
Oat flakes	4		PF of 0.8 was derived by JMPR. A similar PF of 1 was derived in the context of the MRL review while 0.8 is derived by JMPR.
Triticale	5	4	Critical GAP: 1 × 1875 g a.s./ha at BBCH 31 (Ireland) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The use of the proportionality principle was applied to scale residue trials performed on rye with different application rates compared to GAP; trials performed on wheat were not considered as they showed lower residue levels. MRL proposal needs to be converted into chlormequat chloride before being implemented in the EU Regulation. It is noted that the EU MRL for triticale is covered by the EU MRL on wheat.It is noted that the most critical GAP reported in NEU during the MRL review was 1 × 0.6 kg/ha; BBCH 49) while the GAP considered in the JMPR report also comes from EU and is more critical than the one considered in the MRL review. Conclusion: The proposed Codex MRL is sufficiently supported by data and is therefore acceptable. See general comment below
Triticale straw and fodder, dry 80 (dw)	80 (dw)		Critical GAP: 1 × 1875 g a.s./ha at BBCH 31 (Ireland) Number of trials: 23 Sufficiently supported by data: Yes Specific comments/observations: Same as triticale grain Conclusion: Currently, no MRLs are established in the EU for feed items
Wheat	2	4	Critical GAP: 1 × 2025 g a.s./ha at BBCH 21-31 (Argentina) [the most critical GAP from Japan is not clearly defined] Number of trials: 25 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: The use of the proportionality principle was applied to scale up residue trials which were all performed with lower application rates compared to GAP. MRL proposal needs to be converted into chlormequat chloride before being implemented in the EU Regulation. Conclusion: The proposed Codex MRL is acceptable. It is noted that for triticale a higher MRL proposal was derived. In the EU triticale and wheat are normally covered by a common MRL. Therefore, the triticale CXL would be applicable to wheat as well.
Wheat straw and fodder, dry	80 (dw)		Critical GAP: 1 × 2,025 g a.s./ha at BBCH 21-31 (Argentina) Number of trials: 24 Sufficiently supported by data: Yes Specific comments/observations: same as for wheat grain. Conclusion: Currently, no MRLs are established in the EU for feed items
White (type 550) wheat flour	2		PF of 0.29 is derived by JMPR. A similar PF (0.3) was derived in the context of the MRL review
Wheat bran, unprocessed	7		PF of 3.0 is derived by JMPR. A similar PF (3.1) was derived in the context of the MRL review. An MRL of 6 mg/kg should be enough as the MRL on wheat grain is 2 mg/kg and the derived PF is 3. However, currently, no MRLs are established for processed products in the EU
Wholemeal flour	2		PF of 1.2 is derived by JMPR; a similar PF of 1 was derived in the context of the MRL review
Wheat wholemeal bread	2		PF of 0.54 is derived by JMPR; a similar PF of 0.5 was derived in the context of the MRL review.
Wheat wholemeal	2		It is not understood to which product the PF of 1.2 refers (wheat wholemeal?). Whole meal flour and whole meal bread are already covered in the rows above.
Rye	**6**	4	Critical GAP: 1 × 2250 g a.s./ha at BBCH 21-32 (Latvia) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The use of the proportionality principle was applied to scale up residue trials which were performed with a lower application rate compared to GAP. MRL proposal needs to be converted into chlormequat chloride before being implemented in the EU Regulation. It is noted that the most critical reported in NEU during the MRL review was 1 × 1.5 kg/ha; BBCH 37) while the GAP considered in the JMPR report also comes from EU and is more critical than the one considered in the MRL review. Conclusion: The proposed Codex MRL is acceptable. See general comment below
Rye straw and fodder, dry	20 (dw)		Critical GAP: 1 × 2,250 g a.s./ha at BBCH 21-32 (Latvia) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: Same as rye grain. Conclusion: Currently, no MRLs are established in the EU for feed items
Rye bran, unprocessed	20		PF of 3.2 is derived by JMPR from 1 trial only. A similar PF (3.1) was derived in the context of the MRL review
Rye flour	6		PF of 0.99 is derived by JMPR from 1 trial only. A PF of 0.3 was derived in the context of the MRL review.

Commodity	Codex MRL proposal	EU MRL	Comment
Rye whole meal	8		PF of 1.3 is derived by JMPR from 1 trial only. A similar PF (1) was derived in the context of the MRL review for whole meal flour
Rye wholemeal bread	6		PF of 0.95 is derived by JMPR from 1 trial only. A lower PF (0.5) was derived for whole meal bread in the context of the MRL review
Straw and fodder (dry) of cereal grains	W30		The existing CXL is recommended for withdrawal
Grapes	0.04*	0.05 (ft) (table) 0.01* (wine)	Critical GAP: 3 foliar applications (1st 500 + 2nd 1,000 + 3rd 250) g a.s./ha; PHI 91 days (India)) Number of trials: 6 × < 0.04 (according to application rate defined in the GAP) + 2 × < 0.04 (more critical application rate) [samplings on mature grapes are performed at PHI 120–150 days, which is longer than the PHI defined by the GAP]. Sufficiently supported by data: Yes. Specific comments/observations: the metabolism study for fruit crops was not assessed at EU level, but the study confirms the proposed residue definition. It is noted that, for some trials, the PHI in the residue trials was longer than the PHI defined in the GAP. Longer PHI in the residue trials is not covering the GAP with 91 days. According to 25% tolerance rule, PHI 114 d should be the maximum. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. See also general comment below
Cotton seed	W0.5	0.7 (ft)	The existing CXL is recommended for withdrawal.
Rape seed	W5	7 (ft)	The existing CXL is recommended for withdrawal.
Rape seed oil, Crude	W0.1		The existing CXL is recommended for withdrawal.
Maize fodder (dry)	W7	0.01*	The existing CXL is recommended for withdrawal.
Meat (from mammals other than marine mammals)	0.2	0.2	Maximum dietary burden was calculated for the Australian diet for beef and dairy cattle. Feeding study with highest dose level covers the max DB. The HR in meat is only 0.091 mg/kg; thus, a MRL proposal of 0.1 mg/kg (or 0.15) should be enough; no information is available for muscle. However, considering that the residues in meat and fat were in the same range, it is assumed that in muscle the same residue level would occur. Thus, the MRL proposal derived by JMPR for meat would be appropriate also for muscle. Before this, MRL can be taken over in the EU, it needs to be converted into chlormequat chloride (0.1 (or 0.15 mg/kg) ×1.29 = 0.15 (or 0.2 mg/kg). The MRL proposal derived after the conversion would be comparable with the existing EU MRL for muscle (expressed as chlormequat chloride). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. JMPR should be asked for a clarification for the MRL proposal
Mammalian fats (except milk fats)	**0.1**	(swine, 0.02, rest 0.06)	Max Dietary burden = 100 ppm (assumed to be mg/kg DM) Feeding study with highest dose level (93 ppm) covering the max DB HR in fat is only 0.083 mg/kg; thus, a MRL proposal of 0.09 mg/kg should be enough. MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. JMPR should be asked for a clarification for the MRL proposal
Edible offal (mammalian)	**1**	0.5 others 0.15 (liver) 0.5 (kidney)	Max Dietary burden = 100 ppm (assumed to be mg/kg DM) Feeding study with highest dose level (93 ppm) covering the max DB HR in liver/kidney is only 0.88 mg/kg; thus, a MRL proposal of 0.9 mg/kg should be enough. MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. JMPR should be asked for a clarification for the MRL proposal
Meat of cattle, pigs and sheep	W0.2	(see above 0.2)	Replaced by the proposal for all 'mammals other than marine mammals'
Goat meat	W0.2	0.2	Replaced by the new proposal for all 'mammals other than marine mammals'
Liver of cattle, goats, pigs and sheep	W0.1	0.5 others 0.15 (liver) 0.5 (kidney)	Replaced by the proposal for all 'mammals other than marine mammals'
Kidney of cattle, goats, pigs and sheep	W0.5	0.5 others 0.15 (liver) 0.5 (kidney)	Replaced by the proposal for all 'mammals other than marine mammals'
Milks	0.3	0.5	Max Dietary burden = 66.8 ppm (assumed to be mg/kg DM) Feeding study with highest dose level (93 ppm) covering the max DB. Specific comments/observations: MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL. Conclusion: The proposed Codex MRL is acceptable. See general comments below
Milk of cattle, goats and sheep	W0.5		Replaced by the proposal for all 'milks' (see above)
Poultry meat	0.04*	0.04	Maximum dietary burden was calculated for European laying hens (11.4 ppm mg/kg DM) Feeding study with highest dose level (14 ppm) covering the max DB. No residues were found at any of the feeding levels (highest feeding level 4N calculated dietary burden). The MRL in EU should be defined for 'poultry muscle'. Since MRL at LOQ is proposed for meat and fat, it can reasonably be also transposed at an MRL of 0.04* mg/mg in poultry muscle. Conclusion: The proposed Codex MRL is acceptable. See general comments below
Poultry fats	**0.04***	0.03	Max Dietary burden: 11.4 ppm (assumed to be mg/kg DM) Feeding study with highest dose level (14 ppm) covering the max DB Specific comments/observations: MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL. Conclusion: The proposed Codex MRL is acceptable. See general comments below
Poultry, edible offal of	0.1	0.1	Max Dietary burden: 11.4 ppm (assumed to be mg/kg DM) Feeding study with highest dose level (14 ppm) covering the max DB

Commodity	Codex MRL proposal	EU MRL	Comment
			HR in liver is only 0.072 mg/kg; thus, a MRL proposal of 0.08 mg/kg should be enough. MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. JMPR should be asked for a clarification for the MRL proposal
Eggs	0.1	0.1	Max Dietary burden: 11.4 ppm (assumed to be mg/kg DM) Feeding study with highest dose level (14 ppm) covering the max DB HR in eggs is only 0.079 mg/kg; thus, a MRL proposal of 0.08 mg/kg should be enough. MRL proposal needs to be converted into chlormequat chloride before being compared with the EU MRL. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. JMPR should be asked for a clarification for the MRL proposal
General comment:	Acceptable Codex MRL proposals need to be converted into chlormequat chloride before being taken over in the EU MRL legislation		

PHI: preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; DM: dry matter; CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; PF: processing factor; NEU: northern European Union; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.

4.2.5. Consumer risk assessment – chlormequat (Table 10)

Table 10: Summary of the consumer risk assessment for chlormequat

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for all commodities assessed by JMPR. HR values derived by JMPR were multiplied by the molecular factor of 1.29 in order to express the residues as chlormequat chloride, in line with the TRV. Contribution of cereals was assessed with STMR RAC. Two scenarios were calculated, using the EU ARfD (scenario 1) and the JMPR ARfD (scenario 2)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2016d) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for rye grain, wheat grain, table and wine grapes and livestock commodities. STMR values derived by JMPR were multiplied by the molecular factor of 1.29 in order to express the residues as chlormequat chloride, in line with the TRV. Contribution of cereals was assessed with STMR RAC. No refinement was performed with the processing factors. For wheat, the highest STMR between wheat and triticale was considered in the calculation (i.e. STMR triticale)	**Specific comments** Detailed RA values can be assessed for wheat and triticale, which is not possible with the EU PRIMo. RA values are expressed as chlormequat cation, but TRV were also converted accordingly, i.e. divided by 1.29

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: Scenario 1, considering ARfD derived by EFSA (2009a): No short-term exposure concern was identified (max 40% ARfD for milk). Scenario 2: considering ARfD derived by JMPR (FAO, 2017): No short-term exposure concern was identified (max 72% ARfD for milk)	**Results:** Scenario 1, considering ARfD derived by EFSA (2009a): The overall chronic exposure accounted for 40.4% of the ADI (DK child). Main contributors are wheat (16.3% ADI), rye (15.7% ADI) and milk and cream (5.1% ADI). Considering the ADI derived by EFSA (2009a), no long-term consumer health risk was identified. As the ADI derived by JMPR is less critical, no further concern is expected	**Results:** Long-term exposure: 1–7% of the ADI Short-term exposure: Up to 100% ARfD (rye) Up to 100% ARfD (oats) 40% ARfD (milks)

RA: risk assesment; ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; HR: Highest residue; RAC: raw agricultural commodity; STMR: supervised trials median residue.

4.3. 2,4-D (20) (R)

4.3.1. Background information (Table 11)

Table 11: Background information on 2,4-D

		Comments, references
Type of JMPR evaluation	New uses	
RMS	EL	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) 2015/2033[(a)]
EFSA conclusion	Yes, see comments	EFSA, 2014m (corrigendum 2017)
MRL review	Yes, see comments	EFSA (2011g)
MRL applications	Yes, see comments	EFSA (2017b) (import tolerance maize) • Application on modification of MRL in GM soya beans currently on clock-stop (additional data requested)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue limit.
(a): 2015/2033/EU: Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D 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 298, 14.11.2015, p. 8–11.

4.3.2. Toxicological reference values – 2,4-D (Table 12)

Table 12: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.01 mg/kg bw per day	JMPR 1996	0.02 mg/kg bw per day	EFSA (2014m) (Dog, 1-year, safety factor 100) confirmed in European Commission (2017c)	No
ARfD	unnecessary	JMPR 2001	0.3 mg/kg bw	EFSA (2014m) (Rat and rabbit developmental toxicity studies, safety factor 100) confirmed inEuropean Commission (2017c)	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
Conclusion/ comment	The last toxicological assessment of 2,4-D by JMPR was performed in 2001, where JMPR assessed the need for setting an ARfD. The ADI was derived in 1996. 2,4-dichlorophenol (2,4-DCP) was identified in the metabolism studies performed with 2,4-D in GM soybeans expressing the AAD-12 protein (6% of TRR, free and conjugated). This metabolite also occurred in metabolism study with conventional root crops (4% of TRR in potato, 1% of TRR in wheat forage and straw), in livestock metabolism studies performed with 2,4-D (up to 7.3% milk, eggs and chicken liver) and in livestock metabolism studies with 2,4-DB (up to 40% of TRR in conjugated from). Toxicological studies on 2,4-DCP were never assessed by JMPR. At EU level, during the renewal peer review of 2,4-D and 2,4-DB, the toxicological properties of 2,4-DCP were investigated (EFSA, 2014m, 2016k). Based on the available equivocal data, no firm conclusion could be drawn on the genotoxic or carcinogenic potential of metabolite 2,4-DCP (positive results were reported *in vitro*) and on its toxicological profile (2,4-DCP caused embryotoxicity (reduced intrauterine survival, foetal weight and ossification) in rats at maternally toxic doses (mortality and reduced body weight gain)				

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; GM: genetically modified; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRR: total radioactive residue; TRV: toxicological reference values.

4.3.3. Residue definitions – 2,4-D (Table 13)

Table 13: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of 2,4-D	2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D)	No
	Animal products	Sum of 2,4-D Fat solubility not specified	2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D) The residue is not fat soluble	No
RD RA	Plant products	Sum of 2,4-D	Sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D	No
	Animal products	Sum of 2,4-D	Sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D	No
Conclusion/ comments	In GM cotton (AAD-12 cotton), 2,4-DCP and its conjugates were detected at similar or even at higher concentrations than parent 2,4-D. JMPR did not consider appropriate to include this metabolite in the residue definition since it may occur in or on plants not only from the use of 2,4-D but also from its presence in water and the environment. According to EFSA, before a decision on the need to include this metabolite in a residue definition related to the use of 2,4-D containing plant protection products is taken, the toxicological profile of the metabolite need to be investigated			

EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RD-RA: residue definition for risk assessment; RD-ENF: residue definition for enforcement practice; GM: genetically modified.

4.3.4. Codex MRL proposals – 2,4-D (Table 14)

Table 14: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cotton seed	–	0.05*	Due to questionable storage stability of 2,4-D and 2,4-DCP in cotton seed, the trials were not assessed by JMPR and no Codex MRL proposal was derived

EU MRL: European Union maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.
*: Indicates that the input value is proposed at the limit of quantification.

4.3.5. Consumer risk assessment – 2,4-D

Not relevant, since no Codex MRL proposals were derived by JMPR.

4.4. Thiophanate-methyl (77) (T)

4.4.1. Background information (Table 15)

Table 15: Background information on thiophanate-methyl

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	SE	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) 2017/1511[(a)]
EFSA conclusion	Yes, see comments	EFSA (2018b)
MRL review	Yes, see comments	EFSA (2014s)
MRL applications	No	
EU cut-off criteria	Lack of toxicological reference values	Since no toxicological reference values were established, based on genotoxicity concerns, the approval criteria are not met
	Proposed classification by the peer review	The peer review proposed classification for thiophanate-methyl as Muta 1B, H340 (falling under cut-off criteria) while current harmonised classification is Muta 2, H341
	Endocrine disrupting potential	The peer review considered that there is enough evidence to conclude that thiophanate-methyl is an endocrine disruptor and that the mechanism is relevant to humans (cut-off criteria)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union MRL: maximum residue limit.
(a): 2017/1511/EU: Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron. OJ L 224, 31.8.2017, p. 115–117.

4.4.2. Toxicological reference values – thiophanate-methyl (Table 16)

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.09 mg/kg bw per day	JMPR 2017	–	EFSA (2018b)	No
ARfD	1 mg/kg bw	JMPR 2017	–	EFSA (2018b)	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
Conclusion/ comment	Regarding the ADI, the JMPR set an ADI on the basis of a NOAEL of 8.8 mg/kg body weight (bw) per day based on reduction in body weight gain and clinical chemistry, urine analysis and histopathological changes in the kidney, thyroid, liver and adrenals in a 2-year study in rats. This ADI is supported by the overall NOAEL of 10 mg/kg bw per day based on increased thyroid weight and histopathological changes in the thyroid observed in 3-month, 1-year and 2-year toxicity studies in dogs. A safety factor of 100 was used. The ARfD was established at 1 mg/kg bw on the basis of a NOAEL of 125 mg/kg bw for transient reductions in body weight gains (including body weight losses) and feed consumption in an acute neurotoxicity study in rats, using a safety factor of 100. In its 2018 review, the EU peer review considered thiophanate-methyl a clastogenic substance (based on positive micronucleus test *in vitro* and *in vivo;* and centromeric staining showing that a high proportion (66%) of the micronuclei induced by thiophanate-methyl did not contain a centromere, close to the proportion of 76% observed after exposure to the known clastogen mitomycin C and distinctly different from the proportion of 32% observed after exposure to the known aneugen carbendazim) for which no threshold is assumed; therefore, no ADI or ARfD was derived. In addition, a potential for aneugenicity could not be ruled out since its main metabolite, carbendazim, is a recognised aneugenic substance (classified as Muta 1B, H340 in Annex VI to Reg. 1272/2008)				

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; NOAEL: no observed adverse effect level; TRV: toxicological reference values.

4.4.3. Residue definitions thiophanate-methyl

No residue assessment was performed by JMPR.

4.4.4. Codex MRL proposals thiophanate-methyl

No Codex MRL proposals were derived by JMPR.

4.4.5. Consumer risk assessment – thiophanate-methyl

Not relevant since no Codex MRL proposals were derived by JMPR.

4.5. Oxamyl (126) (R/T)

4.5.1. Background information (Table 17)

Table 17: Background information on oxamyl

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	IT	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 1136/2013[(a)]
EFSA conclusion	Yes, see comments	EFSA (2005a) • EFSA ongoing conclusion (AIR III)
MRL review	Yes, see comments	EFSA (2010h)

		Comments, references
MRL applications	No	
General comment		The previous EU assessment of the toxicological properties of oxamyl is more than 12 years old. The renewal process for the approval of the a.s. is ongoing. It may reasonably be expected that in the framework of the renewal process different conclusions on toxicological properties of oxamyl and its metabolites will be derived. Therefore, the comments on the acceptability of toxicological reference values, on Codex MRL proposals and the resulting risk assessment are only tentative and may have to be revised in the light of the outcome of the peer review. If EU GAPs that were the basis of the assessment performed by JMPR will be revised as a consequence of the EU peer review, the Codex MRL proposals will have to be reconsidered

EU: European Union GAP: Good Agricultural Practice; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 1136/2013/EU: Commission Implementing Regulation (EU) No 1136/2013 of 12 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clothianidin, dimoxystrobin, oxamyl and pethoxamid. OJ L 302, 13.11.2013, p. 34–35.

4.5.2. Toxicological reference values – oxamyl (Table 18)

Table 18: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.009 mg/kg bw per day	JMPR 2002, confirmed in 2017 (human volunteers study, safety factor of 10)	0.001 mg/kg bw per day	EFSA (2005a) (Acute neurotoxicity study (rat), with a safety factor of 100) confirmed by European Commission (2011)	No
ARfD	0.009 mg/kg bw	JMPR 2002, confirmed in 2017 (human volunteers study, safety factor 10)	0.001 mg/kg bw	EFSA (2005a) (Acute neurotoxicity study (rat), with a safety factor of 100) confirmed by European Commission (2011)	No
Conclusion/ comment	JMPR and EU assessment considered a different study for the point of departure for setting reference values. According to Regulation EC 1107/2009 *'for ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human 'no observed effect level' of an active substance. Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.'* On this basis, EFSA supported the reference values as proposed during the European peer review. In the JMPR assessment and in the EU peer review, a number of metabolites were discussed as regards to their toxicological profiles and the need to include them in the residue definitions. Considering that the peer review is currently ongoing, at EU level, final conclusion on the toxicological relevance of the individual metabolites is not yet available. Thus, it is recommended to decide on the acceptability of the assessment, once the EU assessment on the renewal of the a.s. is finalised. EFSA, however, noted inconsistency in the naming of one metabolite: IN-N009 (also referred to as DMCF (dimethylcarbonocyanidic amide) is reported in the residue section mainly as IN-N0079. The use of different codes in the section 'Toxicology' and 'Residue and analytical aspects' is confusing and should be avoided			

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; TRV: toxicological reference values.

4.5.3. Residue definitions – oxamyl (Table 19)

Table 19: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Oxamyl	Oxamyl	Yes
	Animal products	Oxamyl The residue is not fat soluble	Oxamyl The residue is not fat soluble	Yes
RD RA	Plant products	Oxamyl	None required	N/A
	Animal products	Oxamyl	None required	N/A
Conclusion/ comments	The existing EU residue definitions will be rediscussed in the framework of the renewal. A final conclusion on the acceptability of the proposed JMPR RD assessment should be postponed until a final EU position is derived			

EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RD: residue definition; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice.

4.5.4. Codex MRL proposals – oxamyl (Table 20)

Table 20: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Apple	W (2)	0.01*	JMPR proposed to withdraw the existing CXL
Brussels sprouts	0.01*	0.01*	Critical GAP: NL, 1 × 4 kg a.i./ha (soil application) Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Brussels sprouts are a category 2 crop; thus, at least 4 trials would be required. Conclusion: Considering that the proposed MRL is at the LOQ, the limited number of trials may be acceptable
Carrot	0.01*	0.01*	Critical GAP: NEU: 1 × 0.09 g a.i./m (seed furrow application) Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: For carrots, at least 8 trials would be required. Conclusion: Considering that the proposed MRL is at the LOQ, the limited number of trials may be acceptable
Cherry tomato	0.01*	0.01* (ft)	Critical GAP: SEU, 4 soil applications with a maximum of 5 kg/ha per crop cycle, PHI 28 days. Number of trials: 20 Sufficiently supported by data: Yes Specific comments/observations: Combined data set of trials in cherry tomatoes and tomatoes Conclusion: The proposed Codex MRL is acceptable
Group of citrus fruit (includes all commodities in this group)	W (3)	0.01*	JMPR proposed to withdraw the existing CXL
Cotton seed	W0.2	0.01*	JMPR proposed to withdraw the existing CXL
Cucumber	**0.02**	0.01* (ft)	Critical GAP: SEU, 2 soil application with a maximum of 3 kg/ha per crop cycle, PHI 50 days. Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: The number of trials is sufficient according to JMPR rules; however, at EU level, two additional trials would be required. For summer squash, a set of 6 trials was provided for the same GAP. The two data sets could be combined to derive a more robust MRL proposal for cucumber and summer squash.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is not acceptable, because the number of trials is insufficient. If the trials on summer squash will be used to support the use on cucumber, an acute consumer health risk cannot be excluded
Edible offal (mammalian)	0.01*	0.01*	The proposed Codex MRL was derived from a feeding study, taking into account the expected dietary burden resulting from the uses assessed by JMPR. It was noted that no storage stability data were available for animal products. Conclusion: The proposed Codex MRL is acceptable
Edible offal of cattle, goats, horse, pigs and sheep	W0.02*	0.01*	JMPR proposed to withdraw the existing CXL and replace it with a new MRL of 0.01* mg/kg
Eggplant (includes all commodities in this subgroup)	0.01*	0.02 (ft)	Critical GAP: SEU, 4 soil applications with a maximum of 5 kg/ha per crop cycle, PHI 28 days. Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: Egg plants are a major crop, and therefore, 8 trials would be necessary. Since in the 5 available trials, the residues were < 0.01 mg/kg, the reduced number of trials is acceptable. It is noted the JMPR derived two MRL proposals for eggplants, one for the individual crop (crop code VO0440) and a second one for the subgroup of eggplants (crop code VO2016). To avoid confusions, one of these MRL proposals should be deleted. Conclusion: The proposed Codex MRL is acceptable.
Eggs	W0.02*	0.01*	JMPR proposed to withdraw the existing CXL
Mammalian fats (except milk fats)	0.01*	0.01*	See the comment on the Edible offal (mammalian)
Meat (from mammals other than marine mammals)	0.01*	0.01*	See the comment on the Edible offal (mammalian)
Melons, except watermelon	0.01	0.01*	Critical GAP: SEU, 2 application with a maximum of 3 kg/ha per crop cycle, PHI 50 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: Melons are a major crop, and therefore, at least 8 trials are required. Since not all residue trials are below the LOQ, it is not appropriate to derive the MRL proposal from a reduced data. Conclusion: The proposed Codex MRL is not acceptable because of insufficient number of trials
Milks	0.01*	0.01*	See the comment on the Edible offal (mammalian)
Parsnip	0.01*	0.01*	The MRL proposal was derived by extrapolation from the trials on carrots. See the comment on carrots
Peanut	W0.05	0.01*	JMPR proposed to withdraw the existing CXL
Peanut fodder	W0.2 (dw)	–	JMPR proposed to withdraw the existing CXL
Peppers, chili (dried)	0.01*		–
Potato	0.01*	0.01*	Critical GAP: NEU, 1 soil application, 5.5 kg/ha, PHI 80 days Number of trials: 8 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: The origin of the trials SEU/NEU is not mentioned in the JMPR report. All the residues were < 0.01 mg/kg, thus a limited number of trials could be acceptable to cover both EU zones. Conclusion: The proposed Codex MRL is acceptable.
Poultry, edible offal of	W0.02*	0.01*	JMPR proposed to withdraw the existing CXL
Poultry meat	W0.02*	0.01*	JMPR proposed to withdraw the existing CXL
Squash, summer	**0.04**	0.01* (ft)	Critical GAP: SEU, 2 applications, with a maximum of 3 kg/ha per crop cycle, PHI 50 days. Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: The number of trials is sufficient according to JMPR rules; however at EU level, two additional trials would be required. For cucumbers, a set of 6 trials were provided for the same GAP. The two data sets could be combined to derive a more robust MRL proposal for cucumber and summer squash. Thus, a MRL of 0.03 mg/kg would be sufficient. It should be investigated why the EU MRL is set at the LOQ, while apparently quantifiable residues are expected. Conclusion: The proposed Codex MRL is not acceptable; a lower MRL proposal of 0.03 mg/kg would be sufficient. In addition, an acute consumer health risk was identified
Subgroup of eggplants (includes all commodities in this subgroup)	0.01*	0.02*(ft) (eggplants)	Critical GAP: SEU, 4 soil applications with a maximum of 5 kg/ha per crop cycle, PHI 28 days. Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: Egg plants are a major crop, and therefore, 8 trials would be necessary. Since in the 5 available trials, the residues were < 0.01 mg/kg, the reduced number of trials is acceptable. It is noted that the JMPR derived two MRL proposals for eggplants, one for the individual crop (crop code VO0440) and a second one for the subgroup of eggplants (crop code VO2016). To avoid confusions, one of these MRL proposals should be deleted. Conclusion: The proposed Codex MRL is acceptable
Subgroup of Peppers (except martynia, okra and roselle)	0.01*	0.01*	Critical GAP: SEU, 3 applications, with a maximum of 4 kg/ha per crop cycle, PHI 35 days. Number of trials: 10 Specific comments/observations: Residues in all trials < 0.01 mg/kg Conclusion: The proposed Codex MRL is acceptable
Sugar beet	0.01*	0.01*	Critical GAP:NL, 0.75–2.5 kg/ha (soil incorporation in furrow at drilling) Number of trials: 19 Specific comments/observations: The residues in sugar beets were all below the LOD (0.005 or 0.01 mg/kg) Conclusion: The proposed Codex MRL is acceptable
Tomato	0.01*	0.01* (ft)	Critical GAP: SEU, 4 soil applications with a maximum of 5 kg/ha per crop cycle, PHI 28 days. Number of trials: 20 Sufficiently supported by data: Yes Specific comments/observations: combined data set of trials in cherry tomatoes and tomatoes, all trials < 0.01 mg/kg. Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Watermelon	0.01	0.01*	Critical GAP: SEU, cycle rate 3 kg/ha, PHI 50 days. Number of trials: 7 (< 0.01 mg/kg) Sufficiently supported by data: No Specific comments/observations: Watermelons are a major crop, and therefore, at least 8 trials are required. Since all residue trials are below the LOQ, a reduced data may be acceptable

GAP: Good Agricultural Practice; CXL: Codex Maximum Residue Limit; NEU: northern European Union; LOD: limit of detection; LOQ: limit of quantification; MRL: maximum residue limit; SEU: Southern European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; PHI: preharvest interval.
*: Indicates that the input value is proposed at the limit of quantification.

4.5.5. Consumer risk assessment – oxamyl (Table 21)

Table 21: Summary of the consumer risk assessment oxamyl

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A risk assessment was conducted for those commodities, where the Codex MRL proposals were higher than the existing EU MRLs, using the current EU ARfD.The result of this risk assessment may change if the toxicological reference value and/or the residue definition will be revised (e.g. in the framework of the peer review that will soon start).	**RA assumptions:** A long-term risk assessment was conducted by updating the exposure calculation from art 12 MRL review (EFSA, 2010h), only for the crops assessed by JMPR and leading to higher MRLs proposals than the current EU MRLs (highlighted in bold above) using the EU toxicological reference values. The EU ADI was used. The result of this risk assessment may change if the toxicological reference value and/or the residue definition will be revised (e.g. in the framework of the peer review that will soon start)	**No comment**
Results: A short-term consumer health risk was identified for courgettes (102% of ARfD). For cucumbers, using the HR derived from trials on cucumbers, the exposure was close to the ARfD, and thus, a very narrow safety margin was identified (94% of ARfD). However, if the HR from the combined data set of courgettes and cucumbers is used in the risk assessment, an exceedance of the ARfD is noted for cucumbers as well (129% of the ARfD)	**Results:** Considering only the exposure to parent oxamyl, no chronic consumer intake concerns was identified (max 28% of ADI)	0–1% of ADI, 0–20% of ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit.

4.6. Propiconazole (160) (R)

4.6.1. Background information (Table 22)

Table 22: Background information on propiconazole

		Comments, references
Type of JMPR evaluation	New use	
RMS	FI	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 2016/2016[(a)]
EFSA conclusion	Yes, see comments	EFSA (2017f)
MRL review	Yes, see comments	EFSA (2015a)
MRL applications	No	

MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2016/2016/EU: Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flazasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, Pseudomonas chlororaphis Strain: MA 342, pyraclostrobin, quinoxyfen, thiacloprid, thiram, ziram, zoxamide. OJ L 312, 18.11.2016, p. 21–23.

4.6.2. Toxicological reference values – propiconazole (Table 23)

Table 23: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.07 mg/kg bw per day	JMPR 2015	0.04 mg/kg bw per day	EFSA (2017f) (Chronic rat study with uncertainty factor of 100)	No
ARfD	0.3 mg/kg bw	JMPR 2015	0.1 mg/kg bw	EFSA (2017f) (Developmental study in rat with uncertainty factor of 300)	No
Conclusion/ comment	In the framework of the renewal of the approval, the ARfD has been recently lowered in the EU (EFSA, 2017f); the ADI has been confirmed. Propiconazole is proposed to be classified as toxic for reproduction category 1B by the RAC of ECHA, in accordance with the provisions of Regulation (EC) No 1272/2008, and toxic effects on the endocrine organs have been observed in the available data. Should the second interim provision of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 be applicable to category 1B, propiconazole may be considered to have endocrine disrupting properties leading to a critical area of concern				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.6.3. Residue definitions – propiconazole (Table 24)

Table 24: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Propiconazole	Propiconazole (sum of isomers)	Yes
	Animal products	Propiconazole The residue is fat soluble	EU Reg. 396/2005: Propiconazole (sum of isomers) Peer review: CGA91305 (free and conjugated) ((1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl) ethanol) The residue is fat soluble	Yes (current RD), No (peer review proposal)
RD RA	Plant products	Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoic acid, expressed as propiconazole.	Primary crops (For all categories of crops): 1) Propiconazole (sum of isomers) 2) CGA 118244 (3,5-dideoxy-1,2-O-[(1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl)ethylidene]-D,L-pentitol) free and glucoside conjugated. Whether the parent compound and CGA 118244 have to be considered together or separately is pending upon the submission of toxicological data to address the toxicity profile on CGA118244). 3) CGA142856 (TAA, 1*H*-1,2,4-triazol-1-ylacetic acid) and CGA131013 (TA, 3-(1*H*-1,2,4-triazol-1-yl)-D,L-alanine) Rotational crops and processed commodities: Open (EFSA, 2017g)	No
	Animal products	Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoic acid, expressed as propiconazole	1) Propiconazole, CGA91305 (free and conjugated) and CGA118244 (The way the residue definition will be expressed is pending upon the requested toxicological profile on CGA91305 and CGA118244) 2) CGA71019 (1,2,4-triazole)	No
Conclusion/comments		Considering that JMPR derived MRL proposals only for fruit crops and for tea, the difference in the residue definitions for risk assessment for animal products are of no relevance. The enforcement RD for plants established in Reg. 396/2005 is comparable with the RD of JMPR. For the risk assessment residue definitions, JMPR covers the common moiety (2,4-dichlorobenzoic acid), while in the EU, the second residue definition covers one metabolite for which open questions on the toxicological profile were identified. JMPR did not set specific residue definitions for the TDSs (TAA and TA). Due to the different risk assessment residue definitions for plant commodities and the open questions as regards the toxicological properties of some of the metabolites, only a tentative risk assessment can be performed		

EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice.

4.6.4. Codex MRL proposals – propiconazole (Table 25)

Table 25: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of oranges, sweet, sour	**15Po**	0.01* (ft)	Critical GAP: USA, post-harvest GAP: 2 × 52.7 g a.s./100L (dip/drench), Number of trials: 16 (8 trials on oranges, 4 trials on mandarins and 4 trials on lemons). Sufficiently supported by data: Yes Specific comments/observations: For the post-harvest use, the MRL proposal should be calculated as mean + 4SD. Thus, a lower MRL of 10 mg/kg would be sufficient. The CF for risk assessment was derived from residue trials in cherries. The validity of this extrapolation is not questionable. No metabolism studies are available for post-harvest treatment. Conclusion: The proposed Codex MRL is not acceptable because it is too high. In addition, the residue trials do not provide information on the actual residue concentration compliant with the residue definition for risk assessment
Subgroup of mandarins	**15Po**	0.01* (ft)	Critical GAP: US post-harvest GAP: 2 × 52.7 g a.s./100L (dip/drench) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: See assessment for the subgroup of oranges. Conclusion: The proposed Codex MRL is not acceptable (see assessment for the sub-group of oranges)
Subgroup of lemons and limes (including citron)	**15Po**	0.01*	Critical GAP: US post-harvest GAP: 2 × 52.7 g a.s./100L (dip/drench) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: See assessment for the subgroup of oranges. Conclusion: The proposed Codex MRL is not acceptable (see assessment for the sub-group of oranges)
Subgroup of pummelo and grapefruits (including Shaddock-like hybrids)	**6Po**	0.01*	Critical GAP: US post-harvest GAP: 2 × 52.7 g a.s./100L (dip/drench) Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: For the post-harvest use, the MRL proposal should be calculated as mean + 4SD. Thus, a lower MRL of 4 mg/kg would be sufficient. The validity of extrapolation of CF from cherries to citrus is not questionable. No metabolism studies are available for post-harvest treatment. Conclusion: The proposed Codex MRL is not acceptable because it is too high. In addition, the residue trials do not provide information on the actual residue concentration compliant with the residue definition for risk assessment
Peach	**1.5Po**	0.01*	Critical GAP: US post-harvest GAP: 1 × 0.54 g a.s./1,000 kg (in-line aqueous/fruit-coating spray) Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Peaches are a category 3 crop for JMPR; therefore, at least 5 trials would be required. Considering that the GAP is a post-harvest use, a reduced data set may be sufficient, but 3 trials are considered insufficient. For the post-harvest use, the MRL proposal should be calculated as mean + 4SD. Thus, a lower MRL of 0.7 mg/kg would be sufficient. It is noted that the proposed MRL is approximately 3 times the application rate. Conclusion: The proposed Codex MRL is not acceptable as the number of residue trials is insufficient and the calculated MRL proposal is too high

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of cherries (includes all commodities in this subgroup)	**3Po**	0.01*	Critical GAP: US post-harvest GAP: 1 × 12.9 g a.s./100 L (in-line dip/drench). Number of trials: 5 Sufficiently supported by data: To be discussed. Specific comments/observations: Cherries are a major crop according the JMPR. Thus, additional residue trials would be required. However, considering that the GAP is a post-harvest use and that the residue trials gave a very homogeneous picture (0.67–1.4 mg/kg), the number of trials may be considered sufficient. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable as regards the number of residue trials
Subgroup of plum including prunes) (includes allcommodities in this subgroup)	**0.5Po**	0.01*	Critical GAP: US post-harvest GAP: 1 × 0.54 g a.s./1,000 kg (in-line aqueous/fruit-coating spray) Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: For the post-harvest use, the MRL proposal should be calculated as mean + 4SD. Thus, a lower MRL of 0.4 mg/kg would be sufficient. Conclusion: The proposed Codex MRL is not acceptable; a lower MRL of 0.4 mg/kg would be appropriate
Pineapple	**4Po**	0.02*	Critical GAP: US post-harvest GAP: 1 × 25.8 g a.s./100 L (drench) + 1 × 25.8 g a.s./100 L (directed peduncle spray). Number of trials: 4 Sufficiently supported by data: To be discussed Specific comments/observations: According the JMPR, pineapples are a category 3 crop, thus, at least 5 residue trials would be required. Considering that it is a post-harvest use and that the residue levels measured in the trials are all in the same range (0.92–1.2 mg/kg), 4 trials might be sufficient. For the post-harvest use, the MRL proposal should be calculated as mean + 4SD. Thus, a lower MRL of 2 mg/kg would be sufficient. It is noted that no metabolism studies are available for post-harvest treatment. Conclusion: The proposed Codex MRL is not acceptable; a lower MRL of 2 mg/kg would be appropriate. To be discussed with RM whether the number of trials is sufficient
Orange oil	2800		A single-processing study is available (PF 185)
Orange juice	None		A single-processing study is available (PF < 0.011)
Pineapple juice	none		A single-processing residue trial analysing for the total propiconazole residues was submitted. A PF < 0.12 was derived for pineapple pulp and for juice
General comments: No metabolism studies are available for post-harvest uses to derive conclusions on the nature of residues in the crops concerned. JMPR did not update the calculation of the dietary burden for livestock because it was assumed that post-harvest treated products are not fed to livestock. According to EFSAs view, this argument is not valid, since it cannot be excluded that citrus fruit pomace			

EU MRL: European Union maximum residue limit; GAP: Good Agricultural Practice; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.

4.6.5. Consumer risk assessment – propiconazole (Table 26)

Table 26: Summary of the consumer risk assessment for propiconazole:

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed for parent propiconazole for citrus fruits, cherries, peaches, plums and pineapples using the HR_{pulp} value for citrus fruit, the HR_{whole} fruit for peaches, cherries and plums and the HR-P for pineapple. The EU ARfD was used. The risk assessment is considered tentative, because of the difference of residue definitions established at EU level and by JMPR. Additional uncertainties in the risk assessment are resulting from the lack of data on the residue concentration compliant with the residue definition for risk assessment for citrus and the lack of information on the possible impact of plant and livestock metabolism on the isomer ratio of propiconazole	**RA assumptions:** The most recent long-term risk assessment for parent propiconazole (EFSA, 2015a) was updated using the approach as outlined in Section 'Assessment', including the $STMR_{pulp}$ values derived by JMPR for citrus fruits, the $STMR_{whole\ fruit}$ cherries, peaches, plums and the STMR-P for pineapple. The EU ADI was used. The risk assessment is considered tentative, because of the difference of residue definitions established at EU level and by JMPR	**Specific comments** –
Results: No short-term exposure concern was identified (57% of the ARfD for oranges) in the tentative risk assessment.	**Results:** No long-term consumer health risk was identified in the tentative risk assessment. The overall chronic exposure accounted for 14.6% of the ADI (WHO Cluster diet B)	**Results:** Long-term exposure: 0.8–6.4% of the ADI Short-term exposure: 0–10% of the ARfD (children)

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; HR: highest residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue.

4.7. Abamectin (177) (T)

4.7.1. Background information (Table 27)

Table 27: Background information on abamectin

		Comments, references
Type of JMPR evaluation	Other evaluation, see comment	Assessment of new studies and published papers regarding the toxicological properties of abamectin.
RMS	AT	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 2017/438[(a)]
EFSA conclusion	Yes, see comments	EFSA (2008b) EFSA (2016j) • EFSA conclusions ongoing (AIR IV)
MRL review	Yes, see comments	EFSA (2014n)
MRL applications	Yes, see comments	EFSA (2017j) (banana) EFSA (2015i) (various crop) • Citrus (Additional data request) • celery and fennel (Additional data request)

MRL: maximum residue limit.

(a): 2017/438/EU: Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance abamectin. OJ L 67, 14.3.2017, p. 67–69.

4.7.2. Toxicological reference values – abamectin (Table 28)

Table 28: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.001 mg/kg bw per day	JMPR 2016 (developmental neurotoxicity in rats)	0.0025 mg/kg bw per day	EFSA (2008b) (18- and 53-wk dog study UF 100)	No
ARfD	0.003 mg/kg bw	JMPR 2016 (first week of treatment in dog studies)	0.005 mg/kg bw	EFSA (2008b) (acute neurotoxicity rat UF 100)	No
Conclusion/ comment	The toxicological reference values derived by JMPR are lower than the ones derived at EU level. It is noted that the ADI/ARfD of JMPR applies also to the 8,9-Z-isomer and the 24-hydroxymethyl metabolite of abamectin. The developmental neurotoxicity study in rats was not peer reviewed by EFSA (2008b). EFSA would consider appropriate to use this study as a point of departure for setting the ADI. The use of the dog studies for setting the ARfD would also be consider appropriate since the effects described by JMPR were observed during the first week of treatment. Regarding metabolites, EFSA (2008b) also concluded that 8,9-Z-isomer showed a similar profile to abamectin. EFSA (2008b) did not discuss the toxicological profile of 24-hydroxymethyl metabolite of abamectin; however, being a major rat metabolite as described by JMPR, EFSA would support the view that it could be considered covered by parent, and then, the reference values of abamectin would apply to this metabolite				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

4.7.3. Residue definitions – abamectin (Table 29)

Table 29: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Avermectin B1a	Reg. 396/2005: Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) Peer review: Sum of avermectin B1a, avermectin B1a 8,9-Z isomer, and avermectin B1b, expressed as avermectin B1a	No
	Animal products	Avermectin B1a The residue is fat soluble	EU Reg. 396/2005: Abamectin B1a Peer review: Not necessary – covered by legal provisions in force for abamectin from veterinary uses The residue is fat soluble	Yes
RD RA	Plant products	Avermectin B1a	Sum of avermectin B1a, avermectin B1a 8,9-Z isomer, and avermectin B1b, expressed as avermectin B1a	No
	Animal products	Avermectin B1a	Not necessary – covered by legal provisions in force for abamectin from veterinary uses	No
Conclusion/ comments	The residue definitions for plant products derived by JMPR and at EU level are not fully compatible			

EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.7.4. Codex MRL proposals – abamectin

No Codex MRL proposals.

4.7.5. Consumer risk assessment – abamectin

Not relevant.

4.8. Fenpropimorph (188) (R/T)

4.8.1. Background information (Table 30)

Table 30: Background information on fenpropimorph

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	LV	
Approval status	Approved	Commission Implementing Regulation No 2008/107/EC[(a)]
EFSA conclusion	Yes, see comments	EFSA (2008c)
MRL review	Yes, see comments	EFSA (2015f)
MRL applications	No	None open

MRL: maximum residue limit.
(a): 2008/107/EC: 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.

4.8.2. Toxicological reference values – fenpropimorph (Table 31)

Table 31: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.004 mg/kg bw per day	JMPR 2016	0.003 mg/kg bw per day	EFSA (2008c) (Rat, 2-year, with uncertainty factor of 100)	No
ARfD	0.1 mg/kg bw (women of childbearing age) 0.4 mg/kg bw (General population)	JMPR 2016	0.03 mg/kg bw	EFSA (2008c) (Rabbit, developmental, with uncertainty factor of 500)	No
Conclusion/ comment	EFSA comments on the toxicological reference values were provided in the EFSA CCPR Report, (2017h) Metabolite BF 421-2: no information on the toxicological profile of this metabolite is reported in the toxicological evaluation of fenpropimorph (FAO, 2016). Metabolite BF 421-10 (cis-2,6-dimethylmorpholine), a major metabolite in rats and in plants, was tested in an adequate range of *in vitro* and *in vivo* genotoxicity tests. No evidence of genotoxicity was found				

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

4.8.3. Residue definitions – fenpropimorph (Table 32)

Table 32: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fenpropimorph	Fenpropimorph (sum of isomers)	Yes
	Animal products	Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2), expressed as fenpropimorph (p. 161 of JMPR report) or 2-methyl-2-{4-[2-methyl-3-(cis-2,6-dimethylmorpholin-4-yl) propyl]phenyl} propionic acid (p. 431 of JMPR report) The residue is not fat soluble	Reg. 396/2005: Fenpropimorph carboxylic acid (BF 421-2) expressed as fenpropimorph MRL review: Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2), expressed as fenpropimorph (sum of isomers) The residue is fat soluble	No
RD RA	Plant products	Sum of fenpropimorph, BF421-1 (free and conjugated) and BF421-10, expressed as fenpropimorph (p. 161 of JMPR report) Fenpropimorph (p. 431 of JMPR report, Annex 1)	Sum of fenpropimorph, fenpropimorph alcohol (BF 421-1, free and conjugated) and 2,6-dimethylmorpholine (BF 421-10), expressed as fenpropimorph (sum of isomers)	Yes
	Animal products	Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2), expressed as fenpropimorph (p. 161 of JMPR report) or 2-methyl-2-{4-[2-methyl-3-(cis-2,6-dimethylmorpholin-4-yl) propyl]phenyl} propionic acid (p. 461 of JMPR report, Annex 1)	Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2), expressed as fenpropimorph (sum of isomers)	Yes
Conclusion/ comments	It is noted that different RDs were reported in the JMPR report (body text, p. 161) and in the Annex 1 of JMPR summary report (p. 431). It is assumed that the RDs reported on p. 161 are the correct ones. However, confirmation by JMPR would be desirable. Parent fenpropimorph is included in the residue definition for animals (in addition to BF 421-2). However, the parent compound was not found in any animal tissues and milk of ruminants. Thus, the different RD for animal products (enforcement) would not have a major impact. For poultry, parent fenpropimorph was found in metabolism studies			

EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice.

4.8.4. Codex MRL proposals – fenpropimorph (Table 33)

Table 33: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Banana (unbagged)	**2**	0.6	Critical GAP: Colombia, up to 0.6 kg a.s./ha, PHI: 0 day, number of applications and interval between applications not specified. Number of trials: 18 Sufficiently supported by data: Yes Specific comments/observations: Trials in unbagged banana were used to derive the MRL proposal. The samples have not been analysed for the full RD RA, but instead a CF of 1 was derived from the metabolism study. For 11 trials on unbagged banana, fenpropimorph residues were analysed in the pulp ranging from < 0.05 to 0.43 mg/kg. For bagged banana, residues in pulp were lower and ranged from < 0.05 to 0.2 mg/kg, but the individual residue values were not provided in the JMPR report. Conclusion: An acute intake concern was identified when the EU ARfD is used (120% of the ARfD, details see below). The proposed Codex MRL is not acceptable due to intake concerns
Barley	0.2	0.4	Critical GAP: Belgium: 2 × 0.75 kg a.s./ha, PHI: 28 days. Number of trials: 15 trials (performed in Belgium and Brazil) Sufficiently supported by data: Yes Specific comments/observations: The samples have not been analysed for the RD RA, but instead, a CF of 1.7. In the EU assessment, a CF of 1 was derived. The EU MRL was derived for a slightly more critical Swedish GAP (NEU, 2× 0.75 kg, PHI 35 days). Conclusion: The proposed Codex MRL is acceptable. The manufacturer should be encouraged to submit the critical EU GAP to JMPR
Barley straw and fodder, dry	0.5		The residue data sets on barley and wheat straw were merged to derive the MRL proposal. Overall, 16 residue trials were available
Edible offal (mammalian)	**0.7**	0.3 in swine for the rest is 3 Kidney: 0.5 except swine 0.05 Liver: 3 except swine is 0.3	Critical DB was identified for the Australian diet. An acceptable cow-feeding study dosed with fenpropimorph and BF 421-2 at dosing levels of 2, 6 and 20 mg/kg DM and covering therefore the estimated maximum dietary burden, i.e. 2.7 mg/kg DM for beef and dairy, cattle was assessed. Conclusion: Although the residue definitions derived at EU level and by Codex, the proposed MRL are different, the MRL might be acceptable, considering the fact that in metabolism studies in ruminants' parent fenpropimorph was not found
Eggs	0.005*	0.01*	Critical DB for EU diet (layers). The proposed Codex MRLs were derived from the poultry metabolism study. Conclusion: The proposed Codex MRL is acceptable. The different residue definition is of no relevance, since the existing EU MRL is higher
Kidney of cattle, goats, pigs and sheep	W 0.05	All 0.5 except pigs: 0.05	The previous CXL is withdrawn
Liver of cattle, goats, pigs and sheep	W 0.3	All 3 except pig with 0.3	The previous CXL is withdrawn
Mammalian fats (except milk fats)	0.05	All 0.2 except pig with 0.01*	Conclusion: The proposed Codex MRL is acceptable. The different residue definition is of no relevance, since the existing EU MRL is higher

Commodity	Codex MRL proposal	EU MRL	Comment
Meat (from mammals other than marine mammals)	0.04	All 0.15 except pig with 0.02	Conclusion: The proposed Codex MRL is acceptable. The different residue definition is of minor relevance, since the existing EU MRL is higher and the parent compound included in the EU RD is unlikely to occur
Milks	0.01	0.015	Conclusion: The proposed Codex MRL is acceptable. The different residue definition is of minor relevance, since the existing EU MRL is higher and the parent compound included in the EU RD is unlikely to occur
Oats	0.2	0.4	Critical GAP: Not provided. The Codex MRL proposal was derived by extrapolation from the residue data set on barley. Conclusion: The proposed Codex MRL is acceptable.
Oats straw and fodder, dry	0.5		Extrapolation from the combined residue data sets on barley and wheat straw
Poultry fats	0.005*	0.01*	A poultry feeding study is not available and not required since based on the poultry metabolism study and at the estimated maximum dietary burden (0.25 mg/kg DM), residues of fenpropimorph and BF 421-2 are expected to be below the LOQ of the method. Conclusion: The proposed Codex MRL is acceptable. The different residue definition is of no relevance, since the existing EU MRL is higher
Poultry meat	0.005*	0.01*	The proposed Codex MRL was derived from a poultry metabolism study which covers the calculated dietary burden (0.25 mg/kg DM); residues of fenpropimorph and BF 421-2 are expected to be below the LOQ of the method. Conclusion: The proposed Codex MRL is acceptable. It is noted that in the EU MRLs are established for poultry muscle, instead of meat. The different residue definition is of no relevance, since the existing EU MRL is higher
Poultry, edible offal of	0.005*	0.01*	The proposed Codex MRL was derived from a poultry feeding study which covers the calculated dietary burden (0.25 mg/kg DM); residues of fenpropimorph and BF 421-2 are expected to be below the LOQ of the method. Conclusion: The proposed Codex MRL is acceptable. The different residue definition is of no relevance, since the existing EU MRL is higher
Rye	0.07	0.15	Critical GAP: Not reported Specific comments/observations: The Codex MRL proposal was derived by extrapolation from wheat. Conclusion: The proposed Codex MRL is acceptable
Rye straw and fodder, dry	0.5		Extrapolation from the combined residue data sets on barley and wheat straw
Sugar beet	0.03	0.01*	Critical GAP: Poland: 1 × 0.25 kg a.s./ha, BBCH 39-49; PHI: 35 days. Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The proportionality approach was applied to the submitted residue trials that were performed at an application rate of 0.75 kg a.s./ha. It is noted that only the residues of fenpropimorph have been analysed for. A CF of 1.3 was derived by JMPR for the dietary intake assessment. It is noted that in the Art. 12 MRL review, a tentative MRL proposal of 0.15 mg/kg was derived (4 overdosed trial from NEU, no scaling applied). However, this MRL has not been taken over in the EU MRL legislation. Conclusion: The proposed Codex MRL is acceptable.

Commodity	Codex MRL proposal	EU MRL	Comment
Fodder beet leaves or tops	W1		JMPR proposed the withdrawal of 1 mg/kg on fodder beet leaves and tops since this is a commodity that is not traded. It is noted that residue trials were provided; the results were used for the dietary burden calculation
Sugar beet pulp, dry	0.1		2 processing trials, CF for residue definition 1.3
Triticale	0.07	0.15 (wheat)	Extrapolation from wheat. See comments on wheat.
Triticale straw and fodder, dry	0.5		Extrapolation from the combined residue data sets on barley and wheat straw provided the same use patterns on barley, wheat and triticale
Wheat	0.07	0.15	Critical GAP: BE, 2 × 0.75 kg a.s./ha, PHI: 28 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: 7 residue trials conducted in Europe have been submitted. As a major crop in the NEU zone, one additional trial compliant with the BE GAP is in principle required. The existing EU MRL was derived for a slightly more critical GAP (SE, 2 × 0.75 kg/ha, PHI 35 days) Conclusion: The proposed Codex MRL might be considered acceptable although one additional trial would be required. The manufacturer should be encouraged to submit the critical EU GAP to JMPR
Wheat bran, unprocessed	0.2		3 processing trials, PF 2.9, CF for residue definition 1.7
Wheat germ	0.3		2 processing trials, PF 3.3, CF for residue definition 1.7
Wheat straw and fodder, dry	0.5		See barley straw
Wheat wholemeal	0.1		3 processing trials, PF 1.4, CF for residue definition 1.7
Beer	none		4 processing trials, PF 0.004, CF for residue definition 1.7
Pot Barley	none		4 processing trials, PF 0.9, CF for residue definition 1.7
Barley flour	none		2 processing trials, PF 2.5 CF for residue definition 1.7
Wheat flour	none		3 processing trials, PF 0.35, CF for residue definition 1.7
Oat flakes	none		3 processing trials, PF 0.8, CF for residue definition 1.7
Sugar beet molasses	none		2 processing trials, PF 0.05, CF for residue definition 1.3
Sugar, refined	none		2 processing trials, PF 0.05, CF for residue definition 1.3

PHI: preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; ADI: acceptable daily intake; ARfD: acute reference dose; PF: processing factor; CF: conversion factor; GAP: Good Agricultural Practice; LOQ: limit of quantification; CXL: Codex Maximum Residue Limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.8.5. Consumer risk assessment – fenpropimorph (Table 34)

Table 34: Summary of the consumer risk assessment for fenpropimorph

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for banana, barley and oats grain, wheat and rye grain, sugar beet, animal tissues, milk and eggs as outlined in Section 2. For bananas, the calculation was based on the HR of 0.43 mg/kg measured in the unbagged bananas (pulp).The EU ARfD was used	**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 banana, barley and oats grain, wheat and rye grain, sugar beet, animal tissues, milk and eggs	**Specific comments** The overall assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of fenpropimorph
Results: An exceedance of the ARfD was identified for banana, representing 120% of the ARfD.	**Results:** No long-term consumer health risk was identified.The overall chronic exposure accounted for 33.4% of the ADI (UK toddler).	**Results:** Long-term exposure: 1–10% of the ADI Short-term exposure: 0–5% of the ARfD (women of childbearing age) 0–9% of the ARfD (General population)

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

4.9. Tebuconazole (189) (R)

4.9.1. Background information (Table 35)

Table 35: Background information on tebuconazole

		Comments, references
Type of JMPR evaluation	New use	
RMS	UK	
Approval status	Approval process ongoing	
EFSA conclusion	Yes, see comments	EFSA (2008d) EFSA (2014a) (amendment of the approval conditions) • EFSA conclusions ongoing (AIR IV)
MRL review	Yes, see comments	EFSA (2011e)
MRL applications	Yes, see comments	EFSA (2017e) (beans with pods) EFSA (2015l) (rye and wheat) EFSA (2015c) (cucumbers and courgettes) • In progress olives • In progress herbal infusion and fresh herbs • Under consideration in rice

MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.9.2. Toxicological reference values – tebuconazole (Table 36)

Table 36: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
Tebuconazole					
ADI	0.03 mg/kg bw per day	JMPR, 2010(Two dog 1-year toxicity studies, SF 100)	0.03 mg/kg bw per day	EFSA (2008d) (1-year dog supported by developmental mouse study, LOAEL with UF of 100 (dog) and 300 (mouse))	Yes
ARfD	0.3 mg/kg bw	JMPR, 2010 (Developmental rat and rabbit studies, supported by a rat 28-day study (gavage), SF 100)	0.03 mg/kg bw	EFSA (2008d) (Developmental mouse study, LOAEL with UF of 300)	No
Conclusion/ comment	While the ADI values derived by JMPR and at EU level are identical, the EU ARfD is 10 times lower. At EU level, TRVs were also derived for the triazole-derivative metabolites (TDMs) 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid to be used in consumer risk assessments for this class of compounds. However, the residues assessment for the triazole-derivative metabolites has been discussed at the expert meeting in December 2017 and a final EFSA conclusion and a final EU agreed approach to the consumer risk assessments for all triazole pesticides have not yet been agreed. Thus, at this time, the TDMs should not have an impact on the MRLs for any triazole pesticide				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

4.9.3. Residue definitions – tebuconazole (Table 37)

Table 37: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Tebuconazole	Reg. 396/2005: Tebuconazole	Yes
			Peer review: Sum of enantiomers contained in tebuconazole (EFSA, 2014a)	
	Animal products	Tebuconazole The residue is not fat soluble	Reg. 396/2005: Sum of tebuconazole, hydroxy-tebuconazole and their conjugates, expressed as tebuconazole Tebuconazole + hydroxy-tebuconazole and their conjugates (sum of enantiomers) expressed as tebuconazole (provisional) (EFSA, 2014a) The residue is not fat soluble	No
RD RA	Plant products	Tebuconazole	1. Sum of enantiomers contained in tebuconazole	Yes
			2. TDMs, harmonised for all active substances of the triazole chemical class (provisional)	No
	Animal products	Tebuconazole	1. Tebuconazole + hydroxy-tebuconazole and their conjugates (sum of enantiomers) expressed as tebuconazole (provisional)	No
			2. TDMs (harmonised for all active substances of the triazole chemical class, provisional)	

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion/ comments	Plant commodities: JMPR derived the residue definition for enforcement and for risk assessment as tebuconazole. At EU level, the residue definitions for plant commodities is similar, covering parent tebuconazole (sum of enantiomers). In addition, TDMs were proposed for inclusion in a separate residue definition for risk assessment, pending the outcome of a global risk assessment approach. The residue assessment for the TDMs was discussed recently in an expert meeting (December 2017). The final EFSA conclusion is not yet published. Animal commodities: JMPR derived the residue definition for enforcement and for risk assessment as tebuconazole, while the EU residue definition for enforcement and for risk assessment includes the metabolite hydroxy-tebuconazole and conjugated forms. Since this year, only Codex MRL proposals for plant commodities are discussed; the difference for the residue definition for animal commodities is not relevant. A separate residue definition for risk assessment covering the TDMs was proposed in the EU for animal products as well. Data on the preferential degradation and/or conversion of the two enantiomers of racemic mixture of tebuconazole in residues and the potential impact on the consumer risk assessment are not available to EFSA and have not been mentioned by JMPR. Conclusion: For the Codex MRL proposal on beans with pods, the difference in the wording of the residue definition for products of plant origin are of no relevance. The methods of analysis used to enforce residues were not reported to be stereoselective.			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.9.4. Codex MRL proposals – tebuconazole (Table 38)

Table 38: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of beans with pods (includes all commodities in this subgroup)	**3**	2 (+)/ (3)[(a)]	Critical GAP: Foliar, 3 × 200 g/ha, interval 7–21 days, PHI 7 days (Kenya), already assessed by EFSA (import tolerance request) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Based on the same set of trials EFSA derived a MRL proposal of 3 mg/kg (EFSA, 2017e). Conclusion: The proposed Codex MRL is acceptable
Common bean (pods and/or immature seeds)	W 2		Existing CXL was proposed to be withdrawn

CXL: Codex Maximum Residue Limit; EU MRL: European Union maximum residue limit.
(+) The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 25 January 2016, or, if that information is not submitted by that date, the lack of it.
(a): The MRL of 3 mg/kg proposed recently by EFSA (EFSA, 2017e) has not yet been presented and voted at PAFF meeting.

4.9.5. Consumer risk assessment – tebuconazole (Table 39)

Table 39: Summary of the consumer risk assessment for tebuconazole

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Tebuconazole: The short-term dietary risk assessment recently performed (EFSA, 2017e) already took into account the reported use on beans with pods in Kenya. The EU ARfD was used and no change in isomer ratio (1:1) in the final residues is assumed. Updated using the HR of 1.9 mg/kg. TDMs: Separate consumer risk assessment not conducted	**RA assumptions:** Tebuconazole: The long-term risk assessment for tebuconazole recently performed (EFSA, 2017e) took into account the reported use on beans with pods in Kenya, the authorised EU uses and the acceptable CXLs. It assumed no change in isomer ratio (1:1) in the final residues. Update not necessary. TDMs: Separate consumer risk assessment not conducted	**Specific comments** JMPR used the HR of 1.9 mg/kg for the risk assessment. EFSA selected the mean (1.5 mg/kg) from two replicates (1.9 and 1.1 mg/kg, PHI 7 days). This different approach in selecting the HR explains why the risk assessment performed in 2017 by EFSA lead to a slightly different result
Results: Tebuconazole: No short-term exposure concern was identified (72% of ARfD) The risk assessment is affected by a non-standard uncertainty related to the lack of information on the possible preferential metabolism of one isomer over another	**Results:** Tebuconazole: No long-term consumer health risk was identified. Overall long-term exposure accounted for 3–16% of the ADI. The contribution of beans with pods to the exposure was 1.18% of the ADI	**Results:** Long-term exposure: 2–9% of the ADI. Short-term exposure: 5% and 9% of the ARfD (0.3 mg/kg bw) for the general population and for children, respectively

ADI: acceptable daily intake; ARfD: acute reference dose; CXL: Codex Maximum Residue Limit; HR: highest residue.

4.10. Fenpyroximate (193) (R/T)

4.10.1. Background information (Table 40)

Table 40: Background information on fenpyroximate

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	AT	
Approval status	Renewal of the approval	Commission Directive 2008/107/EC[(a)] (approval) Commission Regulation (EU) 2016/183 (renewal)
EFSA conclusion	Yes, see comments	EFSA (2008e) EFSA (2013j) (amendment approval and confirmatory data) • EFSA conclusion ongoing (AIR IV)
MRL review	Yes, see comments	EFSA (2015o)
MRL applications	No	

(a): 2008/107/EC: 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.

4.10.2. Toxicological reference values – fenpyroximate (Table 41)

Table 41: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.01 mg/kg bw per day	JMPR 2017; Rat, 2-year study	0.01 mg/kg bw per day	EFSA (2013j); Rat, 2-year study	Yes
ARfD	0.01 mg/kg bw	JMPR 2017; Dog, 1-day and 13-week studies	0.02 mg/kg bw	EFSA (2013j); Dog, 1- and 5-day study	No
Conclusion/ comment	For the derivation of the ADI, JMPR considered the NOAEL of 1 mg/kg bw per day in the 2-year rat study and applying a safety factor of 100. The same derivation was adopted at EU level. For the derivation of the ARfD, JMPR considered the induction of diarrhoea seen in a newly submitted single bolus gavage study and in a 13-week study with dogs. An increased safety factor of 200 was applied since no NOAEL was identified in these studies. For the EU evaluation, it is not clear if the same data were available since a newly submitted single bolus gavage study is mentioned in JMPR 2017, and the agreed ARfD of 0.02 mg/kg bw was based (as in JMPR, 2007) on a NOAEL of 2 mg/kg bw in an acute toxicity study with dogs (1–5 days), where increased incidences of diarrhoea were observed at 5 mg/kg bw per day (and applying an UF of 100). For the metabolites, JMPR concluded that M-1, M-3, M-5, M-21, M-22 and Fen-OH would be covered by the reference values of the parent compound since these metabolites were also detected in rats at significant levels. During the EU evaluation, the metabolites M-1 and M-12 were concluded of equal or lower toxicity than the parent compound				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union; NOAEL: no observed adverse effect level.

4.10.3. Residue definitions – fenpyroximate (Table 42)

Table 42: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fenpyroximate	Reg. 396/2005: Fenpyroximate Peer review: Fenpyroximate (fruit crops, pulses and oilseeds, only)	Yes
	Animal products	Sum of fenpyroximate, 2-hydroxymethyl-2-propyl (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methylenaminooxymethyl] benzoate (Fen-OH), and (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl) methyleneaminooxymethyl] benzoic acid (M-3), expressed as fenpyroximate The residue is fat soluble	Reg. 396/2005: Fenpyroximate for all animal products, except liver and kidney of ruminants: Liver and kidney of ruminants: metabolite M-3 Peer review: Metabolite M-3 expressed as fenpyroximate The residue is fat soluble	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Sum of parent fenpyroximate and its tert-butyl (*Z*)-α-(1,3-dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-p-toluate (its Z-isomer, M-1), expressed as fenpyroximate	Sum of fenpyroximate and its Z-isomer, expressed as fenpyroximate (fruit crops, pulses and oilseeds, only)	Yes
	Animal products	Sum of fenpyroximate, 2-hydroxymethyl-2-propyl (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methylenaminooxymethyl] benzoate(Fen-OH), (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl) methyleneaminooxymethyl] benzoic acid(M-3), and (E)-4-{[(1,3-dimethyl-5-(4-hydroxyphenoxy)pyrazol-4-yl] methyleneaminooxymethyl} benzoic acid (M-5, free and its conjugates), expressed as fenpyroximate	Sum of fenpyroximate, Fen-OH, M-3 and their Z-isomers (M-1), expressed as fenpyroximate	No
Conclusion/ comments	**Plant:** Residue definitions for enforcement and risk assessment in plant commodities are comparable. Additional metabolism studies with fenpyroximate following foliar application to citrus, apples, grapes, snaps beans, cotton and Swiss chard were evaluated by the JMPR. These studies allowed deriving a general residue definition. **Animal:** RD enf: Fen-OH is not included in the residue definition for enforcement established at EU level. However, according to the results of the metabolism and livestock-feeding studies, at the calculated dietary burden, residues in livestock are mainly driven by metabolite M03 (liver and kidney) and fenpyroximate (fat). Therefore, the difference in the residue definitions for enforcement in animal commodities can be considered as minor. RD RA: Regarding the residue definition for risk assessment, metabolite M5 (free and its conjugates) is not included in the residue definition established in EU. It is noted that in the livestock-feeding studies assessed by JMPR, M5 was not analysed in animal tissues and milk. According to the information available in the JMPR report, a conversion factor from enforcement to risk assessment was not derived to consider the exposure to this metabolite. Therefore, apparently the input values used by the JMPR for the risk assessment seem to consider only the levels of fenpyroximate, Fen-OH and M-3, which is in line with the EU residue definition. JMPR should be asked for clarifications as regards the metabolite M-5 and its conjugates		

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.10.4. Codex MRL proposals – fenpyroximate (Table 43)

Table 43: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Apple	0.2	0.3 (ft)	Critical GAP: Belgium (1 × 76.5 g/ha, PHI: 7 days). Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: Results from overdosed residue trials were scaled down according to the proportionality principle. A different GAP was assessed in the EU Article 12 review (102 g/ha; PHI: 21 days). However, the existing EU MRL was based on the old Codex MRL which is now proposed to be withdrawn.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is acceptable. The existing EU MRL should be lowered, since the old Codex MRL will be withdrawn
Avocado	**0.2**	0.01*	Critical GAP: USA, 2 × 117 g/ha; PHI: 1 day Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
Pear	0.2	0.3 (ft)	Critical GAP: USA, 1 × 117 g/ha; PHI: 14 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: combined data set of trials compliant with GAP and overdosed trials. Results from overdosed residue trials were scaled down according to the proportionality principle. An acute intake concern was noted in the risk assessment performed with the JMPR ARfD Conclusion: To discuss with MS whether the proposed Codex MRL is acceptable
Subgroup of cherries (includes all commodities in this subgroup)[(a)]	2	2 (ft) (cherry)	Critical GAP: USA, 2 × 117 g/ha; PHI: 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is sufficiently supported by data. However, an acute intake concern was identified by JMPR for German and Danish children. Using the EU ARfD, no intake concern was identified by EFSA.
Peach	**0.4**	0.3 (ft)	Critical GAP: USA, 2 × 117 g/ha; PHI: 7 days Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: an acute intake concern has been identified by the JMPR (130%) when considering the most critical GAP. An alternative GAP was not available. Conclusion: The proposed Codex MRL is sufficiently supported by data. However, an acute intake concern was identified by JMPR for Japanese and Canadian children. Using the EU ARfD, no intake concern was identified by EFSA.
Apricot	**0.4**	0.3 (ft)	Critical GAP: USA, 2 x 117 g/ha; PHI: 7 days Number of trials: 10 trials on peaches Sufficiently supported by data: No Specific comments/observations: all trials were performed on peaches. According to the current EU guidelines, the extrapolation from peaches to apricots is not possible. According to the JMPR extrapolation rules, trials on peaches can be used to derive an MRL for apricots. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Subgroup of plums (including fresh prunes) (includes all commodities in this subgroup)	**0.8**	0.1 (ft)	Critical GAP: USA, 2 x 117 g/ha; PHI: 7 days Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: According to the current EU guidelines, being plums a major crop, the number of trials is not sufficient to derive an MRL. In Codex, plums are classified as a major crop, for which refinement criteria applied.

Commodity	Codex MRL proposal	EU MRL	Comment
			An acute intake concern has been identified by the JMPR (270%) when considering residues in dried plums. Thus, the MRL for fresh plums would not be acceptable either. Conclusion: The proposed Codex MRL is not acceptable because it is not sufficiently supported by data. In addition, an intake concern was identified by JMPR for Australian children for processed plums. No intake concern for EU population using the EU ARfD; with the lower ARfD of JMPR, an intake concern was identified for children
Group of citrus fruit (includes all commodities in this group)	**0.6**	0.5 (ft) 0.01* for kumquats	Critical GAP: USA, 2 x 235 g/ha; PHI: 14 days Number of trials: 16 Sufficiently supported by data: No Specific comments/observations: combined data set on oranges (8), lemons (4) and grapefruits (4), extrapolation to the whole group of citrus fruits. According to the current EU guidelines, the proposed extrapolation is not fully supported by data (4 additional trials on lemons and/or mandarins would be needed). JMPR reported that trials on tangor, satsuma, Chinese citron and natsudaidai show that residues in flesh were 13% of that fruit are mentioned by the JMPR. The HR and STMR measured in the whole fruit were recalculated to an HR-P and STMR-P using this peeling factor of 13%. It is noted that the trials used for deriving the peeling factor are not compliant with the GAP (only 1 application of 250 g/hg). Overall, it seems that the residues in the pulp are lower, but the calculation of the peeling factor is not presented in sufficiently transparent way to verify the validity. Conclusion: The proposed Codex MRL is not acceptable because it is not sufficiently supported by data and because of possible intake concerns
Grapes	0.1	0.3 (ft) for wine and table	Critical GAP: ES, 1 x 50 g/ha; PHI: 28 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: The EU MRL was derived from NEU trials compliant with the DE GAP (1 × 123 g/ha, PHI 35 days). Conclusion: The proposed Codex MRL is acceptable
Strawberries	0.3	0.3 (ft)	Critical GAP: DE and AT, 1 x 102 g/ha; PHI: 7 days Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The EU MRL is based on the same GAP; JMPR had 8 additional trials that were not provided in the EU. Conclusion: The proposed Codex MRL is acceptable
Raspberry	0.2	1.5 (ft)	Critical GAP: AT, 1 × 76.5 g/ha; PHI: 14 days. Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: The same GAP was assessed in the article 12 review. A smaller data set was available to JMPR compared to the article 12 review (4 vs. 8). In the EU, trials not analysed for the Z-isomers were also considered. Conclusion: The proposed Codex MRL is acceptable
Cucumber	**0.3**	0.08 (ft)	Critical GAP: USA, 2 x 117 g/ha; PHI: 1 day Number of trials: 7 Sufficiently supported by data: No

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: according to the current EU guidelines and the Codex rules, being cucumbers a major crop, the number of trials is not sufficient to derive an MRL. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. It is noted that using the lower ARfD of JMPR, an intake concern was identified for the EU
Squash, summer	0.06	0.08 (ft)	Critical GAP: DE, 1 × 46–92 g/ha, PHI: 3 days. Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: The trials reflect the highest application rate (92 g/ha (± 25%)). It is not specified if the trials were performed indoor or outdoor. Conclusion: The proposed Codex MRL is acceptable
Melons, except watermelon,	**0.2**	0.01*	Critical GAP: USA, 2 × 117 g/ha; PHI: 3 days (in cantaloupe) Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: combined data set with trials on melons (4, performed with one application) and cantaloupe (8, compliant with GAP) used to derive the Codex MRL proposal. Based on the 8 trials in cantaloupe that matched the GAP, a MRL proposal of 0.05 mg/kg would be derived.Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/ compatible with the EU policy on setting MRLs. Using the lower ARfD derived by JMPR, an acute intake concern was noted for the EU
Watermelon	**0.05**	0.01*	Critical GAP: USA, 2 × 117 g/ha; PHI: 3 days. Number of trials: 4 Sufficiently supported by data: No Specific comments/observations: The trials were performed with 2 x 110 g/ha; PHI: 1 day. According to the current EU guidelines and the Codex rules, being watermelon a major crop, the number of trials is not sufficient to derive an MRL. An acute intake concern has been identified by the JMPR (190%). An alternative GAP was not available. Conclusion: The proposed Codex MRL is not acceptable because the number of trials is not sufficient and the trials do not match the critical GAP; in addition, it is noted that acute intake concerns were identified by JMPR and by EFSA (only when using the lower ARfD of JMPR).
Subgroup of peppers (except martynia, okra and roselle)	0.2	0.3 (ft)	Critical GAP: USA, 2 × 117 g/ha; PHI: 1 day Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: It seems that the residue trials used to derive the MRL proposal were not analysed for the metabolite M-1. Thus, the HR and STMR values are likely to underestimate the total residues (sum of fenpyroximate and M-1). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of eggplants (includes all commodities in this subgroup)	**0.3**	0.2 (ft)	Critical GAP: USA, 2 × 117 g/ha; PHI: 1 day. Number of trials: 19 Sufficiently supported by data: Yes Specific comments/observations: data extrapolated from tomato. Conclusion: The proposed Codex MRL is acceptable
Tomato	**0.3**	0.2 (ft)	Critical GAP: USA, 2 × 117 g/ha; PHI: 1 day. Number of trials: 19 Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL derived is expected to cover both tomatoes and cherries tomatoes. Apparently, no trials on cherry tomatoes were available. An acute intake concern has been identified by the JMPR (310%) in tomato dried. An alternative GAP was not available. Conclusion: The proposed Codex MRL is not acceptable because of intake concerns for dried tomatoes
Cherry tomato	**0.3**	0.2 (ft) (tomato)	Critical GAP: USA, 2 × 117 g/ha; PHI: 1 day. Number of trials: 19 Sufficiently supported by data: Yes See tomatoes
Subgroup of beans with pods (includes all commodities in this subgroup)	0.5	0.7 (ft)	Critical GAP: ES, 1 × 102 g/ha; PHI: 7 days. Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The same GAP was assessed in the article 12 review. A larger data set was available to JMPR compared to the article 12 review (16 vs. 8). Conclusion: The proposed Codex MRL is acceptable
Potato	**0.05***	0.01*	Critical GAP: USA, 2 × 117 g/ha, PHI: 7 days. Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: trials on potato tuber compliant with GAP. Conclusion: The proposed Codex MRL is acceptable
Maize	0.01*	0.01*	Critical GAP: USA, 2 × 117 g/ha; PHI: 14 days. Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: The trials on maize grain are compliant with the GAP. Conclusion: The proposed Codex MRL is acceptable
Tree nut	**0.05***	0.01* all tree nuts except almonds 0.05* (ft)	Critical GAP: USA, 2 × 117 g/ha; PHI: 14 days.Number of trials: 13 Sufficiently supported by data: Yes Specific comments/observations: trials on almond (5), pecan (5) and walnut (3) performed with exaggerated rate (450 g/ha; PHI: 14 days). Conclusion: The proposed Codex MRL is acceptable
Coffee beans	**0.07**	0.05*	Critical GAP: BR, 2 × 50–100 g/ha: PHI: 15 days. Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The samples of the supervised trials were analysed only for the parent compound. Thus, the STMR/HR values may be underestimated. Conclusion: To be verified if the proposed Codex MRL is acceptable.

Commodity	Codex MRL proposal	EU MRL	Comment
Hops, dry	15	15 (ft)	Critical GAP: AT, 1 × 76.8–268.8 g/ha; PHI: 21 days. Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: trials on hops conducted in Germany and Japan and approximating the GAP. At EU level, a less critical GAP (CZ, 1 × 125 g/ha; PHI: 21 days) was assessed which lead to the same MRL. Conclusion: The proposed Codex MRL is acceptable.
Tea, green, black, dried	**8**	0.05*	Critical GAP: IN, 1 × 25 g/ha; PHI: 7 days. Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: The trials on tea leaves are approximating the GAP. Conclusion: The proposed Codex MRL is acceptable
Milks	0.01*	0.01*	Max dietary burden: 3.503 mg/kg DM (Australia diet after refinement excluding bean forage). Number of trials: 1 feeding study with highest dose level (10 ppm) covering the max DB. Sufficiently supported by data: Yes Specific comments/observations: See comments on residue definitions. Conclusion: The proposed Codex MRL is acceptable; the different residue definition set at EU level and by JMPR is not relevant in this case
Meat (from mammals other than marine mammals)	**0.1(fat)**	0.01*	Max dietary burden: 3.503 mg/kg DM (Australia diet after refinement excluding bean forage). Number of trials: 1 feeding study with highest dose level (10 ppm) covering the max DB. Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal refers to fat; it reflects the RD derived by JMPR. In muscle residues of 0.02 mg/kg were estimated for the maximum DB reported. Conclusion: The proposed Codex MRL is not fully compatible with the EU residue definition; for muscle an appropriate MRL needs to be derived as well
Edible offal (mammalian)	**0.5**	0.09 except swine with 0.01*	Max dietary burden: 3.503 mg/kg DM (Australia diet after refinement excluding bean forage). Number of trials: the feeding study covered the max DB. Sufficiently supported by data: Yes Specific comments/observations: MRL proposal reflects the residue definition of JMPR which is different than the EU RD. Conclusion: The proposed Codex MRL is not fully compatible with the EU residue definition.
Mammalian fats (except milk fats)	**0.1**	0.01*	Max dietary burden: 3.503 mg/kg DM (Australia diet after refinement excluding bean forage). Number of trials: 1 feeding study with highest dose level (10 ppm) covering the max DB. Sufficiently supported by data: Yes Specific comments/observations: MRL proposal reflects the residue definition of JMPR which is different than the EU RD. HR in fat is 0.089 mg/kg; thus, a MRL proposal of 0.09 mg/kg should be enough. Conclusion: The proposed Codex MRL is not fully compatible with the EU residue definition
Apples, dried	1		Derived PF of 4.4, based on two processing studies

Commodity	Codex MRL proposal	EU MRL	Comment
Dried grapes (= currants, raisins and sultanas)	0.2		Derived PF of 2, based on two processing studies
Citrus oil	25	(processed)	Derived PF of 43, based on two processing studies
Maize fodder	5		Critical GAP: USA, 2 × 117; PHI: 14 days. Number of trials: 10 The MRL proposal is in line with Codex rules
Fruiting vegetable other than cucurbits	W0.2		The existing CXL will be replaced by the new proposed MRL for peppers, tomatoes and eggplants
Pome fruits	W 0.3	Apple and pear: 0.3 (ft) for quinces and medlars, Loquats/ Japanese medlars 0.2 (ft) Others 0.01*	The existing CXL will be replaced by the new proposed MRL for apples and pears.
Prunes dry	W 0.7		The existing CXL was proposed for withdrawal. Although a use for plums was assessed, no new MRL proposal was made, since an intake concern was identified for dried prunes (see comments on plums
Stone fruits	W 0.4	Apricots and peach 0.3 (ft), cherries (sweet) 2 (ft), 0.1 (ft) plumes and 0.01* in others	The existing CXL will be replaced by the new proposed MRL for peaches, apricots and plums.
Common beans (pod and/or immature seeds	W 0.4	0.01*	The existing CXL will be replaced by the new proposed MRL for beans with pods
Peppers, chili, dried	W 1.0		The existing CXL will be replaced by the new proposed MRL for peppers
Apple juice	None		Derived PF of 0.16, based on two processing studies
Apple sauce	None		Derived PF of 0.18, based on two processing studies
Grape juice	None		Derived PF of 0.16, based on two processing studies
Grape wine	None		Derived PF of 0.16, based on two processing studies
Tomato juice	None		Derived PF of 0.64, based on two processing studies
Tomato canned	None		Derived PF of 0.40, based on two processing studies
Tomato purée	None		Derived PF of 0.72, based on two processing studies
Citrus molasses	None		Derived PF of 0.07, based on two processing studies
Citrus juice	None		Derived PF of 0.03, based on two processing studies
Maize meal	None		Derived PF of 0.15, based on one processing study
Maize flour	None		Derived PF of 0.37, based on one processing study
Maize grits	None		Derived PF of 0.016, based on one processing study
Maize oil	None		Derived PF of 0.99 (refined oil, dry milling) and 0.31 (refined oil, wet milling) based on one processing study
Teas (Tea and Herb teas)	None		Derived PF of 0.0098 for dry leaves tea infusion, based on eight processing studies

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union; PHI: preharvest interval; CXL: Codex Maximum Residue Limit; DM: dry matter.
*: Indicates that the input value is proposed at the limit of quantification.

4.10.5. Consumer risk assessment – fenpyroximate (Table 44)

Table 44: Summary of the consumer risk assessment for fenpyroximate

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for all commodities assessed by JMPR. The EU ARfD (scenario 1) and the JMPR ARfD (scenario 2) were used. For apples, a lower variability factor of 2.2, derived in the framework of the Article 12 review (EFSA, 2015o), was considered.The variability factor was not extrapolated to pears. For citrus fruits, in the absence of detailed results for pulp, a refinement was not possible: therefore, residues in the whole fruits were considered. If reliable data on the residues in the edible part of citrus fruit are available, further refinements of the intake calculations might be possible. For peppers and coffee, the HR values derived by JMPR do not cover the metabolite M-1; thus, the calculated exposure may underestimate the real exposure. Since Codex MRL proposals for meat are expressed on a fat basis, EFSA recalculated the corresponding maximum residue levels for meat. The risk assessment for animal products is tentative, since the residue definitions of JMPR differ from the EU residue definition	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015o) was updated using the approach as outlined in Section 'Assessment', including, for those commodities having a CXL higher than the EU MRL, the STMR values derived by JMPR. For citrus fruits, in the absence of detailed results for pulp a refinement was not possible. Therefore, residues in the whole fruits were considered. For peppers and coffee, the STMR values derived by JMPR do not cover the metabolite M-1; thus, the calculated exposure may underestimate the real exposure. Since Codex MRL proposals for meat are expressed on a fat basis, EFSA recalculated the corresponding median residue level for meat. The risk assessment for animal products is tentative, since residue definitions derived by JMPR and EU differ	**Specific comments** Exposure was assessed by the JMPR also for processed commodities
Results scenario 1: Short-term exposure concern were identified for the following commodities: **Oranges** (179% of the ARfD) **Grapefruits** (120% of the ARfD) If reliable data on the residues in the edible part of citrus fruit are available, further refinements of the intake calculations might be possible. **Results scenario 2:** Short-term exposure concern were identified for the following commodities: **Oranges** (358% of the ARfD) **Grapefruits** (241% of the ARfD) **Mandarins** (150% of the ARfD) **Peaches** (148% of the ARfD) **Cucumbers** (140% of the ARfD) **Pears** (137% of the ARfD) **Melons** (137% of the ARfD) **Watermelons** (122% of the ARfD) **Cherries** (121% of the ARfD) **Plums** (109% of the ARfD)	**Results (scenario 1 and 2):** No long-term consumer health risk was identified.The overall chronic exposure accounted for 28% of the ADI	**Results:** Long-term exposure: No long-term consumer health risk was identified. The overall chronic exposure accounted for 10% of the ADI for the 17 GEMS/Food regional diets. Short-term exposure: Short-term exposure concern was identified by the JMPR for the following commodities: **Dried tomatoes** (310% of the ARfD for general population from Australia) **Dried plums** (270% of the ARfD for children from Australia) **Watermelons** (190% of the ARfD for children from CAN) **Peaches** (130% of the ARfD for children from Japan and CAN) **Cherries** (110% of the ARfD for children from NL and DK)

ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.11. Imidacloprid (206) (R)

4.11.1. Background information (Table 45)

Table 45: Background information on imidacloprid

		Comments, references
Type of JMPR evaluation	New use	
RMS	DE	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 485/2013[(a)]
EFSA conclusion	Yes, see comments	EFSA (2008a) EFSA (2014j) EFSA (2014p) EFSA (2015j) EFSA (2016n) EFSA (2016p) EFSA (2018e) (Art. 21 seed treatment and granules uses) • EFSA conclusions ongoing (AIR IV) • Emergency authorisations ongoing
MRL review	No	• Ongoing
MRL applications	Yes, see comments	EFSA (2010d) • Art 10 – various crop (ongoing, additional data request)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 485/2013/EU Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.5.2013, p. 12–26.

4.11.2. Toxicological reference values – imidacloprid (Table 46)

Table 46: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.06 mg/kg bw per day	JMPR 2015	0.06 mg/kg bw per day	EFSA (2008a) (Rat, 2-yr safety factor 100)	Yes
ARfD	0.4 mg/kg bw	JMPR 2015	0.08 mg/kg bw	EFSA (2008a) (Dog, 90-day (acute effects) supported by the developmental study in the rabbit Safety factor 100)	No
Conclusion/ comment	In 2013, EFSA assessed the developmental neurotoxicity potential for imidacloprid. The PPR Panel concluded that the ADI set for imidacloprid would provide adequate protection against its potential adverse effects from the developing nervous system.As regards the ARfD, the Panel recommended to conservatively lower the reference values to the level of the ADI, i.e. 0.06 mg/kg bw. JMPR assessed imidacloprid in 2015 where the ADI and ARfD have been confirmed. The ARfD of JMPR was based an acute neurotoxicity study in rats				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.11.3. Residue definitions – imidacloprid (Table 47)

Table 47: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. The residue is not fat soluble	EU Reg. 396/2005: imidacloprid Peer review: No definitive decision on the residue definition for enforcement was taken. SCFCAH October 2009: Sum of imidacloprid, imidacloprid-5- hydroxy and imidacloprid-olefin, expressed as imidacloprid	No
	Animal products		Reg. 396/2005: Imidacloprid Peer review: Sum of imidacloprid and its metabolites imidacloprid-5-hydroxy (M1) and imidacloprid-olefin (M6), expressed as imidacloprid The residue is not fat soluble SCFCAH October 2009: Sum of imidacloprid, imidacloprid-5- hydroxy and imidacloprid-olefin, expressed as imidacloprid Proposal RMS in ER (plant and animal products) drafted for Art. 12 review: Imidacloprid	No
RD RA	Plant products	Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid	Peer review: Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid	Yes
	Animal products			Yes
Conclusion/ comments	The residue definitions for risk assessment are comparable. However, residue definitions for enforcement are still under discussion in the EU. Pending a final decision taken in the framework of the MRL review, the proposed Codex MRLs need to be checked individually as to whether they can be taken over in the EU legislation or whether adaptations will be required			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.11.4. Codex MRL proposals – imidacloprid (Table 48)

Table 48: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

General comments	The Meeting received supervised trial data (4) for applications of imidacloprid on pistachios. However, trials were not compliant with the GAP (Iran, 3 × 014 kg/ha; PHI: not applicable). Moreover, in these trials, residues were not analysed according to the residue definition (only levels of imidacloprid and imidacloprid olefin were measured). Therefore, no CXL could be derived from these data

GAP: Good Agricultural Practice; CXL: Codex Maximum Residue Limit.

4.11.5. Consumer risk assessment – imidacloprid (Table 49)

Table 49: Summary of the consumer risk assessment for imidacloprid

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant	Not relevant	–

4.12. Cyprodinil (207) (R)

4.12.1. Background information (Table 50)

Table 50: Background information on cyprodinil

		Comments, references
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 678/2014[(a)]
EFSA conclusion	Yes, see comments	EFSA (2006) • EFSA conclusions ongoing (AIR III)
MRL review	Yes, see comments	EFSA (2013i)
MRL applications	Yes, see comments	EFSA (2015e) (celery)

MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 678/2014/EU: Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac. OJ L 180, 20.6.2014, p. 11–12.

4.12.2. Toxicological reference values – cyprodinil (Table 51)

Table 51: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.03 mg/kg bw per day	JMPR, 2003(2-year rat, SF 100)	0.03 mg/kg bw per day	EFSA (2006) (2-year rat, UF 100)	Yes
ARfD	Unnecessary	JMPR, 2003	Not necessary	EFSA (2006)	Yes
Conclusion/ comment	The TRV values derived by JMPR and at EU level are identical. The RMS informed EFSA that an ARfD of 1.5 mg/kg bw based on the rabbit developmental toxicity study is proposed in the RAR				

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; RMS: rapporteur Member State; RMS: rapporteur Member State; ARfD: acute reference dose; TRV: toxicological reference values.

4.12.3. Residue definitions – cyprodinil (Table 52)

Table 52: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyprodinil	Cyprodinil	Yes
	Animal products	Cyprodinil The residue is fat soluble	Milk: Cyprodinil (sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil) Other animal products: Cyprodinil (sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil) The residue is fat soluble	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Cyprodinil	Cyprodinil	Yes
	Animal products	Cyprodinil	Milk: Cyprodinil (sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil) Other animal products: Cyprodinil (sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil)	No
Conclusion/ comments	Plant products: The residue definition for enforcement and risk assessment derived by JMPR and at EU level is identical. Animal products: For animal products, the EU residue definition for enforcement and risk assessment is wider as comprises the metabolite CGA304075 (4-[(4-cyclopropyl-6-methylpyrimidin-2-yl)amino)]phenol) for tissues. In the framework of the MRL review also the conjugates of CGA 304075 were also included in the residue definition for milk. The RMS informed EFSA that the following residue definition is proposed in the RAR (both for monitoring and risk assessment purposes): Sum of cyprodinil and CGA304075 (free form and glucuronide) expressed as cyprodinil			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; RMS: rapporteur Member State; RAR: renewal assessment report.

4.12.4. Codex MRL proposals – cyprodinil (Table 53)

Table 53: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Artichoke, globe	**4**	0.02*	Critical GAP: Foliar use in USA, 4 × 366 g/ha, PHI 3 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: one trial was slightly deviating from the GAP (five applications instead of four); however, this deviation was accepted the residues were comparable. Conclusion: The proposed Codex MRL is acceptable.
Carrot	1.5	1.5	Critical GAP: Foliar use in DE, 3 × 375 g/ha, PHI 7 days Number of trials: 20 Sufficiently supported by data: Yes Specific comments/observations: none JMPR reported that the use on carrots did not have a significant impact on the dietary burden calculation for farm animals. Conclusion: The proposed Codex MRL is acceptable.
Celery	**30**	0.1*	Critical GAP: Foliar use in USA, 4 × 368 g/ha, PHI 0 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: none Conclusion: The proposed Codex MRL is acceptable.
Guava	**1.5**	0.02*	Critical GAP: Foliar use in USA, 4 × 368 g/ha, PHI 0 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: none Conclusion: The proposed Codex MRL is acceptable.
Pomegranate	**10 (Po)**	0.02*	Critical GAP: US post-harvest (dip/drench) GAP, 1 × 54 g/hL before storage + 1 × 54 g/hL before trading, PHI 0 days (US) Number of trials: 1 storage facility, 4 trials at different dates

Commodity	Codex MRL proposal	EU MRL	Comment
			Sufficiently supported by data: No Specific comments/observations: 1) The GAP is not sufficiently defined: the interval between the first and the second treatment should be established. 2) Metabolism studies in fruit crops are available only for foliar uses; evidence needs to be provided that the fate of residues following post-harvest use is comparable with foliar use. 3) The residue trials were conducted in a single facility with identical technique and variables (i.e. temperature, humidity, aeration); the trials are therefore not independent. 4) Considering that the GAP is a post-harvest treatment, the MRL should be calculated as 'mean + 4 SD'; thus, a MRL proposal of 5 mg/kg (unrounded 4.63 mg/kg) would be sufficient. Conclusion: The proposed Codex MRL is not acceptable.
Subgroup of beans with pods (includes all commodities in this subgroup)	2	2	Critical GAP: Spanish indoor GAP, 2 × 375 g/ha, PHI 3 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: trials with three instead of two applications. This set of trials is compliant with indoor GAP assessed in the MRL review. Conclusion: The proposed Codex MRL is acceptable
Common bean (pods and/or immature seeds)	W 0.7		Existing CXL was proposed to be withdrawn
Potato	0.01*	0.02*	Critical GAP: Foliar use in USA, 4 × 366 g/ha, PHI 14 days Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: JMPR reported that the use on potatoes did not have a significant impact on the dietary burden calculation for farm animals. Conclusion: The proposed Codex MRL is acceptable.
Tree nuts (except almond and pistachio)	**0.04**	0.02*	Critical GAP: Foliar use in USA, 4 × 366 g/ha, PHI 14 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: extrapolation from trials on pecan (5 trials) and almond (4 trials) to tree nuts group (except almond and pistachio) is acceptable. Conclusion: The proposed Codex MRL is acceptable

EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; GAP: Good Agricultural Practice.
*: Indicates that the input value is proposed at the limit of quantification.

4.12.5. Consumer risk assessment – cyprodinil (Table 54)

Table 54: Summary of the consumer risk assessment for cyprodinil

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: –	**RA assumptions:** The long-term risk assessment (EFSA, 2015e) was updated with the STMRs derived by JMPR in 2013 and 2015 for the CXLs implemented in the EU legislation and using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for tree nuts (except almond and pistachio), pomegranate, guava and celery, globe artichokes. Peeling factor used for cucurbits, inedible peel	**Specific comments** –
Results: A short-term exposure assessment not necessary	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 5–40% of the ADI. The contribution of to the exposure was 3.6% ADI for celery, 0.7% ADI for globe artichokes and < 0.4% ADI for the remaining commodities	**Results:** Long-term exposure resulted by JMPR is 8–70% of the ADI

ADI: acceptable daily intake; supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue.

4.13. Trifloxystrobin (213) (R)

4.13.1. Background information (Table 55)

Table 55: Background information on trifloxystrobin

		Comments, references
Type of JMPR evaluation	New use	
RMS	UK	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 2017/841[(a)]
EFSA conclusion	Yes, see comments	EFSA (2017k)
MRL review	Yes, see comments	EFSA (2014c)
MRL applications	Yes, see comments	EFSA (2016a) (celeriac) EFSA (2014l) (cane fruit) EFSA (2018c) (various crop)

MRL: maximum residue limit.

(a): 2017/841/EU: Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, Ampelomyces quisqualis strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, Gliocladium catenulatum strain: j1446, imazamox, imazosulfuron, isoxaflutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin. OJ L 125, 18.5.2017, p. 12–15.

4.13.2. Toxicological reference values – trifloxystrobin (Table 56)

Table 56: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.04 mg/kg bw per day	JMPR, 2004	0.1 mg/kg bw per day	EFSA (2017k) (2-year rat, UF 100)	No
ARfD	unnecessary	JMPR, 2004	0.5 mg/kg bw	EFSA (2017k) (rabbit, developmental, UF 100)	No
Conclusion/ comment	The EU ARfD has been established just recently in the framework of the renewal of the approval.				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

4.13.3. Residue definitions – trifloxystrobin (Table 57)

Table 57: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Trifloxystrobin	Trifloxystrobin	Yes
	Animal products	Sum of trifloxystrobin and [(*E,E*)-methoxyimino-{2-[1-(3-trifluoromethylphenyl) ethylideneamino-oxymethyl] phenyl}acetic acid] (CGA 321113, M5), expressed as trifloxystrobin. The residue is fat soluble	Sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin. The residue is fat soluble	Yes
RD RA	Plant products	Sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3- trifluoromethylphenyl) ethylideneaminooxymethyl] phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin	**Primary Crops**: Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin. **Processed commodities:** Sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin. The RD RA was amended with EFSA (2017i).	No
	Animal products	Sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl) ethylideneamino-oxymethyl] phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin	Ruminants: Sum of trifloxystrobin and CGA 321113 (M5) (free and conjugated), expressed as trifloxystrobin. Poultry: Sum of trifloxystrobin and CGA 321113 (M5) (only free), expressed as trifloxystrobin.	No
Conclusion/ comments	RD RA for plant products: It should be verified, if isomer specific analytical methods were used to analyse the samples of the residue trials assessed by JMPR. If this was not the case, and the results refer to the sum of isomers and M5, the different residue definitions for plant products would not have a practical relevance. RD RA for animal products: Not fully compatible since the conjugates were in the EU RD for ruminant liver and kidney			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.13.4. Codex MRL proposals – trifloxystrobin (Table 58)

Table 58: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cabbages, Head	**1.5**	0.5	Critical GAP: USA, 3 × 139 g ai/ha; RTI 7–14 days, PHI 0; seasonal rate 281 g ai/ha per yr Number of trials: 6 Sufficiently supported by data: No, head cabbage is major crop, both in the EU and according to JMPR criteria. Specific comments/observations: The MRL proposal is based on head cabbage with wrapper leaves, while the STMR is derived from head cabbage without wrapper leaves. Given that consumers may eat outer leaves if they are not damaged, it would be more appropriate to use the STMR and HR being based on inclusion of the wrapper leaves. A PHI of 0 days would not be acceptable for EU GAPs, but is usually acceptable for import tolerances. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs.
Cotton seed	**0.4**	0.01*	Critical GAP: 3 × 137 g ai/ha, RTI: 14 days, PHI 30 days, country with cGAP not reported Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: - Conclusion: The proposed Codex MRL is acceptable.
Ginseng	0.03*	0.05*	Critical GAP: Republic of Korea, 3 × 3.35 g ai/ha RTI 10 days, PHI 21 Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: Residues below the LOQ of either 0.03* or 0.06*mg/kg. Conclusion: The proposed Codex MRL is acceptable.
Spinach	**20**	0.01*	Critical GAP: USA 2 × 139 g ai/ha, RTI 14 days, PHI 0 Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: At EU level a PHI of 0 days would not be acceptable. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Cotton seed refined oil, edible	none		Two processing studies were available, PF = 0.02

EU MRL: European Union maximum residue limit; GAP: Good Agricultural Practice; HR: highest residue; PF: processing factor; STMR: supervised trials median residue.
*: Indicates that the input value is proposed at the limit of quantification.

4.13.5. Consumer risk assessment – trifloxystrobin (Table 59)

Table 59: Summary of the consumer risk assessment for trifloxystrobin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for head cabbage, spinach, cotton seed and ginseng as outlined in Section 4.13.2. The EU ARfD was used. For head cabbage, the HR value was based on cabbage with wrapper leaves. The risk assessment is tentative, because of the lack of information on the metabolites included in the EU RD that were not considered in the JMPR assessment (i.e. CGA 357262, CGA 357261 and CGA 331409)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2017k) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for spinach, cotton seed and ginseng. For head cabbage, the STMR derived from cabbage with wrapper leaves (0.42 mg/kg) was used. This risk assessment is considered tentative, because of the lack of information on the metabolites included in the EU RD that were not considered in the JMPR assessment (i.e. CGA 357262, CGA 357261 and CGA 331409)	**Specific comments**
Results: No short-term exposure concern was identified (45% and 6% of the ARfD for spinach and head cabbage, respectively).	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for up to 8.4% of the ADI (FR toddler). The contribution of spinach and head cabbage to the exposure was up to 5.4% (FR toddler) and 0.3% of the ADI, respectively	**Results:** Long-term exposure: 7% of the ADI Short-term exposure: Not relevant for JMPR

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.14. Difenoconazole (224) (R)

4.14.1. Background information (Table 60)

Table 60: Background information on difenoconazole

		Comments, references
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 1100/2011[(a)]
EFSA conclusion	Yes, see comments	EFSA (2011a) EFSA (2014r) • EFSA conclusions ongoing (AIR III)
MRL review	No	In progress
MRL applications	Yes, see comments	EFSA (2017g) (various crop) EFSA (2014q) (leafy veg) EFSA (2014e) (peppers and aubergines) EFSA (2013a) (various crop) EFSA (2012f) (various crop) EFSA (2011c) (beet, artichokes, strawberry) EFSA (2010f) (peppers and aubergine) EFSA (2010a) (swedes and turnips) EFSA (2009b) (leafy veg)

MPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit.
(a): 2011/1100/EU: Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole and imazaquin. OJ L 285, 1.11.2011, p. 10–14.

4.14.2. Toxicological reference values – difenoconazole (Table 61)

Table 61: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.01 mg/kg bw per day	JMPR, 2007 (Rat, 2-year combined toxicity and carcinogenicity study, safety factor 100)	0.01 mg/kg bw per day	EFSA (2011a) (2-year rat safety factor 100)	Yes
ARfD	0.3 mg/kg bw	JMPR, 2007 (Rat single dose neurotoxicity study, supported by maternal effects in rabbit developmental study, NOAEL 0.25 mg/kg bw/day in both cases AF: 100)	0.16 mg/kg bw	EFSA (2011a) (developmental rat safety factor 100)	No
Conclusion/ comment	–				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.14.3. Residue definitions – difenoconazole (Table 62)

Table 62: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Difenoconazole	Difenoconazole	Yes
	Animal products	Sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol) (=CGA-205375), expressed as difenoconazole. The residue is fat soluble	EU Reg. 396/2005: Difenoconazole Peer review: Difenoconazole alcohol (CGA-205375) expressed as difenoconazole The residue is fat soluble	Not fully compatible
RD RA	Plant products	Difenoconazole	Two separate residue definitions: 1) Difenoconazole 2) Triazole-derivative metabolites (TDM) (provisional, pending the definition of a common and harmonised approach for all the active substances of the triazole chemical class)	Not fully compatible

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	Sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole.	Two separate residue definitions: 1) Difenoconazole alcohol (CGA-205375) expressed as difenoconazole 2) Triazole-derivative metabolites (provisional, pending information on metabolism of TDM in animals and pending the definition of a common and harmonised approach for all the active substances of the triazole chemical class)	Not fully compatible
Conclusion/ comments	–			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.14.4. Codex MRL proposals – difenoconazole (Table 63)

Table 63: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Pome fruits	**4**	0.8 all group	Critical GAP: US GAP with 5 × 77 g/ha foliar + post-harvest dip or drench 30 g ai/hL or post-harvest spray 1.3 g ai/t Number of trials: 27 (9 for foliar + drenching, 9 for foliar + drench and 9 for foliar + post-harvest spray) Sufficiently supported by data: Yes Specific comments/observations: - Conclusion: The proposed Codex MRL is not acceptable for apples and pears because the ARfD of 0.16 mg/kg and the ADI are exceeded. Furthermore, it is noted that since the US GAP applies only to apples and pears, it is not justified to set a group tolerance
Blueberries	**4**	0.1	Critical GAP: CAN, foliar, 4 × 127 g ai/ha, RTI 6–9 days, PHI 1Number of trials: 10 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable.
Strawberries	**2**	0.4	Critical GAP: USA, foliar application, 4 × 127.5 g ai/ha; RTI 7 days, PHI: 0 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: At EU level a PHI of 0 days would not be acceptable. Conclusion: The proposed Codex MRL is acceptable.
Pitaya (dragon fruit)	**0.15**	0.1	Critical GAP: Indonesia, foliar, 3 × 50 g ai/ha RTI 9–11 days, PHI 7 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: Scaling was applied, as the trials were overdosed (3 × 94 g/ha). Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Watermelon	0.02	0.2	Critical GAP: BR, 6 × 50 g ai/ha, RTI 7 days, PHI 3 days. Number of trials: 4 overdosed trials which were scaled to match the GAP. Sufficiently supported by data: No Specific comments/observations: Watermelons are considered a major crop, and therefore, 8 trials would be required. Conclusion: The proposed Codex MRL is not compliant with the data requirements. Risk managers should discuss the need to make a reservation, considering that the existing EU MRL is higher. In general, the manufacturer should be encouraged to send a European GAP to establish a Codex MRL that covers also the European uses
Fruiting vegetables other than cucurbits	W0.6	Tomatoes: 2; Sweet peppers/bell peppers 0.8; Aubergines/ eggplants 0.6; Okra/ lady's fingers, sweet corns, other Solanacea and other fruiting veg. 0.05*	The existing CXL is replaced by the new CXL reported below
Group of Fruiting vegetables other than cucurbits (except peppers, chili)[a]	0.6		The previous CXL was maintained, excluding chili peppers
peppers, chili	**0.9**	0.8	Critical GAP: foliar, 4 × 80 g ai/ha; RTI 10 days; PHI 2 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: EU MRL relates to sweet peppers. Peppers are a major crop, and therefore, 8 trials would be required in the EU. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/ compatible with the EU policy on setting MRLs
Peppers, chili, dried	5		The existing CXL for dried Chili peppers should be replaced by a new MRL proposal of 4, derived from the specific residue trials in chili peppers (see above) and the specific processing factor of 4.5
Sweet corn (corn on the cob) (kernels plus cob with husk removed)	0.01*	0.05*	Critical GAP: USA, seed treatment 1 × 300 g ai/t seed Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: residues below LOQ Conclusion: The proposed Codex MRL is acceptable
Subgroup of dry beans (except soya bean)	0.05	0.06	Critical GAP: USA, foliar, 4 × 127.5 g ai/ha, RTI 14 ± 2 days; PHI 14 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: The number of trials is not sufficient to derive a MRL proposal for dry beans. However, the trials on dry beans, peas and chickpeas could be combined to derive a MRL of 0.1 mg/kg for the three crops. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/ compatible with the EU policy on setting MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of dry peas(includes all commodities in this subgroup)	**0.15**	0.1	Critical GAP: USA, foliar, 4 × 127.5 g ai/ha, RTI 14 ± 2 d; PHI 14 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: see subgroup of dry beans. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/ compatible with the EU policy on setting MRLs
Ginseng, dried	0.8	20	Critical GAP: USA, foliar, 4 × 127.5 g ai/ha; RTI 6–8 days; PHI: 0 Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: The trials results refer to dried ginseng. Conclusion: The proposed Codex MRL is acceptable.
Globe artichoke	**1.5**	1	Critical GAP: USA, foliar; 4 × 127.5 g ai/ha; RTI 12–16 days; PHI 3 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Based on JMPR, at least 4 trials are required for globe artichokes. The HR value proposed by JMPR was based on the highest individual analytical result (0.64 mg/kg), not the highest residue level found in the residue trial (0.57). Conclusion: The proposed Codex MRL is acceptable
Rice	**8**	3	Critical GAP: foliar, 2 × 137 g ai/ha; RTI 14 days; PHI: 35 days (USA). Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: The results of the residue trials refer to rice grain, which is according to Codex classification the rice with husks. In the EU, the MRLs for rice are set for husked rice (rice without husk, brown rice) (see Commission Regulation (EU) 2018/62). Conclusion: The proposed Codex MRL is acceptable, but it cannot be taken over without adjustment because of different crop description
Rice, polished	0.07		A processing factor of 0.0078 was reported in the JMPR report. In the JMPR Evaluation, 4 processing studies were reported with the individual PF of 0.0078, < 0.91, 0.48 and 0.95. It is unclear why the proposed PF was based only on the first value, ignoring the three remaining results. The validity of the first PF should be verified, since the residue in the unprocessed RAC was 48 mg/kg while in the other trials the residues in the RAC, having received a similar application rate, ranged from 0.011 mg/kg to 2.9 mg/kg. Thus, it is questionable that the processing factor of 0.0078 is reliable. See also comments on the dietary risk assessment performed by JMPR
Rice straw	17 (dw)		14 trials were available
Coffee beans	0.01*	0.05*	Critical GAP: BR, foliar, 3 × 50 g ai/ha; RTI 12–16 days; PHI 30 days Number of trials: 4

Commodity	Codex MRL proposal	EU MRL	Comment
			Sufficiently supported by data: Yes Specific comments/observations: Trials were overdosed, but below LOQ. Although coffee is a major crop, given the no residue situation, 4 trials are sufficient. No need to take over, as only the LOQ is lowered. Conclusion: The proposed Codex MRL is acceptable
Sweet corn stover	0.01	0.05*	9 trials were available
Rice bran, unprocessed	none		Only one processing study was available.

PHI: preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ADI: acceptable daily intake; CXL: Codex Maximum Residue Limit; LOQ: limit of quantification; GAP: Good Agricultural Practice.
*: Indicates that the input value is proposed at the limit of quantification.

4.14.5. Consumer risk assessment – difenoconazole (Table 64)

Table 64: Summary of the consumer risk assessment for difenoconazole

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for all commodities for which a CXL was sought as outlined in Section 4.14.2. The EU ARfD was used. For pome fruits, HR values were included per commodity. Azarole and persimmon were included in the assessment, as they belong to the group of pome fruits according to the Codex food classification	**RA assumptions:** Scenario 1: The most recent long-term risk assessment (EFSA, 2017g) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the commodities. For pome fruits, the STMR was used for the individual commodities covered by the Codex classification of pome fruit including also azaroles and persimmon. For rice, the proposed STMR-P derived by JMPR was used. Scenario 2: The same as scenario 1, except that the STMR values for apples and pears were based on the existing EU MRLs	**Specific comments** For the dietary risk assessment, JMPR calculated the STMR-P for polished rice, using the PF of 0.0078. The validity of this PF is questionable. Thus, the acute and chronic dietary exposure should be recalculated, using a recalculated PF
Results: Considering the ARfD of 0.16 mg/kg, a short-term exposure concern was identified for apples and pears (159% and 148% of the ARfD, respectively). For the other commodities, the exposure was below the ARfD (highest was persimmon contributing to 64.8% of ARfD). If the ARfD derived by JMPR is considered, no short-term intake concern is identified. The short-term exposure for apples and pears would be up to 85% and 79% of the ARfD, respectively	**Results:** Scenario 1: A long-term consumer health risk was identified, the overall chronic exposure exceeded 100% of the ADI in three diets (199% DE child, 135% NL child; 101.7% WHO Cluster diet B), apple was the major contributor in these diets (133%, 70% and 11%, respectively, except for WHO diet B, in which tomato was the major contributor). Scenario 2: No long-term consumer health risk identified. Chronic exposure was up to 88.9% of the ADI (WHO Cluster diet B)	**Results:** 9–80% of the ADI Short-term exposure: Up to 60% of the EU ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; HR: highest residue; STMR: supervised trials median residue; RD: residue definition.

4.15. Azoxystrobin (229) (R)

4.15.1. Background information (Table 65)

Table 65: Background information on azoxystrobin

		Comments, references
Type of JMPR evaluation	New use	Except rape seed
RMS	UK	
Approval status	Approved	Commission Implementing Regulation (EU) No 703/2011[(a)]
EFSA conclusion	Yes, see comments	EFSA (2010b)
MRL review	Yes, see comments	EFSA (2013k)
MRL applications	No	EFSA (2016c) (grapes) EFSA (2016h) (chervil, chervil, rhubarb, linseed, safflower) None ongoing

RMS: rapporteur Member State; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.
(a): Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, 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 190, 21.7.2011, p. 33–37.

4.15.2. Toxicological reference values – azoxystrobin (Table 66)

Table 66: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.2 mg/kg bw per day	JMPR 2008 (2-year rat carcinogenicity, safety factor 100)	0.2 mg/kg bw per day	EFSA (2010b) (2-year rat, safety factor 100)	Yes
ARfD	Unnecessary	JMPR 2008	Not necessary	–	Yes
Conclusion/ comment	–				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.15.3. Residue definitions – azoxystrobin (Table 67)

Table 67: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Azoxystrobin	Azoxystrobin	Yes
	Animal products	Azoxystrobin The residue is fat soluble	Azoxystrobin Po/w lower than 3: The residue is not fat soluble	Yes
RD RA	Plant products	Azoxystrobin	Azoxystrobin	Yes
	Animal products	Azoxystrobin	Azoxystrobin	Yes
Conclusion/ comments	–			

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

4.15.4. Codex MRL proposals – azoxystrobin (Table 68)

Table 68: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Pitaya (Dragon fruit; 0162040 - 001)	0.3	0.01*	Critical GAP: Vietnam and Indonesia, foliar application 3 × 0.08 kg ai/ha, RTI 10 days, PHI 7 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: proportionality applied, scaling factor 1.875 Conclusion: The proposed Codex MRL is acceptable
Sugarcane	**0.05**	0.01*	Critical GAP: Brazil, foliar, 5 × 0.06 kg ai/ha, RTI, PHI 30 days Number of trials: 6 Sufficiently supported by data: According to JMPR classification, 8 trials would be required (major crop). In the EU, it is considered a minor crop. Specific comments/observations: processing factors for bagasse (**7.5**), refined sugar (0.33) and molasses (0.25) Conclusion: The proposed Codex MRL is acceptable.
Rape seed	0.5	0.5	Critical GAP: USA, CAN, 3× : 0.125 kg/ha BBCH 12-16 and 67-79 and 0.250 BBCH 60-63 Number of trials: 9 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable

CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.
*: Indicates that the input value is proposed at the limit of quantification.

4.15.5. Consumer risk assessment – azoxystrobin (Table 69)

Table 69: Summary of the consumer risk assessment for azoxystrobin:

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was not performed as no ARfD necessary	**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 dragon fruit (Cactus fruit, 0162040) and sugar cane. Rape seed was already included in previous assessment with similar value.	**Specific comments** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 21% of the ADI. The contribution of dragon fruit (pitaya) and sugar cane negligible. Rape seed already included in previous assessment.	**Results:** –

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

4.16. Prothioconazole (232) (R)

4.16.1. Background information (Table 70)

Table 70: Background information on prothioconazole

		Comments, references
Type of JMPR evaluation	New use	
RMS	UK	
Approval status	Renewal of the approval	Commission Directive No 2008/44/EC[(a)]
EFSA conclusion	Yes, see comments	EFSA (2007b) • EFSA conclusions ongoing (AIRIII)
MRL review	Yes, see comments	EFSA (2014f)
MRL applications	Yes, see comments	EFSA (2015h) (shallots)
		EFSA (2015n) (sunflowers)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2008/44/EU: Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances. OJ L 94, 5.4.2008, p. 13–20.

4.16.2. Toxicological reference values – prothioconazole (Table 71)

Table 71: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day 0.01 mg/kg bw (prothioconazole-desthio)	JMPR 2008	0.05 mg/kg bw per day 0.01 mg/kg bw (prothioconazole desthio)	EFSA (2007b) (Rat, 2 year study; dog, 1 year study Safety factor 100) Rat oncogenicity study, SF 100	Yes
ARfD	0.8 mg/kg bw (for women of childbearing age) Prothioconazole-desthio: 0.01 mg/kg bw (for women of childbearing age); 1 mg/kg bw (for general population)	JMPR 2008	0.2 mg/kg bw 0.01 mg/kg bw (prothioconazole desthio)	EFSA (2007b) (Rat, developmental study Safety factor 100) Supplementary rat developmental study, SF 100	No
Conclusion/ comment	For prothioconazole desthio, the toxicological reference values derived by JMPR and at EU level are identical. However, it is noted that the ARfD of 0.01 mg/kg for prothioconazole-desthio derived by JMPR refers only to women of childbearing age)				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.16.3. Residue definitions – prothioconazole (Table 72)

Table 72: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Prothioconazole-desthio	Prothioconazole-desthio (sum of isomers)	Yes
	Animal products	Prothioconazole-desthio. The residue is not fat soluble	EU Reg. 396/2005: prothioconazole-desthio (sum of isomers Peer review: Prothioconazole-desthio (sum of isomers) Peer review and MRL review (in case DB increases): Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio (not enforced). The residue is fat soluble	Yes
RD RA	Plant products	Prothioconazole-desthio.	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)	No
	Animal products	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio.	MRL review: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (tentative)	No
Conclusion/ comments	The EU residue definition for risk assessment for plants is more comprehensive, covering all the metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety; conversion factors for enforcement to risk assessment were derived: 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables; 3 for cereal straw. Since for fruit crops metabolism, data are not available, a generic conversion factor for risk assessment is not available. For animal commodities, the EU and JMPR risk assessment residue definitions are not identical. From the metabolism studies presented in the 2008 JMPR report, it seems that some of the major metabolites identified in animal commodities are not covered by the JMPR residue definition. The JMPR RA residue definition reflects those metabolites which were analysed in the cow-feeding study. The potential inclusion of glucuronide conjugate in the enforcement residue definition for all livestock matrices was recommended by the MRL review in case the EU livestock DB is increasing. From livestock metabolism studies, conversion factors from enforcement to risk assessment were derived as 2 for liver and 9 for kidney and 1 for other matrices.			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.16.4. Codex MRL proposals – prothioconazole (Table 73)

Table 73: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cotton seed	**0.3**	0.02*	Critical GAP: USA: 3 × 0.2–0.21 kg/ha, 14 days interval, PHI 30 days Number of trials: 12 (USA trials) Sufficiently supported by data: Yes Six USA trials supporting the USA GAP are also available to derive residues in cotton gin by-products (feed item). Conclusion: The proposed Codex MRL is acceptable
Milks	0.004*	0.01* (ft)	The mean and maximum dietary burden calculated for AUS dairy cattle was used to estimate the Codex MRL in milk. The feed commodities used for the calculation of DB are those referred to in the JMPR assessments in 2009 (CXL for animal matrices proposed) and 2014 (no CXLs for animal matrices proposed). Addition of prothioconazole residues in cotton seed and cotton gin by-products slightly affect only the calculated mean DB. (See also general comments on DB calculation). The existing Codex MRL for milk at the LOQ of 0.004 mg/kg is confirmed, based on no residue situation in milk at two lowest dose levels from the cow-feeding study. Conclusion: The proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	**0.02**	0.01*	The Codex MRL proposal of 0.02 mg/kg for fat (which was proposed by the JMPR in 2008 and then withdrawn by the JMPR 2009) is confirmed, based on the residues in fat at two lowest dose levels from the cow-feeding study. See general comment on DB calculation. Conclusion: The proposed Codex MRL is acceptable.
Meat (from mammals other than marine mammals)	0.01	0.01*	The existing Codex MRL for meat at 0.01 mg/kg is confirmed, based on residues in muscle at two lowest dose levels from the cow-feeding study. The Codex MRL refers to meat but is based on residues in muscle, thus acceptable for the EU food classification. See also general comments on DB calculation. Conclusion: The proposed Codex MRL is acceptable
Edible offal (mammalian)	**0.3**	0.5 (ft)	The existing Codex MRL of 0.5 mg/kg for edible offal is lowered to 0.3 mg/kg, based on residues in liver at two lowest dose levels from the cow-feeding study. The lowering is justified. See general comments on DB calculation. The existing EU MRL is based on the CXL of 0.5 mg/kg (assessed in Art.12). Once the existing CXL is withdrawn, the EU MRL for animal products should be reconsidered, taking into account the EU uses in feed. Conclusion: The proposed Codex MRL is acceptable
Eggs	0.005*	0.01*	The maximum and mean dietary burdens calculated for poultry (layers) for EU diet were used to estimate Codex MRL and STMR in eggs and poultry products. The Codex MRL proposal for eggs is estimated from the total radioactive residues (TRR) observed in eggs from the poultry metabolism study performed with prothioconazole (56N the calculated max DB). Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Poultry edible offal	**0.1**	0.01*	The Codex MRL proposal is estimated from the total radioactive residues (TRR) observed in liver from the poultry metabolism study performed with prothioconazole (56N the calculated max DB). The Codex MRL in edible offal refers to prothioconazole-desthio. Conclusion: The proposed Codex MRL is acceptable
Poultry fats	0.01*	0.01*	Conclusion: The proposed Codex MRL is acceptable
Poultry meat	0.01*	0.01*	The Codex MRL proposal is estimated from the total radioactive residues (TRR) observed in muscle from the poultry metabolism study performed with prothioconazole (56N the calculated max DB). The Codex MRL refers to meat but is based on residues in muscle, thus acceptable for the EU food classification. Conclusion: The proposed Codex MRL is acceptable
General comments	Errors were noted that in the dietary burden calculations performed by JMPR for beef cattle: • the HR was inserted for cotton gin by-products (1.8 mg/kg) instead of the STMR (1.1 mg/kg) (see p. 702 of the JMPR report). • the input value for field corn silage/forage used was not correct (in 2017 JMPR used 3.6 mg/kg, whereas the value reported by the JMPR 2014 is 4.08 mg/kg, see p. 307 of 2014 JMPR Report). However, these mistakes are not expected to significantly change the result.		

CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues**;** EU: European Union.
(ft) EFSA identified some Information on residue trials on grass (major component of the livestock dietary burden), as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, of that information is not submitted by that date, the lack of it.
*: Indicates that the input value is proposed at the limit of quantification.

4.16.5. Consumer risk assessment – prothioconazole (Table 74)

Table 74: Summary of the consumer risk assessment for prothioconazole

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for cotton seed and for those animal commodities for which higher CXLs than the existing EU MRL were derived: mammalian fat and poultry liver, kidney and edible offal. The ARfD for prothioconazole desthio was used.	**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 cotton seed, mammalian fat and poultry liver, kidney and edible offal. The STMR values for those CXL proposals which were assessed by the JMPR in 2014 and implemented in the EU legislation in 2016 Reg. (EU) 2016/1902 were also included in the assessment (potatoes, maize, and cranberries). The input values for poultry liver and kidney were not multiplied by the default CF, as it is assumed that residues of all metabolites are already considered when deriving CXL (total TRR from metabolism studies). The STMR value for cotton seed was multiplied by the default CF of 2	**Specific comments** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure concern was identified (highest exposure 1.2% of the ARfD from intake of eggs). For cotton seed, no consumption data are available to assess the exposure	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 8% of the ADI	**Results:** Long-term exposure: 3% of the ADI Short-term exposure: 30% for women of childbearing age, 0% of the ARfD for children and general population

HR: highest residue; STMR: supervised trials median residue; CXL: Codex Maximum Residue limit; ADI: acceptable daily intake; ARfD: acute reference dose.

4.17. Spinetoram (233) (R)

4.17.1. Background information (Table 75)

Table 75: Background information on spinetoram

		Comments, references
Type of JMPR evaluation	New use	
RMS	UK	
Approval status	Approved	Commission Implementing Regulation (EU) No 140/2014[(a)]
EFSA conclusion	Yes, see comments	EFSA (2013f)
MRL review	No	Ongoing
MRL applications	Yes, see comments	EFSA (2017d) (various crop) EFSA (2012e) (cherries, raspberry, blueberry) EFSA (2009d) (import tolerance peach and apricots)

(a): 140/2014/EU: Commission Implementing Regulation (EU) No 140/2014 of 13 February 2014 approving the active substance spinetoram, 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 44, 14.2.2014, p. 35–39.

4.17.2. Toxicological reference values – spinetoram (Table 76)

Table 76: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR 2008	0.025 mg/kg bw per day	EFSA (2013f) (1-year dog, safety factor 100)	No
ARfD	unnecessary	JMPR 2008	0.1 mg/kg bw	EFSA (2013f) (1-year dog, safety factor 100)	No
Conclusion/ comment	The active substance assessed in the peer-review assessment (EFSA, 2013f) was defined as consisting of 70–90% of XDE-175-J and 10–30% of XDE-J-L. The toxicological reference values derived in the peer review were based on studies complying with this specification. A change of the ratio of constituents might lead to alterations of the toxicity of the duplication of the toxicological burden of the residues. In 2008, JMPR assessed spinetoram which was described as consisting of XDE-175-J and XDE-175-L approximately in a three to one ratio				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.17.3. Residue definitions – spinetoram (Table 77)

Table 77: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Spinetoram	Reg. 396/2005: Spinetoram (XDE-175) Peer review: XDE-175 (sum of XDE-175-J and XDE-175-L)	Yes
	Animal products	Spinetoram The residue is fat soluble	Reg. 396/2005: Spinetoram No definition agreed upon during peer review The residue is fat soluble	Yes
RD RA	Plant products	Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component	XDE-175 (Sum of XDE-175-J and XDE-175-L) and the N-demethyl-175-J and N-formyl-175-J metabolites, expressed as XDE-175	Yes
	Animal products	Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component	No definition agreed upon during peer review	No
Conclusion/comments		The residue definitions for plant products and the enforcement residue definition for animal products derived at EU level and by JMPR are identical. For animal origin commodities, no residue definition was derived under the EU process.		

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.17.4. Codex MRL proposals – spinetoram (Table 78)

Table 78: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of mandarin	0.15	0.2	Critical GAP: Brazil 3 × 25–100 g/ha PHI 1 day Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: Mandarins are a major crop in Codex, and therefore, at least 8 trials would be required. All trials were scaled down to match the GAP. Conclusion: The proposed Codex MRL is not sufficiently supported by data
Subgroup of cherries	0.09	2	Critical GAP: Italy, 1 × 100 g/ha PHI 7 days Number of trials: 12 residues trials from the EU, combining NEU (2 trials) and SEU. Sufficiently supported by data: Yes Specific comments/observations: The EU MRL was derived for a different GAP (2 × 75 g/ha, 3 days PHI) based on 7 SEU trials. Conclusion: The proposed Codex MRL is acceptable. However, the manufacturer should be encouraged to submit the most critical GAP, supported by the relevant data, to JMPR for assessment

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of plums (includesall commodities in this subgroup)	**0.09**	0.05*	Critical GAP: Italy 1 × 100 g/ha PHI 7 days. Number of trials: 10 trials approximating the GAP plus 11 trials with 3–4 applications of approximately 100 g/ha (assessed in 2012 by JMPR). Sufficiently supported by data: Yes Specific comments/observations: EFSA checked the trials reported in 2012 JMPR: in 6 of these trials, the samples did not contain quantifiable residues before the last treatment. Conclusion: To be discussed with MS if the proposed Codex MRL is acceptable, considering that not all trials exactly matched the GAP
Apricot	0.15	0.2	Critical GAP: Italy 1 × 100 g/ha PHI 7 days. Number of trials: 6, all trials with 2 instead of 1 application Sufficiently supported by data: Yes Specific comments/observations: For JMPR apricots are in crop category 2; thus, 4 trials are sufficient. In the EU, 8 trials would be required. 3 of the residue trials were decline studies where the residue concentration was also measured before the second application. Since the residues were below the LOQ, it was concluded that first applications do not have an impact on the final residue concentrations. Conclusion: The proposed Codex MRL is acceptable.
Currant, Black, Red, White	**0.5**	0.4	Critical GAP: USA 6 × 105 g/ha RTI 6 days PHI 3 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: The existing EU MRL was established for a different GAP (NEU/SEU, 2 × 60 g/ha, PHI 3 days) Conclusion: The proposed Codex MRL is acceptable.
Strawberry	0.15	0.20	Critical GAP: Brazil 4 × 50 g/ha PHI 3 days Number of trials: 24, combined data set of trials from BR and EU, indoor and outdoor. Sufficiently supported by data: Yes Specific comments/observations: Although in the EU, a different policy for merging trials from indoor and outdoor as well as from different geographic regions is in place; in this case, the Codex MRL proposal is considered to be sufficiently supported by data. The same MRL proposal would be derived using only Brazilian trials. Conclusion: The proposed Codex MRL is acceptable
Table olives	**0.07**	0.05*	Critical GAP: Greece, 2 × 25 g/ha PHI 21 days RTI 21 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Avocado	**0.3**	0.05*	Critical GAP: Australia 4 × 4.8 g/hL RTI 7–14 days, PHI 0 days Number of trials: 9 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: combination of residue data from Columbia and New Zealand. For all except two trials, the treatment regime in the residue trials differed significantly from the cGAP (e.g. 4 × 2.4 kg/hL, 3 × 4.0 to 3 × 7.3 kg/hL). From the information presented in the JMPR evaluation and the JMPR report, it is not clear how the scaling factors were calculated. Conclusion: From the available information it cannot be concluded if the proposed MRL is valid
Litchi	**0.06**	0.05*	Critical GAP: Thailand, 3 × 60 g/ha PHI 14 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
Mango	0.01*	0.05*	Critical GAP: Thailand 3 × 60 g/ha RTI 7 days PHI 14 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
Passion fruit	**0.4**	0.05*	Critical GAP: Australia 4 × 4.8 g/hL RTI 7–14 days PHI 0 days Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Passion fruit are a crop of category 2; thus, at least 4 trials would be required. Conclusion: The proposed Codex MRL is not acceptable because the minimum number of residue trials were insufficient
Leek	0.05	0.06	Critical GAP: EU, NL GAP 2 × 60 g/ha RTI 28 days PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The EU MRL was derived for the same GAP. The residue concentrations reported for the trials assessed in the EU are different (probably resulting from rounding/recalculation of the results). Conclusion: The proposed Codex MRL is acceptable
Subgroup of fruiting vegetables, cucurbits – cucumbers and Summer squashes (includes all commodities in this subgroup)	0.04	0.2 (cucurbits with edible peel)	Critical GAP (cucumber): Brazil, 4 × 50 g/ha PHI 3 days Critical GAP (summer squash): Australia, 4 × 48 g/ha PHI 3 days. Number of trials: 20 for cucumber and 12 for summer squash. Sufficiently supported by data: Sufficient data are available. Based on the European indoor trials on cucumbers (6 trials) and Specific comments/observations: MRL proposal was derived from merged data set (indoor and outdoor and Europe and Brazil trials). While merging indoor and outdoor trials is not common practice in the EU, the extrapolation from cucumbers and courgette (summer squash) to the whole group is acceptable in the EU. Conclusion: Overall, the proposed Codex MRL is acceptable
Melons, except watermelon	0.01*	0.05*	Critical GAP: Brazil, 4 × 40 g/ha PHI 3 days Number of trials: 8 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: Combination of residue trials (indoor outdoor) from Brazil and Europe. Application of proportionality in the case of the European trials. However, since application rates were > 50% higher than the maximum application rate. Conclusion: The proposed Codex MRL is acceptable
Subgroup of peppers (except martynia, okra and roselle)	0.4	0.5	Critical GAP: Brazil, 4 × 50 g/ha PHI 3 days Number of trials: Combination of indoor and outdoor residue trials performed in the EU and in Brazil. Total of 24 residue trials. Sufficiently supported by data: MRL proposal was derived from merged data set (indoor and outdoor Europe and Brazil on bell pepper and non-bell pepper). Merging indoor and outdoor trials is not common practice in the EU. Conclusion: Overall, the proposed Codex MRL is acceptable
Soya bean (dry)	0.01*	0.05*	Critical GAP: Brazil, 2 × 18 g/ha PHI 7 days Number of trials: 4 slightly overdosed trials Sufficiently supported by data: No Specific comments/observations: Although normally 8 trials would be required, considering that the MRL proposal is at the LOQ, the deviation may be acceptable. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Potato	0.01*	0.05*	Critical GAP: Brazil, 3 × 50 g/ha PHI 1 day Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: merged data set of trials from New Zealand and Brazil, reflecting slightly different application pattern. Although normally 8 trials would be required, considering that the MRL proposal is at the LOQ, the deviation may be acceptable. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Peppers, chili, dried	4		Critical GAP: See Peppers. The default processing factor of 10 was applied. It is noted that for trials on chili peppers, the default dehydration factor of 7 should have been used
Husked rice	0.02*	0.05*	Critical GAP: China, 2 × 27 g/ha PHI 21 days. Number of trials: 6 Sufficiently supported by data: No. Specific comments/observations: Since rice is a major crop, at least 8 trials would be required. Considering that the MRL proposal is at the LOQ, the deviation may be acceptable. The trials did not completely match the critical GAP (shorter PHI of 14 days). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Maize	0.01*	0.05*	Critical GAP: Brazil 3 × 12 g/ha PHI 7 days Number of trials: 4 Sufficiently supported by data: No, same as above. No enough residue trials worldwide. Specific comments/observations Since maize is a major crop, at least 8 trials would be required. Considering that the MRL proposal is at the LOQ, the deviation may be acceptable. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Sweet corn (Corn on the cob) (kernels plus cob with husk removed)	0.01*	0.05*	Critical GAP: Australia, 4 × 48 g/ha PHI 3 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: No residue situation has been reported.Conclusion: The proposed Codex MRL is acceptable
Cotton seed	0.01*	0.05*	Critical GAP: Brazil, 4 × 18 g/ha, PHI 7 days Number of trials: 19. Sufficiently supported by data: Yes Specific comments/observations: combination of residue trials from Brazil matching the GAP and Greece, reflecting different use pattern (2 app at 60 g/ha). Considering that the MRL proposal is at the LOQ, the deviation of the trials may be acceptableConclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Milks	**0.02**	0.01*	The dietary burden calculation took into account the uses assessed by JMPR in 2017 and crops for which CXLs were established previously. However, JMPR should be asked for clarifications, why cabbage/kale was not included in the dietary burden calculation. The Codex MRL proposal was derived from a feeding study 4N higher than the calculated dietary burden. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Milk fats	0.15		See comments on dietary burden calculation (milks). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Meat (from mammals other than marine mammals)	**1 (fat)**	0.01*	Sufficiently supported by data: Yes Specific comments/observations: See comments on dietary burden calculation (milks). In the EU, an MRL should also be established for muscle. For muscle, an MRL of 0.06 mg/kg would be appropriate if the updated dietary burden does not differ significantly from the one used by JMPR in 2017. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. If the dietary burden calculation is verified, the proposed Codex MRL is acceptable
Edible offal (mammalian)	**0.08**	0.01* (edible offal and kidney and liver)	Sufficiently supported by data: Yes Specific comments/observations: See comments on dietary burden calculation (milks). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	**1**	0.2	Sufficiently supported by data: Yes Specific comments/observations: See comments on dietary burden calculation (milks). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Persimmons	0.05	0.05*	Critical GAP: Australia 4 × 4.8 g/hL RTI 14 days PHI 0 days Number of trials: 2 Sufficiently supported by data: No Specific comments/observations: JMPR noted that the existing CXL for pome fruit (0.05 mg/kg) covers also persimmon. Since the GAP for persimmon is different from the GAP used to derive the MRL in pomefruit, an extrapolation of the MRL is not appropriate.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: To be discussed with MS whether the existing CXL for pome fruit should be taken over in the EU legislation for persimmon (e.g. in the framework of the MRL review)
Poultry meat	0.01* (fat)	0.01	Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal was derived from a metabolism study in poultry, performed at a significantly higher dose rate than the calculated dietary burden (160 N rate). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, since the residues may not increase proportionally to the dosing rate
Poultry, edible offal	0.01*	0.01* (edible offals and kidney and liver)	See comments on poultry meat
Poultry fats	0.01*	0.01*	See comments on poultry meat
Eggs	0.01*	0.01*	See comments on poultry meat
Rice straw and fodder, dry	1.5		Critical GAP: China GAP Number of trials: 6 Sufficiently supported by data: Yes
Sweet corn fodder	0.15		Critical GAP: Australia GAP Number of trials: 4 Sufficiently supported by data: Yes

PHI: preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; GAP: Good Agricultural Practice; PF: processing factor; NEU: northern European Union; HR: highest residue; LOQ: limit of quantification.
*: Indicates that the input value is proposed at the limit of quantification.

4.17.5. Consumer risk assessment – spinetoram (Table 79)

Table 79: Summary of the consumer risk assessment for spinetoram

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for those commodities where the CXLs proposal is higher than the existing EU MRL as outlined in Section 4.17.2. HR values were retrieved from the residue trials presented in the JMPR report. The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2017d) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for those commodities that will impact in the EU consumer exposure in case that the CXL is implemented in the EU regulation. Input values for meat were expressed in terms of meat (80% muscle and 20% fat). The EU ADI was used	**Specific comments**
Results: No short-term exposure concern was identified. (Max. 7.3% of ARfD for avocados)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for approximately 50% of the ADI, being the German children the most critical diet.	**Results:** Long-term exposure: 0.2–3% of the ADI Short-term exposure: Not performed. No ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; CXL: Codex Maximum Residue Limit.

4.18. Fluopyram (243) (R)

4.18.1. Background information (Table 80)

Table 80: Background information on fluopyram

		Comments, references
Type of JMPR evaluation	New use	
RMS	DE	
Approval status	Approved	Commission Implementing Regulation (EU) 802/2013[(a)]
EFSA conclusion	Yes, see comments	EFSA (2013b) EFSA (2018a) (confirmatory data)
MRL review	No	Ongoing
MRL applications	Yes, see comments	EFSA (2017i) (purslanes)
		EFSA (2016o) (various crop) EFSA (2014t) (various crop) EFSA (2011f) (import tolerance various crops)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit.

(a): 802/2013/EU: Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, 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 225, 23.8.2013, p. 13–16.

4.18.2. Toxicological reference values – fluopyram (Table 81)

Table 81: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0–0.01 mg/kg bw per day	JMPR 2010	0.012 mg/kg bw per day	EFSA (2013b) (2-yr, rat, safety factor 100) confirmed in European Commission (2013)	No
ARfD	0.5 mg/kg bw	JMPR 2010	0.5 mg/kg bw	EFSA (2013b) (Acute neurotoxicity, rat, safety factor 100) confirmed in European Commission (2013)	Yes
Conclusion/ comment	The ADI values differ only slightly; the ARfD values of JMPR and EU are identical.				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.18.3. Residue definitions – fluopyram (Table 82)

Table 82: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fluopyram	Fluopyram	Yes
	Animal products	Sum of fluopyram and 2-(trifluoromethyl) benzamide (M25), expressed as fluopyram The residue is not fat soluble	Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram The residue is not fat soluble	Yes
RD RA	Plant products	Fluopyram	Sum fluopyram and fluopyram-benzamide (M25), expressed as fluopyram	No
	Animal products	Sum of fluopyram, 2-(trifluoromethyl)benzamide (M25) and the combined residues of N-{(*E*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl] ethenyl}-2-trifluoromethyl) benzamide (M02) and N-{(Z)-2-[3-chloro-5-(trifluoromethyl) pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide (M03), all expressed as fluopyram.	Sum fluopyram, fluopyram-benzamide (M25), fluopyram-E/Z-olefine (M02/M03), expressed as fluopyram	Yes
Conclusion/ comments	The residue definitions for enforcement (plant and animal commodities) derived by JMPR and applicable in the EU are identical. Thus, the Codex MRLs are compatible with the EU legal framework. As regards the residue definition for risk assessment for plants, the EU residue definition is wider. It is noted that metabolite M25 was observed at important proportions in the metabolism study in beans. At EU level, a conversion factor was derived for fruit crops (1.1), peas without pods (1.5), peas/beans with pods, oilseeds and stem vegetables (1.2). The lack of conversion factors introduces an uncertainty in the exposure calculations and the consumer risk assessment should be considered as tentative and may underestimate the actual exposure for plant products for which JMPR derived MRL proposals that are higher than the existing EU MRLs. Rotational crop studies in cereals, leafy vegetables and roots were assessed in the peer review (EFSA, 2013b). Fluopyram and the metabolites resulting from the cleavage of the parent (fluopyram-benzamide (M25) and fluopyram-PCA (M43)) major components of the residues in rotational crops. 7-hydroxy metabolites observed in higher proportions than in primary crops. Residues in rotational crops cannot be excluded. (Default MRL proposals have been made for root/tuber and leafy crops (0.1 mg/kg), cereals, oilseeds and perennial crops (0.01*)		

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.
*: Indicates that the input value is proposed at the limit of quantification.

4.18.4. Codex MRL proposals – fluopyram (Table 83)

Table 83: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Artichoke, globe	0.4	0.5	Critical GAP: Greek GAP 3 × 0.075 kg/ha PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The critical GAP is reported from EU; however, the EU MRL higher than CXL proposal. Conclusion: The proposed Codex MRL is acceptable.
Barley	0.2	0.2	Critical GAP: EU GAP (Estonia) 1 × 0.078 kg/ha BBCH max 61 Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: The CXL proposal and the EU MRL are the same. Conclusion: The proposed Codex MRL is acceptable.
Barley/oat forage (straw) and fodder (hay)	2		Number of trials: 12 Sufficiently supported by data: Yes
Basil	**70**	8	Critical GAP: Canada 2 × 0.25 kg/ha PHI 0 days Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Basil is a category 2 crop, thus, at least 4 trials are required. Conclusion: The proposed Codex MRL is not acceptable because the number of trials is insufficient
Basil, dry	400		The MRL proposal was derived from 3 trials where the leaves were dried on the field.
Bean fodder	70		Critical GAP: Canada 2 × 0.25 kg/ha PHI 0 days Number of trials: 9 Sufficiently supported by data: Yes
Beans (dry)	W0.07		The previous CXL will be covered by the proposed CXL for the Subgroup of Dry Beans
Blackberries	W3	3	The previous CXL will be covered by the proposed CXL for the Subgroup of Cane berries
Cherry tomato	0.4	0.9	Sufficiently supported by data: Yes Specific comments/observations: See tomatoes section. The EU MRL covers this residue situation. Conclusion: The proposed Codex MRL is acceptable.
Chickpea (dry)	W0.07		The previous CXL will be covered by the CXL proposal for the grouping of Dry Peas
Cottonseed	**0.8**	0.02*	Critical GAP: USA seed treatment (max. 0.35 mg/seed) combined with soil treatment and foliar treatment (max. 0.5 kg/ha), PHI 30 days Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: - Conclusion: The proposed Codex MRL is acceptable.
Cotton gin trash	30		Critical GAP: USA GAP (above) Number of trials: 6 Sufficiently supported by data: Yes
Dill seed	**70**	0.05*	Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: - Conclusion: The proposed Codex MRL is acceptable.

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (mammalian)	**8**	0.7 Kidney: 0.8 except 0.7 for equine Liver: 5 except equine 0.7	Sufficiently supported by data: Yes Specific comments/observations: The maximum dietary burden for ruminants was calculated for the Australian diet. The Codex MRL proposal was based on the residues in liver expected at the calculated dietary burden. Conclusion: The proposed Codex MRL is acceptable
Eggs	**2**	1	Sufficiently supported by data: Yes Specific comments/observations: The maximum dietary burden for poultry was calculated for the EU diet. Since the calculated dietary burden exceeds the highest feeding level, the MRL proposals for poultry tissues and eggs were derived from the interpolation from the residues detected in a feeding study at the highest feeding level and the residues of a metabolism study in poultry (expected residue at DB= 1.3 mg/kg). According to EFSA, a MRL of 1.5 mg/kg would be sufficient. Conclusion: It is recommended to discuss with MS whether a lower MRL would be more appropriate
Hops (dry)	**50**	3	Critical GAP: USA 2 × 0.25 kg/ha PHI 7 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: - Conclusion: The proposed Codex MRL is acceptable
Kidney of cattle, goats, pigs and sheep	W0.8	Kidney: 0.8 except 0.7 for equine	
Lentil (dry)	W0.07		The previous CXL is suggested for withdrawal
Liver of cattle, goats, pigs and sheep	W5	Liver: 5 except equine 0.7	Sufficiently supported by data: Yes Specific comments/observations: See edible offal (mammalian) comment. Conclusion: The proposed Codex MRL is acceptable.
Lupin (dry)	W0.07		The previous CXL will be covered by the CXL proposal for the grouping of Dry Peas.
Maize fodder (stover)	18		Critical GAP: Based on the USA critical GAP for grain cereals 2 × 0.25/ha PHI 14 days. Samples for stover taken at 12–14 days. Number of trials: 14 Sufficiently supported by data: Yes
Maize forage	2		Critical GAP: Based on the USA critical GAP for grain cereals 2 × 0.25/ha PHI 14 days Number of trials: 3
Mammalian fat	**1.5**	0.5	Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable.
Mango	**1**	0.01*	Critical GAP: Malaysia 2 × 0.15 kg/hL Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Data to derive a peeling factor of 0.11 were available to derive HR and STMR for edible portion. Conclusion: The proposed Codex MRL is acceptable.
Meat (from mammals other than marine mammals)	**1.5**	0.8	Sufficiently supported by data: Yes At the maximum dietary burden, the residues expected in muscle are 1 mg/kg. Conclusion: Since at EU level the MRL is established for muscle and not for meat, the Codex MRL proposal is not compatible with the EU system. The feeding study would allow to derive an MRL for muscle (i.e. 1 mg/kg)

Commodity	Codex MRL proposal	EU MRL	Comment
Milks	**0.8**	0.6	Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is not acceptable because it caused a exceedance of the ADI (see below chronic risk assessment)
Oat straw and fodder, dry	2		Critical GAP: EU GAP 1 × 0.078 kg/ha BBCH max 61 Number of trials: 12 Sufficiently supported by data: Yes
Oats	0.2	0.2	Critical GAP: EU GAP 1 × 0.078 kg/ha BBCH max 61Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: See also barley. Conclusion: The proposed Codex MRL is acceptable
Onion, Welsh	**2**	2	Critical GAP: Greece 1 × 0.16 kg/ha PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: In the EU food classification, Welsh onions and spring onions are covered by the same food code. Conclusion: The proposed Codex MRL is acceptable.
Pea vines, pea fodder (dry), Pea hay	100		Critical GAP: Canada 2 × 0.25 kg/ha PHI 14 days Number of trials: 5 Sufficiently supported by data: Yes
Peanut	**0.2**	0.03	Critical GAP: USA, seed treatment (0.35 mg ai/seed) and/or foliar application (0.25 kg ai/ha). Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: Treated crops should not be used to feed livestock according to the label of the critical GAP. Conclusion: The proposed Codex MRL is acceptable.
Peanut fodder (hay)	47		Critical GAP: Canada, 2 × 0.25 kg/ha PHI 7 days Number of trials: 13 Sufficiently supported by data: Yes
Peppers Chili, dried	30		Critical GAP: USA 2 × 0.25 kg/ha PHI 0 days Number of trials: 9 trials on sweet peppers Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal was derived applying the default dehydration factor of 10. Conclusion: No MRLs are set in the EU for processed products.
Potato	**0.15**	0.1	Critical GAP: USA soil application 1 in furrow soil treatment (0.25 kg/ha) + 1 foliar use (1 × 0.25 kg/ha), PHI 7 days Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Poultry fat	**1**	0.2	Specific comments/observations: See eggs section. No health concern has been identified for EU consumers Conclusion: The proposed Codex MRL is acceptable
Poultry meat	**1.5**	0.5	Specific comments/observations: See eggs section. No health concern has been identified for EU consumers. Conclusion: Since at EU level the MRL is established for muscle and not for meat, the Codex MRL proposal is not compatible with the EU system The available feeding study would allow to derive a MRL proposal for muscle (i.e. 1 mg/kg)

Commodity	Codex MRL proposal	EU MRL	Comment
Poultry, Edible offal of	**5**	2 (edible offal and liver and kidney)	Specific comments/observations: See eggs section. No health concern has been identified for EU consumers Conclusion: A lower MRL of 3 mg/kg might be sufficient
Pummelo and grapefruits (including Shaddock-like hybrids, among others grapefruit)	**0.4**	0.01*	Critical GAP: USA 2 × 0.25 kg/ha PHI 7 daysNumber of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Raspberries, red, black	W3	3	The previous CXL will be covered by the proposed CXL for the Subgroup of Cane berries.
Rice	**4**	0.01*	Critical GAP: Thailand 2 × 0.024 kg/hL (up to BBCH 59) Number of trials: 8 trials in rice grain Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal refers to cereal grain (GC 0649). No processing data are available that could be used to recalculate the MRL proposal to husked rice. Conclusion: The proposed Codex MRL is acceptable. The MRL proposal is however not compatible with the EU food classification (MRLs are set for husked rice)
Rice straw and fodder, dry	17		Critical GAP: Thailand 2 × 0.024 kg/hL (up to BBCH 59) Number of trials: 10 Sufficiently supported by data: Yes
Rye	**0.9**	0.8	Sufficiently supported by data: Yes Specific comments/observations: Extrapolated from wheat Conclusion: The proposed Codex MRL is acceptable.
Rye straw and fodder, dry	23		Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 15/16 Sufficiently supported by data: Yes
Soya bean (dry)	0.3	0.2	Critical GAP: USA/CAN, 2 × 250 g/ha, PHI 14 days Number of trials: 20 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Soya bean fodder	35		Critical GAP: Canada 2 × 0.25 kg/ha PHI 7 days Number of trials: 19 Sufficiently supported by data: Yes
Spring onion	**15**	2	Critical GAP: USA/Canada 2 × 0.25 kg/ha PHI 0 days Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Not enough residue trials to be compliant with EU requirements; according to JMPR rules, at least 5 trials would be required. Conclusion: The proposed Codex MRL is not acceptable because the number of residue trials is not sufficient. However, the MRL proposal for Welsh onions is sufficiently supported
Subgroup of bush berries (includes all commodities in this subgroup)	**7**	3	Critical GAP: USA/Canada 2 × 0.25 kg/ha PHI 0 days Number of trials: 8 trials in blueberries Sufficiently supported by data: Yes for JMPR; in the EU, trials on blueberries would not be used to extrapolate to the whole group of bush berries (the main crops of this group are blueberries, currants, gooseberries, rose hips); instead trials in currants or a mixed data set of currants and other small fruit trials would be required to set an MRL for the EU crop group of small fruit and berries.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Subgroup of cane berries(includes all commodities in this subgroup)	**5**	3	Critical GAP: USA/Canada 2 × 0.25 kg/ha PHI 0 days Number of trials: 5 is raspberries, boysenberries and blackberries Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Subgroup of cherries (includes all commodities in this subgroup)	**2**	1.5	Critical GAP: USA 2 × 0.25 kg/ha PHI 0 days Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: Cherries are a major crop in Codex (crop for which refinement criteria applied) and in the EU. Thus, a minimum of 8 residue trials is needed. Conclusion: The proposed Codex MRL is not acceptable because it is not sufficiently supported by data
Subgroup of dry beans (except Soya bean (dry))	0.15	0.4	Critical GAP: USA/CAN, 2 × 250 g/ha, PHI 14 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: EU MRL is an import tolerance for a US/CAN GAP (6 × 250 g/ha, 14 days PHI). Conclusion: The existing EU MRL should be lowered, since it is based on a GAP that apparently is no longer valid
Subgroup of dry peas(includes all commodities in this subgroup)	**0.7**	0.4	Critical GAP: Canada 2 × 0.25 kg/has PHI 14 days Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: Peas are considered a major crop and residue data should be supported by 8 residue trials. The existing EU MRL is an import tolerance for a US/CAN GAP (6 × 250 g/ha, 14 days PHI). It seems strange that for the less critical GAP assessed by JMPR, a significantly higher MRL was derived. Conclusion: The proposed Codex MRL is not acceptable because of insufficient data
Subgroup of eggplants(includes all commodities in this subgroup)	0.5	0.9 (eggplants) while for tomato:0.9 and Sweet peppers/ bell peppers 2	Critical GAP: USA GAP (2 × 0.25 mg/kg PHI 0 days). Number of trials: 11 trials on tomatoes Sufficiently supported by data: Yes Specific comments/observations: Extrapolation from tomatoes to aubergines is also acceptable at EU level.Conclusion: The proposed Codex MRL is acceptable
Subgroup of lemons and limes (includes allcommodities in this subgroup)	**1**	0.01*	Critical GAP: USA 2 × 0.25 kg/ha PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Subgroup of maize cereals(includes all commodities in this subgroup)	0.02	0.02 maize, 0.01* millet, 1.5 sorghum,	Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: The subgroup of maize cereals covers also millet and sorghum. Conclusion: The proposed Codex MRL is acceptable.
Subgroup of mandarins(includes all commodities in this subgroup)	**0.6**	0.01*	Critical GAP: USA 2 × 0.25 kg/ha PHI 7 daysNumber of trials: 8 trials in oranges, 2 trials in mandarins. Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of oranges, sweet, sour (includes all commodities in this subgroup)	**0.6**	0.01*	Critical GAP: USA 2 × 0.25 kg/ha PHI 7 daysNumber of trials: 8 trials on oranges, 2 trials in mandarins Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Subgroup of peppers (except martynia, okra, roselle)	**3**	2 pepper 0.01* okra,	Critical GAP: USA 2 × 0.25 kg/ha PHI 0 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL for subgroup of peppers covers also okra which is a separate crop in the EU food classification. Extrapolation from peppers to okra is compliant with EU extrapolation rules. Conclusion: The proposed Codex MRL is acceptable.
Sunflower seed	**0.7**	0.3	Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Sweet corn (Corn on the cob) (kernels plus cob with husk removed)	0.01*	0.01*	Critical GAP: GAP for maize and sweet corn in HU 2 × 0.125 kg/ha PHI 14 days Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Tomato	0.5	0.9	Critical GAP: USA 2 × 0.25 kg/ha PHI 0 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Triticale	**0.9**	0.8 (wheat)	Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 15 (trials on wheat) Sufficiently supported by data: Yes Specific comments/observations: Extrapolated from residue trials on wheat which is acceptable. Conclusion: The proposed Codex MRL is acceptable.
Triticale straw and fodder, dry	23		Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 15/16 Sufficiently supported by data: Yes
Wheat	**0.9**	0.8	Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Wheat straw and fodder, dry	23		Critical GAP: USA 2 × 0.25 kg/ha PHI 14 days Number of trials: 15/16 Sufficiently supported by data: Yes
Witloof chicory (sprouts)	0.15	0.30	Critical GAP: EU GAP (Belgium) including preplant root dip 0.01 kg/hL + preforcing root collar spray 0.5 g/sq. meter, PHI 21 days Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: The EU MRL was derived from 4 residue trials which seemed to be different than the trials provided to JMPR. Manufactures should be encouraged to submit all available data to avoid different conclusions at EU and JMPR level.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs.
Cottonseed oil (refined)	None		Processing factor: < 0.01 Number of studies to derive the PF: 1
Cottonseed meal	None		Processing factor: 0.022 Number of studies to derive the PF: 1
Maize bran	None		Processing factor: 2.7 Number of studies to derive the PF: 1
Maize flour	None		Processing factor: 0.85 Number of studies to derive the PF: 1
Maize grits	None		Processing factor: 0.51 Number of studies to derive the PF: 1
Maize meal	None		Processing factor: 0.81 Number of studies to derive the PF: 1
Maize oil (dry milled)	None		Processing factor: < 0.36 Number of studies to derive the PF: 1
Maize oil (wet milled)	None		Processing factor: 0.58 Number of studies to derive the PF: 1
Maize starch	None		Processing factor: 0.36 Number of studies to derive the PF: 1
Orange juice	None		Processing factor: 0.01 Number of studies to derive the PF: 1
Orange oil, edible	None		Processing factor: 16 Number of studies to derive the PF: 1
Orange peel	None		Processing factor: 1.8 Number of studies to derive the PF: 1
Orange flesh	None		Processing factor: 0.16 Number of studies to derive the PF: 1
Peanut butter	None		Processing factor: 0.22 Number of studies to derive the PF: 1
Peanut meal	None		Processing factor: 0.19 Number of studies to derive the PF: 1
Peanut oil	None		Processing factor: 0.01 Number of studies to derive the PF: 1
Potato (peeled)	None		Processing factor: < 0.64 Number of studies to derive the PF: 1
Potato chips (crisps)	None		Processing factor: < 0.64 Number of studies to derive the PF: 1
Potato flakes	None		Processing factor: 1 Number of studies to derive the PF: 1
Potato wet peel	None		Processing factor: 4.3 Number of studies to derive the PF: 1
Rice bran, unprocessed	None		Processing factor: 1.1 Number of studies to derive the PF: 2
Rice hulls	None		Processing factor: 2 Number of studies to derive the PF:2
Rice, cooked	None		Processing factor: 0.04 Number of studies to derive the PF:2
Rice, Polished	None		Processing factor: 0.11 Number of studies to derive the PF: 2
Soya bean asp grain fraction	None		Processing factor: 223 Number of studies to derive the PF: 1

Commodity	Codex MRL proposal	EU MRL	Comment
Soya bean flour	None		Processing factor: 0.04 Number of studies to derive the PF: 1
Soya bean meal	None		Processing factor: 0.05 Number of studies to derive the PF: 1
Soya bean milk	None		Processing factor: < 0.02 Number of studies to derive the PF: 1
Soya bean oil	None		Processing factor: 0.02 Number of studies to derive the PF: 1
Sunflower seed oil (refined)	None		Processing factor: < 0.01 Number of studies to derive the PF: 1
Sunflower seed meal	None		Processing factor: 0.02 Number of studies to derive the PF: 1
Tomato juice	None		Processing factor: 0.36 Number of studies to derive the PF: 5
Tomato paste	None		Processing factor: 0.46 Number of studies to derive the PF: 1
Tomato preserve	None		Processing factor: 0.21 Number of studies to derive the PF: 5
Tomato puree	None		Processing factor: 0.73 Number of studies to derive the PF: 5
Tomato pulp	None		Processing factor: 0.1 Number of studies to derive the PF: 4
Wheat bran, Processed	None		Processing factor:2.7 Number of studies to derive the PF:1
Wheat flour	None		Processing factor: 0.12 Number of studies to derive the PF: 1
Wheat germ	None		Processing factor: 2.4 Number of studies to derive the PF: 1

GAP: Good Agricultural Practice; MRL: maximum residue limit; PHI: preharvest interval.
*: Indicates that the input value is proposed at the limit of quantification.

4.18.5. Consumer risk assessment – fluopyram (Table 84)

Table 84: Summary of the consumer risk assessment for fluopyram

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for those plant and animal origin commodities for which higher Codex MRL proposals than the existing EU MRLs were derived, as outlined in Section 4.18.2. HR residue values were used for the exposure calculations. Conversion factors have been used to accommodate residue values in the PRIMo according to the risk assessment residue definition (1.1 for fruit, 1.2 for oilseeds) The residues conversion from enforcement to risk assessment residue definitions has not been done for the rest of the plant origin commodities due to the lack of reliable CFs. In those	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2017i) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for those commodities were the CXL is higher than the existing EU MRL. I.e. Basil, cottonseeds, dill seeds, mammals tissues, milk, poultry tissues, eggs, hops, mango, peanuts, potatoes, citrus fruits, rye, bush berries, cane fruits, cherries, peas, peppers, sunflower seeds, triticale and wheat. STMR values for those commodities under the fruit crop group were converted into the risk assessment residue definition to perform a more accurate risk assessment. Due to the lack of reliable conversion factors for the rest of the food commodities, the risk assessment needs to be considered in tentative basis.	**Specific comments** None

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
cases, the risk assessment needs to be considered in tentative basis. The EU ARfD was used	Where EU MRL and the CXL proposal are the same, but STMR values differ, the STMRs derived during the EU process have been used for the exposure calculations and risk assessment. Those cases were peppers and oat/barley. The EU ADI was used	
Results: No short-term exposure concern was identified (max. 18% of the ARfD; peppers). For dill seeds, no consumption data are available; therefore, the exposure was no calculated. Risk not assessed	**Results:** A long-term consumer health risk was identified. The overall chronic exposure accounted for 205% of the ADI. The food item contributing the most to the most critical diet and for which a CXL has been proposed was milk representing the 158% of the ADI	**Results:** Long-term exposure: Max. 80% of the ADI Short-term exposure: 10% of the ARfD (milk) 100% of the ARfD (lettuce) – not under assessment

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; HR: highest residue; STMR: supervised trials median residue; EU MRL: European Union maximum residue limit.

4.19. Acetamiprid (246) (T)

4.19.1. Background information (Table 85)

Table 85: Background information on acetamiprid

		Comments, references
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) 2016/2016[(a)]
EFSA conclusion	Yes, see comments	EFSA (2016q)
MRL review	Yes, see comments	EFSA (2011d)
MRL applications	Yes, see comments	EFSA (2016b) (various crops) EFSA (2015k) (leafy Brassicacea) EFSA (2014o) (banana) EFSA (2013l) (apricots and tree nuts) EFSA (2012j) (in purslane, legume vegetables and pulses) Ongoing for: • Art. 10 barley and oats • Art. 10 Table olives and oil • Art. 43

MRL: maximum residue limit; RMS: rapporteur Member State.

(a): 2016/2016/EU: Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flazasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, Pseudomonas chlororaphis Strain: MA 342, pyraclostrobin, quinoxyfen, thiacloprid, thiram, ziram, zoxamide. OJ L 312, 18.11.2016, p. 21–23.

4.19.2. Toxicological reference values – acetamiprid (Table 86)

Table 86: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.07 mg/kg bw per day	JMPR, 2011	0.025 mg/kg bw per day	EFSA (2016q) (rat, developmental neurotoxicity study, uncertainty factor 100)	No
ARfD	0.1 mg/kg bw	JMPR, 2011	0.025 mg/kg bw	EFSA (2016q) (rat, developmental neurotoxicity study, uncertainty factor 100)	No
Conclusion/ comment	Following a request from CCPR, acetamiprid was on the agenda for follow-up evaluation for toxicology. However, no relevant new data were provided to JMPR				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.19.3. Residue definitions – acetamiprid (Table 87)

Table 87: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Acetamiprid	Acetamiprid	Yes
	Animal products	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid. The residue is not fat soluble	Reg. 396/2005: Acetamiprid Peer review: Metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid The residue is not fat soluble	No
RD RA	Plant products	Acetamiprid	Acetamiprid	Yes
	Animal products	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid	Yes
Conclusion/ comments	–			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.19.4. Codex MRL proposals – acetamiprid (Table 88)

Table 88: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Pistachios	–	0.07	Critical GAP: Iran – Foliar spray, 3 × 0.05 kg a.s./ha (Interval between applications: 20–30 days), PHI not specified. Number of trials: 4 Sufficiently supported by data: No Specific comments/observations: The submitted residue trials were not compliant with the supported GAP; these were performed with 3 applications at 0.05 kg a.s./ha (time interval: 29–60 days) and a PHI of 28–30 days. No Codex MRL was proposed. It is noted that, in 2011, a CXL of 0.06 mg/kg was established for tree nuts (including pistachios) for the same GAP as the EU MRL
General comments	Further clarification on the proposed GAP on pistachio nuts should be provided either on the BBCH growth stage at which the applications take place or on the PHI		

PHI: preharvest interval; MRL: maximum residue limit; CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice.

4.19.5. Consumer risk assessment – acetamiprid

No risk assessment was required since JMPR did not derive a MRL proposal.

4.20. Isopyrazam (249) (R)

4.20.1. Background information (Table 89)

Table 89: Background information on isopyrazam

		Comments, references
Type of JMPR evaluation	New use	
RMS	NO	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/1106[(a)] [candidate for substitution – two PBT criteria]
EFSA conclusion	Yes, see comments	EFSA (2012c)
MRL review	No	On-going
MRL applications	Yes, see comments	EFSA (2015b) (fruiting vegetables)
		EFSA (2013h) (various vegetables) EFSA (2013c) (various crops) EFSA (2011b) (banana) EFSA (2010g) (cereals and animal origin)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

(a): 2015/1106/EU: Commission Implementing Regulation (EU) 2015/1106 of 8 July 2015 amending Implementing Regulations (EU) No 540/2011 and (EU) No 1037/2012 as regards the conditions of approval of the active substance isopyrazam. OJ L 181, 9.7.2015, p. 70–71.

4.20.2. Toxicological reference values – isopyrazam (Table 90)

Table 90: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.06 mg/kg bw per day	JMPR, 2011	0.03 mg/kg bw/day, applicable to isopyrazam containing up to 50% anti-isomers and to metabolites CSCD656800, CSCD459488, CSCD459489, CSCD465008, CSCD591489 and CSCD563692	EFSA (2012c) (rat, 2-year study, safety factor of 200) confirmed by European Commission (2012b)	No
ARfD	0.3 mg/kg bw	JMPR, 2011	0.2 mg/kg bw, applicable to isopyrazam containing up to 50% anti-isomers and to metabolites CSCD656800, CSCD459488, CSCD459489, CSCD465008, CSCD591489 and CSCD563692	EFSA (2012c) (rat, developmental toxicity study, safety factor of 100) confirmed by European Commission (2012b)	No
Conclusion/ comment	–				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.20.3. Residue definitions – isopyrazam (Table 91)

Table 91: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Isopyrazam (sum of syn-isomer and anti-isomer)	Isopyrazam (sum of isomers)	Yes
	Animal products	Isopyrazam (sum of syn-isomer and anti-isomer). The residue is fat soluble	Isopyrazam (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1*RS*, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl] amide (CSCD459488), expressed as isopyrazam	Isopyrazam (sum of isomers) plus its metabolite CSCD459488 [*syn*- hydroxyl isopyrazam] (free and conjugated), expressed as isopyrazam	No
	Animal products	Isopyrazam (sum of syn-isomer and anti-isomer).	Isopyrazam (sum of isomers) plus all its metabolites containing the CSAA798670 moiety [3-(difluromethyl)-1-methyl-pyrazole-4-methanoic acid] expressed as Isopyrazam	No
Conclusion/ comments	The residue definitions for enforcement are identical. Due to the difference of the residue definitions for risk assessment derived by JMPR and applicable in the EU, the dietary exposure/ risk assessment is affected by uncertainties and allows only a tentative risk assessment. However, considering that the existing EU MRLs are in general higher than the proposed Codex MRL proposals, this uncertainty is of minor relevance			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.20.4. Codex MRL proposals – isopyrazam (Table 92)

Table 92: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Group of Pome fruits(includes all commodities in this group)	0.4	0.7 (EU pome fruit group); 0.01* kaki, azaroles	Critical GAP: 2 foliar applications of 150 g ai/ha with a PHI of 21 days (Chile) Number of trials: 16 trials on apples Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal for pome fruit applies also to azaroles and kaki, which do not belong in the pome fruit category according to the EU classification. Conclusion: The proposed Codex MRL is acceptable
Cucumber	0.06	0.4	Critical GAP: 2 foliar applications at a rate of 12.5 g ai/hL, up to 1,000 L/ha (maximum of 125 g ai/ha) with a PHI of 1 day (protected – indoor use, United Kingdom) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The trials were conducted in cucumber (indoor). Conclusion: The proposed Codex MRL is acceptable
Melon, except watermelon	0.15	0.3	Critical GAP: 2 foliar applications at rate of 12.5 g ai/hL, up to 1,000 L/ha (maximum of 125 g ai/ha) with a PHI of 7 days (protected – indoor use, United Kingdom) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Trials conducted in melons (indoor). Residues of isopyrazam were analysed in the whole fruit (n = 8) and melons flesh (n = 8). STMR of 0.015 mg/kg and HR of 0.015 mg/kg for melon flesh were estimated. Conclusion: The proposed Codex MRL is acceptable
Peppers, sweet (including pimento or pimiento)	0.09	0.09	Critical GAP: 2 foliar applications at rate of 12.5 g ai/hL, up to 1,000 L/ha (maximum of 125 g ai/ha) with a PHI of 3 days (protected – indoor use, United Kingdom) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Trials conducted in peppers (indoor). Conclusion: The proposed Codex MRL is acceptable
Cherry tomato	0.4	0.5 (tomato)	Critical GAP: 2 foliar applications at rate of 12.5 g ai/hL, up to 1000 L/ha (maximum of 125 g ai/ha) with a PHI of 1 day (protected – indoor use, United Kingdom) Number of trials: 8 (trials conducted in cherry tomato) Sufficiently supported by data: Yes Specific comments/observations: Trials were done in cherry tomato (indoor). In the EU, no separate MRLs are established for cherry tomatoes. Thus, this MRL proposal would be applicable to all tomatoes. Conclusion: The proposed Codex MRL is acceptable.
Tomato	0.4	0.5	Critical GAP: 2 foliar applications at rate of 12.5 g ai/hL, up to 1,000 L/ha (maximum of 125 g ai/ha) with a PHI of 1 day (protected – indoor use, United Kingdom) Number of trials: 8 (trials conducted in cherry tomato) Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal derived for cherry tomatoes was extrapolated tomatoes. Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of Eggplants (includes all commodities in this group)	0.4	0.5	Critical GAP: 2 foliar applications at rate of 12.5 g ai/hL, up to 1,000 L/ha (maximum of 125 g ai/ha) with a PHI of 1 day (protected – indoor use, United Kingdom) Number of trials: 8 (trials conducted in cherry tomato) Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal derived for cherry tomatoes was extrapolated to the subgroup of eggplants. The extrapolation from tomatoes to eggplants is also possible according to the current EU guidance document. However, residue trials on cherry tomatoes are expected to overestimate the residues in eggplants. Conclusion: The proposed Codex MRL is acceptable, although it may overestimate the residues
Carrot	0.15	0.2	Critical GAP: 2 foliar applications at rate of 125 g ai/ha with a PHI of 14 days (United Kingdom) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Barley	0.6	0.6	Critical GAP: 2 foliar applications at rate of 125 g ai/ha before beginning of flowering (first anthers visible, BBCH 61) (United Kingdom) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residues measured in barley grain. Conclusion: The proposed Codex MRL is acceptable.
Wheat	0.03	0.2	Critical GAP: 2 foliar applications at a rate of 125 g ai/ha before grain watery ripe stage (BBCH 71) (United Kingdom) Number of trials: 8 trials in wheat Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable.
Rye	0.03	0.2	Critical GAP: UK, 2 foliar applications at a rate of 125 g ai/ha before grain watery ripe stage (BBCH 71) (United Kingdom) Number of trials: 8 (trials on wheat) Sufficiently supported by data: Yes Specific comments/observations: Extrapolated from trials on wheat. Conclusion: The proposed Codex MRL is acceptable.
Triticale	0.03	0.2 (wheat)	Critical GAP: UK, 2 foliar applications at a rate of 125 g ai/ha before grain watery ripe stage (BBCH 71) (United Kingdom) Number of trials: 8 (trials on wheat) Sufficiently supported by data: Yes Specific comments/observations: Extrapolated from trials no wheat. Conclusion: The proposed Codex MRL is acceptable
Rape seed	0.2	0.4	Critical GAP: 1 foliar application at rate of 125 g ai/ha up to the end of flowering (BBCH 71) (United Kingdom) Number of trials: 20 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Peanut	0.01	0.01*	Critical GAP: 2 foliar application at rate of 100–125 g ai/ha with PHI of 7 days (Nicaragua) Number of trials: 4 (conducted at 3 × 125 g ai/ha, PHI not reported) Sufficiently supported by data: No Specific comments/observations: Residues measured in peanuts and peanuts seed. According to the JMPR, peanuts belong to the minor crops category 3, for which a minimum of 5 residue trials are necessary to propose a CXL. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable
Apple, dry	3		Processing Factor (PF) of 6.03 derived by JMPR and used to propose the CXL. The same PF was derived by EFSA (2015b)
Tomato, dry	5		PF of 11 derived by JMPR and used to propose the CXL. The same value was derived by EFSA (2015b)
Barley straw and fodder, dry	15 (dw)		Critical GAP: 2 foliar applications at rate of 125 g ai/ha before beginning of flowering up to BBCH 61 (United Kingdom) Number of trials: 13 (barley straw) + 8 (wheat straw) Sufficiently supported by data: Yes Specific comments/observations: Combined data set of residues of isopyrazam in barley straw and wheat straw were combined to derive the proposed CXL. Conclusion: For feed items no MRLs are established in the EU
Rye straw and fodder, dry	15 (dw)		Critical GAP: 2 foliar applications at rate of 125 g ai/ha before beginning of flowering up to BCH 71 (United Kingdom) Number of trials: 13 (barley straw) + 8 (wheat straw) Sufficiently supported by data: Yes Specific comments/observations: Combined data set of residues of isopyrazam in barley straw and wheat straw were combined to derive the proposed CXL. Conclusion: For feed items no MRLs are established in the EU.
Triticale straw and fodder, dry	15 (dw)		Critical GAP: 2 foliar applications at rate of 125 g ai/ha before beginning of flowering up to BCH 71 (United Kingdom) Number of trials: 13 (barley straw) + 8 (wheat straw) Sufficiently supported by data: Yes Specific comments/observations: Combined data set of residues of isopyrazam in barley straw and wheat straw were combined to derive the proposed CXL. Conclusion: For feed items no MRLs are established in the EU
Wheat straw and fodder, dry	15 (dw)		Critical GAP: 2 foliar applications at rate of 125 g ai/ha before beginning of flowering up to BCH 71 (United Kingdom) Number of trials: 13 (barley straw) + 8 (wheat straw) Sufficiently supported by data: Yes Specific comments/observations: Combined data set of residues of isopyrazam in barley straw and wheat straw were combined to derive the proposed CXL. Conclusion: For feed items no MRLs are established in the EU
Mammalian fats (except milk fats)	**0.03**	0.01*	Max Dietary burden is 22 ppm (equivalent to mg/kg DM) Feeding study with highest dose level (127 ppm) covering the max DB. Conclusion: The proposed Codex MRL is acceptable
Meat (from mammals other than marine mammals)	**0.03 (fat)**	0.01*	Specific comments/observations: At EU level, an MRL for muscle should be established. Based on the feeding studies, no quantifiable residues are expected in muscle and the existing EU MRL would be appropriate

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (mammalian)	**0.02**	0.01*	Conclusion: The proposed Codex MRL is acceptable
Milks	0.01*	0.01*	Conclusion: The proposed Codex MRL is acceptable
Milk fats	0.02		Conclusion: The proposed Codex MRL is acceptable
Apple juice	None		PF of 0.02 derived by JMPR has the same value as the PF derived by EFSA (EFSA, 2013h,c)
Canned apple	None		PF of 0.05 derived by JMPR has the same value as the PF derived by EFSA (2013h,c)
Apple sauce	None		PF of 0.18 derived by JMPR has the same value as the PF derived by EFSA (2013h,c)
Barley malt	None		PF of 0.55 derived by JMPR has the same value as the PF derived by EFSA (2010g)
Barley beer	None		PF of < 0.13 derived by JMPR has the same value as the PF derived by EFSA (2010g)
Pot barley	None		PF of 0.37 derived by JMPR has the same value as the PF derived by EFSA (2010g)
Rape seed oil, edible	None		PF of 1.81 derived by JMPR. It was not possible to confirm if a PF was derived at the EU level by EFSA

PHI: preharvest interval; GAP: Good Agricultural Practice; STMR: supervised trials median residue; PF: processing factor; MRL: maximum residue limit; CXL: Codex Maximum Residue Limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.20.5. Consumer risk assessment – isopyrazam (Table 93)

Table 93: Summary of the consumer risk assessment for isopyrazam

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 assessed by JMPR. The risk assessment is tentative, because of the different residue definitions for risk assessment derived by JMPR and applicable in the EU. Contribution of cereals was assessed with the STMR RAC. No refinement was performed with STMR-p. For wheat, the higher STMR of triticale was used in the calculation	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015b) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for rye grain, wheat grain and livestock commodities. The risk assessment is tentative, because of the different residue definitions for risk assessment derived by JMPR and applicable in the EU.	**Specific comments:** Acute exposure for cereals is assessed with STMR and/or STMR-p, which is a different approach from EU. Detailed RA values can be assessed for wheat and triticale, which is not possible with the EU PRIMo
Results: No short-term exposure concern was identified (apples: 12% of the ARfD)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 13% of the ADI. The contribution of apples to the exposure was 12% of the ADI	**Results:** Long-term exposure: 0–1% of the ADI Short-term exposure: 6–10% of the ARfD

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

4.21. Propylene oxide (250) (R/T)

4.21.1. Background information (Table 94)

Table 94: Background information on propylene oxide

		Comments, references
Type of JMPR evaluation	New use	
RMS	–	
Approval status	–	Not assessed in the EU
EFSA conclusion	No	–
MRL review	No	–
MRL applications	No	–

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.21.2. Toxicological reference values – propylene oxide (Table 95)

Table 95: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.04 mg/kg bw per day	JMPR, 2011, 2017; Rat, chronic inhalation supported by reproductive toxicity study	–	No EU assessment	N/A
ARfD	0.04 mg/kg bw	JMPR, 2011, 2017; Rat, chronic inhalation supported by reproductive toxicity study	–		N/A
Propylene chlorohydrin					
ADI	0.3 mg/kg bw per day	JMPR, 2017; Rat, acute neurotoxicity supported by reproductive toxicity studies	–	No EU assessment	N/A
ARfD	0.3 mg/kg bw	JMPR, 2017; Rat acute neurotoxicity, supported by developmental toxicity study	–		N/A
Propylene bromohydrin					
ADI	0.03 mg/kg bw per day	JMPR, 2017; Same as propylene chlorohydrin	–	No EU assessment	N/A
ARfD	0.03 mg/kg bw	JMPR, 2017; Same as propylene chlorhydrin	–		N/A
Conclusion/ comment	For **propylene oxide**, the ADI was derived with an additional factor of 10 (to the default SF of 100) to address the limitations in the available database and ensure a margin of 100 to the LOAEL of 4.3 mg/kg bw per day in the gavage carcinogenicity study. The ARfD was derived on the same basis. EFSA: Considering that propylene oxide is classified as mutagen (cat 1B) and carcinogen (cat 1B) according to EU CLP Regulation (EC) No. 1272/2008, the conclusions on genotoxicity and carcinogenicity and the derivation of reference values from JMPR might not be supported in an EU evaluation.				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	For **propylene chlorohydrin**, the ADI was derived on the basis of reduced motor activity observed in the rat acute neurotoxicity study (NOAEL 25 mg/kg bw) and applying a safety factor of 100. This is supported by parental, offspring and embryo/foetal toxicity in the reproductive toxicity studies. The ARfD was also derived on the basis of the rat acute neurotoxicity study, supported by the rat developmental toxicity study. For **propylene bromohydrin**, JMPR considered a read across from propylene chlorohydrin. Considering the uncertainties and the available evidence that propylene bromohydrin was of greater potency than propylene chlorohydrin, an extra safety factor of 10 was applied to the derivation of the ADI and ARfD. EFSA: Considering the same uncertainties related to the genotoxic potential than for propylene oxide, the JMPR conclusion and derivation of reference values for the 2 metabolites might not be supported in an EU evaluation				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.21.3. Residue definitions – propylene oxide (Table 96)

Table 96: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Propylene oxide	–	N/A
	Animal products	Not reported The residue is not fat soluble	–	N/A
RD RA	Plant products	Propylene oxide, propylene chlorohydrin and propylene bromohydrin. Propylene chlorohydrin and propylene bromohydrin to be considered separately from propylene oxide.	–	N/A
	Animal products	Not reported	–	N/A
Conclusion/ comments	The data assessed by JMPR in 2011 to derive the residue definitions was very limited. The residue definitions were derived by analogy based on the similarity in reactions and chemistry between ethylene oxide and propylene oxide. The database is considered insufficient to derive residue definitions for propylenoxide uses			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.21.4. Codex MRL proposals – propylene oxide (Table 97)

Table 97: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Almonds, walnuts	No proposal	No EU MRLs	Critical GAP: USA, post-harvest fumigation at 2 g ai/L in a sealed chamber. JMPR considered the residue data not valid. No Codex MRL proposal was derived
General comments	–		

GAP: Good Agricultural Practice; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.21.5. Consumer risk assessment – propylene oxide (Table 98)

Table 98: Summary of the consumer risk assessment for propylene oxide

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant		

4.22. Saflufenacil (251) (R/T)

4.22.1. Background information (Table 99)

Table 99: Background information on saflufenacil

		Comments, references
Type of JMPR evaluation	New use	
RMS	–	
Approval status	Not approved	–
EFSA conclusion	No	–
MRL review	No	–
MRL applications	Yes, see comments	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)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.22.2. Toxicological reference values – saflufenacil (Table 100)

Table 100: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR, 2011	0.046 mg/kg bw per day	EFSA (2012b) (Mouse, 18-month carcinogenicity)	Yes
ARfD	Unnecessary	JMPR, 2011	0.05 mg/kg bw	EFSA (2012b) (Rat, developmental toxicity with an uncertainty factor of 100)	No
TFA (Trifluoroacetic acid)					
ADI	–	–	0.05 mg/kg bw per day	(90-day oral rat study with an uncertainty factor of 200) EFSA (2014b)	N/A
ARfD	–	–	0.05 mg/kg bw	(90-day oral rat study with a safety factor 200) EFSA (2014b)	N/A
Conclusion/ comment	–				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.22.3. Residue definitions – saflufenacil (Table 101)

Table 101: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Saflufenacil	Sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil	No
	Animal products	Saflufenacil The residue is not fat soluble	Saflufenacil Metabolite M800H10 to be considered if poultry feed might be affected by saflufenacil uses (EFSA, 2012b) The residue is not fat soluble	Yes
RD RA	Plant products	Saflufenacil	Sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil	No
	Animal products	Saflufenacil	Saflufenacil. Metabolite M800H10 to be considered if poultry feed might be affected by saflufenacil uses	Yes
Conclusion/ comments	–			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.22.4. Codex MRL proposals – saflufenacil (Table 102)

Table 102: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Mustard seed	**0.6**	0.03*	Critical GAP for rape seed (JMPR, 2011): single late-season application, as harvest aid/desiccant at 0.049–0.051 kg ai/ha, PHI 3 days (allowing up to 7 days for optimum desiccation effect depending on environmental conditions) Number of trials: 14 trials in rape seed, to be extrapolated to mustard seeds. Sufficiently supported by data: Yes The extrapolation from rape seed trials to mustard seed is also accepted in the EU. The previously established CXL for rape seed has been taken over in the EU legislation, although the residue definitions set by JMPR and in the EU were different (in the EU, the residue definition was provisionally proposed in the framework of the import tolerance application. The residue definition was amended in the same period as the CXL was adopted. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs.
Linseed	**0.6**	0.03*	Critical GAP for rape seed (JMPR, 2011): single late-season application, as harvest aid/desiccant at 0.049–0.051 kg ai/ha, PHI 3 days (allowing up to 7 days for optimum desiccation effect depending on environmental conditions) Number of trials: 14 trials in rape seed, to be extrapolated to mustard seeds. Sufficiently supported by data: Yes Specific comments/observations: accepted EU extrapolation from rape seed trials to linseed taken by EU legislation. See comments on mustard seeds. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; CXL: Codex Maximum Residue Limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.22.5. Consumer risk assessment – saflufenacil (Table 103)

Table 103: 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 for mustard seed and linseed as outlined in Section 4.22.2. The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2014b) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for mustard seed and linseed	**Specific comments:** In 2017 JMPR report, no livestock exposure assessment was conducted including 'Flaxseed/Linseed meal' which could be fed to animal. In 2011, JMPR livestock exposure assessment conducted was incomplete not taken crops that were fed to item and considering MRLs taken by CODEX. Livestock assessment has been done for CODEX items and for EU items. For CODEX as well as for EU, no differences on the outcome if linseed is taken or not. However, there are concerns for sheep and beef
Results: No short-term exposure concern was identified (0.9% of the ARfD for linseed and 0.2% of the ARfD for mustard seed)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 4% of the ADI. The contribution of rape seed to the exposure was 0.017% of the ADI for linseed and 0.002% of the ADI for mustard seed	

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.23. Picoxystrobin (258) (R)

4.23.1. Background information (Table 104)

Table 104: Background information on picoxystrobin

		Comments, references
Type of JMPR evaluation	New use	
RMS	CZ	
Approval status	Not approved	Commission Implementing Regulation (EU) No 2017/438[(a)]
EFSA conclusion	Yes, see comments	EFSA (2016l)
MRL review	Yes, see comments	EFSA (2011h)
MRL applications	Yes, see comments	Ongoing in rice EFSA (2014h) (sugar beet)

(a): 2017/438/EU: Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance abamectin. OJ L 67, 14.3.2017, p. 67–69.

4.23.2. Toxicological reference values – picoxystrobin (Table 105)

Table 105: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments**	
ADI	0.09 mg/kg bw per day	JMPR	**No toxicological reference values could be derived.** (previous ADI was 0.043 mg/kg bw European Commission, 2003)	Setting of reference values was postponed until conclusion on the genotoxic potential of picoxystrobin	No
ARfD	0.09 mg/kg bw	JMPR	**No toxicological reference values could be derived**	Setting of reference values was postponed until conclusion on the genotoxic potential of picoxystrobin	No
Conclusion/ comment	During the renewal process, no toxicological references were proposed since a genotoxic potential of picoxystrobin could not be excluded (picoxystrobin was positive in the *in vitro* mammalian gene mutation assay). In addition for several metabolites relevant for the risk assessment residue definition in plant, a conclusion on the toxicological profile could not be derived (IN-H8612 a clastogenic/aneugenic potential cannot be excluded, while for IN-K2122, IN-QGU64 no toxicological data were provided) (EFSA, 2016l). In 2012, JMPR established the ADI and ARfD listed above. However, no conclusion was reached on the toxicological relevance of IN-H8612 and IN-QGU64, both metabolites have structural alerts for genotoxicity. For IN-H8612, JMPR concluded in 2013, on the basis of a mouse micronucleus study and an estimate of the exposure using TTC that this metabolite is of no concern for dietary exposure. In 2016, JMPR concluded that further information was required for IN-QGU64, because a possible interconversion of IN-H8612 and IN-QGU64 cannot be excluded In 2017, JMPR assessed the new metabolism studies in soybeans, tomatoes and potatoes; in none of them, IN-QGU64 was not observed. With this information, the meeting concluded that in the 2006 soybean metabolism study, IN-H8612 had been incorrectly characterised as IN-QGU64				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.23.3. Residue definitions – picoxystrobin (Table 106)

Table 106: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Picoxystrobin	EU Reg. 396/2005: picoxystrobin Picoxystrobin (pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites)	Yes
	Animal products	Picoxystrobin The residue is fat soluble	EU Reg. 396/2005: Picoxystrobin Peer review: Picoxystrobin (pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites) The residue is fat soluble	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Picoxystrobin	**Not proposed,** pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites	Not applicable
	Animal products	Picoxystrobin	**Not proposed**, pending conclusion on the metabolites to be included in the plant residue definition for risk assessment.	Not applicable
Conclusion/ comments	The EU residue definitions for enforcement derived under the peer review are provisional. For metabolites IN-K2122, IN-QGU64, (both relevant for risk assessment), insufficient toxicological information was available to conclude on their toxicological profile; for IN-H8612, a clastogenic potential cannot be exclude. Thus, no risk assessment residue definitions were derived			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.23.4. Codex MRL proposals – picoxystrobin (Table 107)

Table 107: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	0.3	0.3	Critical GAP: 3 × 0.22 kg/ha, PHI 45 days Number of trials: 17 Conclusion: Although a sufficient number of residue trials are available, the proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted. The existing EU MRL for barley should be reconsidered, taking into account that the approval for picoxystrobin has not been renewed
Barley straw and fodder, dry	7 (dw)		–
Edible offal (mammalian)	**0.02**	0.01*	The Codex MRL proposal was derived from a feeding study where at the estimated dietary burden residues at 0.012 mg/kg were calculated for liver. In kidney, no residues were found. The CXL proposal is not acceptable since a consumer risk assessment cannot be conducted
Eggs	0.01*	0.01*	From the feeding study, it was concluded that at the expected dietary burden, no quantifiable residues are expected in eggs and other poultry products
Maize	**0.015**	0.01*	Critical GAP: 3 × 0.22 kg/ha, PHI 7 days Number of trials: 15 Conclusion: Although a sufficient number of residue trials are available, the proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted.
Maize fodder	20 (dw)		–
Maize oil, edible	0.15		–
Mammalian fats (except milk fats)	**0.02**	0.01*	The Codex MRL proposal was derived from a feeding study; at the calculated burden, residues of 0.015 mg/kg are expected in fat. The proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted
Meat (from mammals other than marine mammals) (fat)	**0.02**	0.01*	Since picoxystrobin is fat soluble, the MRL proposal for fat is applied to meat (fat). The proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted
Milks	0.01*	0.01	From the feeding study, it was concluded that at the expected dietary burden no quantifiable residues are expected in milk
Oats	0.3	0.3	See comment on barley

Commodity	Codex MRL proposal	EU MRL	Comment
Oat straw and fodder, dry	7 (dw)		–
Pea hay or pea fodder (dry)	150 (dw)		–
Popcorn	0.015		–
Poultry, edible offal of	0.01*	0.01*	See the comment on eggs
Poultry fats	0.01	0.01*	See the comment on eggs
Poultry meat	0.01*	0.01*	See the comment on eggs
Rye	0.04	0.05	See the wheat
Rye straw and fodder, dry	7 (dw)		–
Soya bean fodder	5 (dw)		–
Soya bean oil, refined	0.2		–
Subgroup of dry beans (includes all commodities in this subgroup)	**0.06**	0.01*	Critical GAP: 2 × 0.22 kg/ha, PHI 14 days Number of trials: 11 Conclusion: Although a sufficient number of residue trials are available, the proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted.
Subgroup of dry peas (includes all commodities in this subgroup)	**0.06**	0.01*	Critical GAP: 2 × 0.22 kg/ha, PHI 14 days Number of trials: 11 Conclusion: Although a sufficient number of residue trials are available, the proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted.
Sweet corn (corn on the cob) (kernels plus cob with husk removed)	0.01*	0.01*	Critical GAP: 4 × 0.22 kg/ha, PHI 7 days Number of trials: 11 (all below 0.01 mg/kg) Conclusion: Although a consumer risk assessment cannot be conducted (see below), it is not necessary to raise a reservation, since the proposed MRL is at the LOQ
Triticale	0.04	0.05 (wheat)	See the comment on wheat
Triticale straw and fodder, dry 7(dw)	7 (dw)		
Wheat	0.04	0.05	Critical GAP: 3 × 0.22 kg/ha, PHI 45 days Number of trials: 23 Conclusion: Although a sufficient number of residue trials are available, the proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted. The existing EU MRL for barley should be reconsidered, taking into account that the approval for picoxystrobin has not been renewed
Wheat bran, processed	0.15		–
Wheat germ	0.15		–
Wheat straw and fodder, dry	7 (dw)		–

GAP: Good Agricultural Practice; MRL: maximum residue limit; LOQ: limit of quantification.
*: Indicates that the input value is proposed at the limit of quantification.

4.23.5. Consumer risk assessment – picoxystrobin (Table 108)

Table 108: Summary of the consumer risk assessment for picoxystrobin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: No short-term consumer intake exposure could be conducted since in the EU, no toxicological reference values and no residue definitions for risk assessment could be derived in the peer review process on the renewal of the approval	**RA assumptions:** No long-term consumer intake exposure could be conducted since in the EU, no toxicological reference values and no residue definitions for risk assessment could be derived in the peer review process on the renewal of the approval	**Specific comments**
Results: –	**Results:** –	**Results:** 0–0.1% of ADI 0–3% of ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union; RA: risk assesment.

4.24. Fluensulfone (265) (R)

4.24.1. Background information (Table 109)

Table 109: Background information on fluensulfone

		Comments, references
Type of JMPR evaluation	New use	
RMS	–	
Approval status	–	Not assessed in the EU
EFSA conclusion	No	–
MRL review	No	–
MRL applications	No	–

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; EU: European Union.

4.24.2. Toxicological reference values – fluensulfone (Table 110)

Table 110: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.01 mg/kg bw per day	JMPR, 2013	–	No EU assessment	N/A
ARfD	0.3 mg/kg bw	JMPR, 2013			N/A
Conclusion/comment	No new information. Comments were provided by EU for 2016 and 2017 CCPR. At its meeting in 2013, WHO/JMPR evaluated the toxicology of fluensulfone and a monograph was published in 2014 (FLUENSULFONE 271–315 JMPR, 2013). Following chronic oral administration, the substance showed carcinogenic effects in lungs of mice and led to proliferative changes in the respiratory epithelium of rats. The JMPR meeting concluded that fluensulfone would be unlikely to be genotoxic *in vivo* and that there would be a threshold for lung tumours in mice. Accordingly, an ARfD of 0.3 mg/kg bw and an ADI of 0–0.01 mg/kg bw were derived				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
	At the request of CCPR, JMPR reviewed existing and new information of the mode of action for lung tumours at its meeting in 2016 (FAO, 2016). According to the published meeting report from JMPR, 2016, induction of carcinoma in mice was linked to Cyp2f2-mediated metabolic activation of fluensulfone in Clara cells of the lung and increased cell proliferation. Based on the lack of genotoxicity in the available studies, the earlier conclusion from 2013 on the likely existence of a threshold for carcinogenicity in rodents was confirmed by the meeting. Based on the previous meetings, conclusion that fluensulfone is unlikely to be genotoxic *in vivo* and that the mode of action for lung tumours in mice will exhibit a threshold and is unlikely to be relevant to humans, the present meeting concluded that fluensulfone is unlikely to pose a carcinogenic risk to humans from the diet. The reference values derived by JMPR are associated with a significant level of uncertainty. This uncertainty arises from the observation of lung tumours in mice and the assumption of a threshold with regard to genotoxicity in the Cyp2f competent target tissue and an incomplete understanding of the mode(s) of action involved: Following chronic oral administration, **the substance showed carcinogenic effects in lungs of mice from doses of 39 mg/kg bw/d** and led to proliferative changes in the respiratory epithelium of rats. JMPR reviewed information on the mode of action for these lung tumours at its meeting in 2016 (FAO, 2016). The respective revised monograph is not yet publicly available. According to the meeting report, experts postulated that induction of carcinoma in mice results from Cyp2f2-mediated metabolic activation of fluensulfone in Clara cells of the lung into an unidentified reactive intermediate, cell-specific toxicity and regenerative epithelial cell proliferation. The meeting excluded an alternative genotoxic mode-of-action based on the lack of genotoxicity in the available studies, and the likely existence of a threshold for carcinogenicity of fluensulfone in rodents was concluded. However, this conclusion is uncertain as the genotoxicity test methods used for fluensulfone are lacking sufficient Cyp2f metabolic activity. An uncertainty for genotoxicity was already identified by the first JMPR meeting in 2013 (FLUENSULFONE 271–315 JMPR, 2013, refer to page 288: 'Alternative modes of action have not been addressed. There are no specific genotoxicity data on lung tissue/cells.'). An equivocal finding was noted for chromosome damage *in vitro*. The negative *in vivo* micronucleus assay addressed genotoxicity in bone marrow is to be considered irrelevant, as bone marrow cells are known not to express Cyp2f2 (e.g. Wong, 2009) In its most recent publication on the subject matter, the manufacturer confirmed that site-specific genotoxicity in the lung was not yet investigated (Strupp, 2016). Therefore, there is still a data gap for genotoxicity in the appropriate (target) tissue. Accordingly, the conclusion on the existence of a threshold and the current reference values are associated with substantial uncertainty. In their Global Joint Review, Australian OCS, US EPA and Canadian PMRA also concluded 'The evidence to support the proposed MoA is currently insufficient due to uncertainties, inconsistencies and gaps in the currently available data.' (APVMA, 2015). When assessing acceptability of this uncertainty, it could be taken into account that Cyp2F activity in human lung (Cyp2F1) is approximately 100 fold lower than in mouse lung (Cyp2f2). From the toxicological perspective, the uncertainty on genotoxicity should be addressed using a Cyp2f competent test system and/or target tissue.				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.24.3. Residue definitions – fluensulfone (Table 111)

Table 111: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.	–	N/A
	Animal products	Fluensulfone The residue is fat soluble	–	N/A
RD RA	Plant products	Fluensulfone	–	N/A
	Animal products	Fluensulfone	–	N/A
Conclusion/ comments	No new information in JMPR, 2017			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.24.4. Codex MRL proposals – fluensulfone (Table 112)

Table 112: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

General comments	Plant commodities: The Meeting received supervised trial data for applications of fluensulfone to citrus, soya beans, sugarcane, coffee and black pepper. However, no evidence on approval of the GAP was provided. Therefore, JMPR did not assess the studies. Animal commodities: Of the uses under consideration by the Meeting, citrus, soya bean and sugarcane have significant livestock feed items. JMPR had no GAPs available for the data considered by the meeting, and therefore, previous dietary burdens and recommendations from the 2016 Meeting were not re-evaluated

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit.

4.24.5. Consumer risk assessment – fluensulfone (Table 113)

Table 113: Summary of the consumer risk assessment for fluensulfone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant	Not relevant	–

4.25. Imazapyr (267) (R)

4.25.1. Background information (Table 114)

Table 114: Background information on imazapyr

		Comments, references
Type of JMPR evaluation	New use	
RMS	–	
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[(a)]
EFSA conclusion	No	–
MRL review	No	–
MRL applications	Yes, see comments	EFSA (2014k) (genetically modified soya bean and other oilseeds and lentils)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

(a): 2076/2002: 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. OJ L 319, 23.11.2002, p. 3–11.

4.25.2. Toxicological reference values – imazapyr (Table 115)

Table 115: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	3 mg/kg bw per day	JMPR, 2013 (1 year oral dog study)	2.5 mg/kg bw per day	EFSA (2014k)Dog, 1-year study and rat, 2-year study safety factor 100	Yes, see below
ARfD	Unnecessary	JMPR, 2013	Not necessary		Yes
Conclusion/ comment	Although the ADI values are established at different levels, they are in the same order of magnitude				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

4.25.3. Residue definitions – imazapyr (Table 116)

Table 116: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Imazapyr	Imazapyr	Yes
	Animal products	Imazapyr The residue is not fat soluble	Imazapyr No fat soluble	Yes
RD RA	Plant products	Imazapyr	Imazapyr	Yes
	Animal products	Imazapyr	Imazapyr	Yes
Conclusion/comments	The residue definitions derived in the framework of the import tolerance application (EFSA, 2014k) are identical with the JMPR residue definitions.			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.25.4. Codex MRL proposals – imazapyr (Table 117)

Table 117: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	0.7	0.01* (default MRL, no specific MRL mentioned in Reg. 396/2005)	Critical GAP: AUS (use on imidazolidone-tolerant barley); 0.025 kg/ha at early growth stage (between 5 leaf stage to 1st node stage). Number of trials: 6 Sufficiently supported by data: No, for barley, at least 8 residue trials would be required at EU level. Specific comments/observations: It should be verified if the import of imidazolidone tolerant barley to the EU is approved. Conclusion: To be discussed with MS whether the proposed Codex MRL is not acceptable considering the limited number of trials

Commodity	Codex MRL proposal	EU MRL	Comment
Barley straw and fodder, dry	0.05*		Critical GAP: see above Number of trials: 6 Specific comments/observations: At EU level, no MRLs are set for feed. Conclusion: The residues in barley straw and fodder were taken into account in an updated dietary burden calculation in livestock. No amendment of MRLs for animal commodities is required. No comments required.

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; EU: European Union.
*: Indicates that the input value is proposed at the limit of quantification.

4.25.5. Consumer risk assessment – imazapyr (Table 118)

Table 118: Summary of the consumer risk assessment for imazapyr

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was established	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2014k) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for rape seed.	**Specific comments**
Results: –	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.05% of the ADI. The contribution of barley to the exposure was insignificant (< 0.01%).	**Results:** Long-term exposure: 0% of the ADI

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.26. Imazamox (276) (R)

4.26.1. Background information (Table 119)

Table 119: Background information on imazamox

		Comments, references
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) 2016/950[(a)]
EFSA conclusion	Yes, see comments	EFSA (2016f)
MRL review	Yes, see comments	EFSA (2013g)
MRL applications	No	

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2016/950/EU: Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin. OJ L 159, 16.6.2016, p. 3–5.

4.26.2. Toxicological reference values – imazamox (Table 120)

Table 120: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	3 mg/kg bw per day	JMPR, 2014	3 mg/kg bw per day	European Commission (2002) not confirmed in EFSA (2016f) AIR III (Rabbit developmental study, uncertainty factor 100) confirmed in European Commission (2017b)	Yes
ARfD	3 mg/kg bw	JMPR, 2014	3 mg/kg bw	European Commission (2002) not confirmed in EFSA (2016f) AIR III (Rabbit developmental study, uncertainty factor 100) confirmed in European Commission (2017b)	Yes
Conclusion/ comment	The toxicological reference values derived for the active substance are fully comparable. Toxicological properties of metabolites: EU assessment: The metabolite **CL 263284** was of low acute oral toxicity to rats. The metabolite showed positive results in the *in vitro* MN test and negative results in the *in vivo* MN test; however, there was no sufficient evidence that the target tissue, i.e. bone marrow, was reached in the *in vivo* MN test. The experts agreed that target tissue exposure needs to be further demonstrated (data gap). The agreed NOAEL in the 28-day rat study on CL 263284 is 333 mg/kg bw per day. The glucose conjugate CL 189215 was not genotoxic in a standard *in vitro* test battery. However, EFSA considered that the genotoxic potential of CL 189215 should be reconsidered once the genotoxic potential of the aglycon metabolite CL 263284 is finally addressed since hydrolysis of the metabolite is expected *in vivo*. Once the genotoxicity of CL 263284 and its glucose conjugate (CL 189215) is addressed, the relative toxicity profile and possible derivation of reference values for metabolite CL 263284 and its glucose conjugate CL 189215 should be reconsidered. JMPR, 2014: **CL 263284** was tested for genotoxicity in an adequate range of assays *in vitro* and *in vivo*. It gave a positive response in the *in vitro* micronucleus assay, but was negative in the *in vivo* micronucleus assay. **CL 263284** is an O-demethylation product of imazamox and is a common metabolite with imazapic. Although there is some indication of slightly higher toxicity of this metabolite when compared with imazamox in a 28-day toxicity study in rats, the effects observed were mild changes in body weight gain in males only. Taking into account the close structural similarity to imazamox and the effects and effect levels observed in the developmental toxicity study in rats with imazamox, JMPR concluded that CL 263284 is of similar toxicity to imazamox and that it would be covered by the ADI and ARfD for imazamox. Considering that there are still open issues as regards the toxicological properties of the metabolites, the risk assessment is considered as tentative				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.26.3. Residue definitions – imazamox (Table 121)

Table 121: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Imazamox	Reg. 396/2005: (imazamox and its salts, expressed as imazamox) Peer review: Sum of imazamox and CL 263284, expressed as imazamox (limited to the cereal/grass and Oilseeds/pulses crop groups) – Provisional pending the conclusions on the toxicological properties of metabolite CL 263284	Yes (for RD in Reg. 396/2005)
	Animal products	Imazamox The residue is not fat soluble	Reg. 396/2005: Imazamox (Sum of imazamox and its salts, expressed as imazamox) Peer review: Imazamox The residue is not fat soluble	Yes
RD RA	Plant products	Sum of imazamox and 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imazazolin-2-yl) nicotinic acid (CL 263284), expressed as imazamox	Sum of imazamox, CL 263284, and CL 189215, expressed as imazamox (Provisional, pending the conclusions on the toxicological properties of metabolite CL 263284 and its glucose conjugate CL 189215)	No
	Animal products	Sum of imazamox and 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imazazolin-2-yl) nicotinic acid (CL 263284), expressed as imazamox	Imazamox	No
Conclusion/ comments	Basically, the residue definitions for enforcement derived by JMPR and at EU level (Reg. 396/2005) are comparable. The residue definition derived in the peer review has not yet been implemented. The risk assessment residue definitions differ; the different residue definition for animal products is of no relevance, since no MRL proposals were made by JMPR. The fact that the glucose conjugate of metabolite CL 263284 is not included in the JMPR residue definition may lead to an underestimation of the dietary exposure if the STMR/HR values derived by JMPR are used in the risk assessment, resulting in some additional uncertainties			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.26.4. Codex MRL proposals – imazamox (Table 122)

Table 122: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	0.02	0.05*	Critical GAP: AUS (use on imidazolidone-tolerant barley); 0.025 kg/ha at early growth stage (between 5 leaf stage to 1st node stage). Number of trials: 6 Sufficiently supported by data: No; for barley, at least 8 residue trials would be required. Specific comments/observations: It should be verified if the import of imidazolidone tolerant barley to the EU is approved. Conclusion: Although the number of trials is not compliant with the EU requirements, there is currently no need to make a reservation, since the existing EU MRL is higher. However, if the residue definition will be modified as proposed in the peer review (including metabolite CL263284), the Codex MRL proposal would not be compatible with the EU legislation and a higher would be required. The RMS noted that metabolism data show that in wheat, parent imazamox is higher than CL263284; however, for a number of commodities, including, maize, oilseeds and rice, the metabolite is higher than the parent, which justified its inclusion in the enforcement residue definition in the EU
Barley straw and fodder, dry	0.05		Critical GAP: see above Number of trials: 6 Specific comments/observations: At EU level, no MRLs are set for feed. Conclusion: The residues in barley straw and fodder were taken into account in an updated dietary burden calculation in livestock. No amendment of MRLs for animal commodities is required. No comments required

EU MRL: European Union maximum residue limit; GAP: Good Agricultural Practice; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State.
*: Indicates that the input value is proposed at the limit of quantification.

4.26.5. Consumer risk assessment – imazamox (Table 123)

Table 123: Summary of the consumer risk assessment for imazamox:

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions:	**RA assumptions:**	**Specific comments**
Considering that there are still open issues as regards the toxicological properties of the metabolites, the risk assessment is considered as tentative The risk assessment is affected by non-standard uncertainties due to the fact that the EU RD for RA comprises an additional metabolite. However, considering the low exposure (see results below), this difference will not result in a significant underestimation of a consumer health risk		–
The short-term dietary risk assessment was performed for barley	The most recent long-term risk assessment (MRL review, EFSA, 2013g) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for barley	
Results: No short-term exposure concern was identified (0.002% of the ARfD)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.013% of the ADI. The contribution of barley to the exposure was 0.002% of the ADI	**Results:** Long-term exposure: 0% of the ADI Short-term exposure: 0%of the ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue; HR: highest residue.

4.27. Flonicamid (283) (R)

4.27.1. Background information (Table 124)

Table 124: Background information on flonicamid

		Comments, references
Type of JMPR evaluation	New use	
RMS	FI	FR was the previous RMS
Approval status	Renewal of the approval	Commission Directive 2010/29/EU[(a)]
EFSA conclusion	Yes, see comments	EFSA (2010e) • Ongoing AIR IV
MRL review	Yes, see comments	EFSA (2014i)
MRL applications	Yes, see comments	EFSA (2017a) (various crops) EFSA (2016i) (herbs) EFSA (2015g) (several crops) • In progress for radishes and various crops

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(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.

4.27.2. Toxicological reference values – flonicamid (Table 125)

Table 125: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.07 mg/kg bw per day	JMPR, 2015	0.025 mg/kg bw per day	European Commission (2010a,b) confirmed in EFSA (2014i) (Rabbit development, with safety factor 100)	No
ARfD	unnecessary	JMPR, 2015	0.025 mg/kg bw		No
Conclusion/ comment	–				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.27.3. Residue definitions – flonicamid (Table 126)

Table 126: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Flonicamid	Sum of flonicamid, TFNA and TFNG, expressed as flonicamid	No
	Animal products	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	Yes
RD RA	Plant products	Flonicamid	Sum of flonicamid, TFNA and TFNG expressed as flonicamid	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	Flonicamid and the metabolite TFNA-AM, expressed as flonicamid	Sum of flonicamid and TFNA-AM expressed as flonicamid	Yes
Conclusion/ comments	The residue definitions derived by JMPR for plant commodities (enforcement and risk assessment) do not cover the metabolites TFNA and TFNG while these compounds were major components of the metabolism studies in cereals and root crops (less in fruits). The current EU MRLs include these compounds as they were considered relevant marker compounds (ratio of parent, TFNA and TFNG are not stable enough to derive robust conversion factors). Therefore, the Codex MRL proposals derived by JMPR are not compatible with the EU legislation. In 2017 CCPR, the EU made a reservation for the Codex MRL proposals presented because the residue definitions were not compatible			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.27.4. Codex MRL proposals – flonicamid (Table 127)

Table 127: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of beans with pods (except soya bean (succulent seeds in pods))	0.7	1.5	Critical GAP: 3 × 100 g a.s./ha; PHI : 7 days (Canada, USA) Number of trials: 6 Sufficiently supported by data: No; as major crop in EU, 8 trials would be needed. According to JMPR rules, the number of trials is sufficient. Specific comments/observations: The EU rules for extrapolations allow extrapolating trials from beans with pods to peas with pods and vice versa. As the same GAP is authorised on both crops, it is not understood why a combined data set was not proposed. This would allow deriving a common robust MRL on both commodities. Conclusion: The proposed Codex MRL is not acceptable because the residue definitions for enforcement are not compatible
Subgroup of Peas with pods	0.8	1.5	Critical GAP: 3 × 100 g a.s./ha; PHI : 7 days (Canada, USA) Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: The EU rules for extrapolations allow extrapolating trials from beans with pods to peas with pods and vice versa. As the same GAP is authorised on both crops, it is not understood why a combined data set was not proposed. This would allow deriving a common robust MRL on both commodities. Conclusion: The proposed Codex MRL is not acceptable because the residue definitions for enforcement are not compatible
Subgroup of Succulent beans without pods (except soya bean (succulent seeds))	0.3	0.03*	Critical GAP: 3 × 100 g a.s./ha; PHI : 7 days (Canada, USA) Number of trials: 6 Sufficiently supported by data: No; as major crop in EU, 8 trials would be needed; however, for Codex, the number of trials is sufficient (crop category 3, 6 trials are required). Specific comments/observations: The EU rules for extrapolations allow extrapolating trials from beans without pods to peas without pods and vice versa. As the same GAP is authorised on both crops, it is not understood why a combined data set was not proposed. This would allow deriving a common robust MRL on both commodities. Conclusion: The proposed Codex MRL is not acceptable because the residue definitions for enforcement are not compatible

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of succulent peas without pods	0.4	0.7	Critical GAP: 3 × 100 g a.s./ha; PHI : 7 days (Canada, USA Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: In Codex peas without pods are crop category 3; thus, the number of trials is sufficient for JMPR. The EU rules for extrapolations would allow extrapolating trials from beans without pods to peas without pods and vice versa. As the same GAP is authorised on both crops, it is not understood why a combined data set was not proposed. This would allow deriving a common robust MRL on both commodities. 6 trials for peas without pods are sufficient Conclusion: The proposed Codex MRL is not acceptable because the residue definitions for enforcement are not compatible
Subgroup of dry beans (except soya bean (dry))	0.15	0.03*	Critical GAP: 3 × 100 g a.s./ha; PHI : 7 days (Canada, USA Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: The EU rules for extrapolations allow combining trials performed on dry beans and dry peas. However, considering that residue levels in these commodities were found to be highly different, it is approved not to pool both data sets. Conclusion: The proposed Codex MRL is not acceptable because the residue definitions for enforcement are not compatible
Subgroup of dry peas	1	0.03*	Critical GAP: 3 × 100 g a.s./ha; PHI : 7 days (Canada, USA Number of trials: 5 Sufficiently supported by data: No; as major crop in EU and in Codex, 8 trials would be needed. Specific comments/observations: The EU rules for extrapolations allow combining trials performed on dry beans and dry peas. However, considering that residue levels in these commodities were found to be highly different, it is not appropriate to pool both data sets. Conclusion: The proposed Codex MRL is not acceptable because the residue definitions for enforcement are not compatible and because of insufficient trials

PHI:preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GAP: Good Agricultural Practice; CXL: Codex Maximum Residue Limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.27.5. Consumer risk assessment – flonicamid (Table 128)

Table 128: 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 for commodities assessed by JMPR (beans and peas with and without pods, dry beans and dry peas). Although they may be considered as bulked products, the consumer exposure was assessed considering HR of each crop. No refinement considering STMR was performed. It is noted that residue trials did not analyse for metabolites TFNA and TFNG which are expected to be significant part of the residues. No conversion factor is available to consider these metabolites in the risk assessment. Therefore, the risk assessment is indicative only. The EU ARfD was used. There is no JMPR ARfD	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2017a) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for dry beans and dry peas. For beans with and without pods and for peas with and without pods, where the STMR derived from EU assessments (EFSA, 2016i, 2017a) were higher than the STMR derived by JMPR, no changes were done. The EU ADI was used. The JMPR ADI is less critical	**Specific comments** The chronic exposure assessment only considers uses on legume vegetables and dry beans and beans assessed in this report. JMPR should have performed the chronic risk assessment, taking into account all commodities (including also those for which CXLs have been established earlier)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure concern was identified (Max 18.6% of the ARfD for beans with pods)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 18.1% of the ADI. The contribution of commodities assessed in this report did not exceed 1.5% of the ADI (beans with pods)	**Results:** Long-term exposure: 0–10% of the ADI Short-term exposure: Was not assessed as JMPR 2015 decided that an ARfD for flonicamid was not necessary

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue.

4.28. Flupyradifurone (285) (R)

4.28.1. Background information (Table 129)

Table 129: Background information on flupyradifurone

		Comments, references
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/2084[(a)]
EFSA conclusion	Yes, see comments	EFSA (2015d) EFSA (2017c) (conf. data M-Tox and Phys/chem)
MRL review	No	–
MRL applications	Yes, see comments	Strawberries, blackberries and raspberries: EFSA (2016e)
		• Art. 10 in progress (various crop)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(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.

4.28.2. Toxicological reference values – flupyradifurone (Table 130)

Table 130: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.08 mg/kg bw per day	JMPR, 2015	0.064 mg/kg bw per day	EFSA (2015d) (Rat, two-generation study, with safety factor 100)	Yes
ARfD	0.2 mg/kg bw	JMPR, 2015	0.15 mg/kg bw	EFSA (2015d) (Rabbit, developmental study, with safety factor 100)	Yes

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
Conclusion/ comment	The EU pesticides peer review concluded that the reference values of parent flupyradifurone are also applicable to the metabolite difluoroacetic acid (DFA, found in plants, livestock and environment; EFSA, 2015d). Although the ADI and ARfD values derived by JMPR are not exactly the same as the ones derived by EFSA, they are in the same range and therefore considered comparable				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.28.3. Residue definitions – flupyradifurone (Table 131)

Table 131: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Flupyradifurone	**EU Reg. 396/2005:** 1) Difluoroacetic acid (DFA) 2) Flupyradifurone	No, see comments below
	Animal products	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents The residue is not fat soluble	**EU Reg. 396/2005:** 1) Difluoroacetic acid (DFA) 2) Flupyradifurone The residue is not fat soluble	No, see comments below
RD RA	Plant products	Sum of flupyradifurone, difluoroacetic acid (DFA) and 6-chloropyridine-3-carboxylic acid (6-CNA), expressed as parent equivalents	**EFSA (2015d):** Sum flupyradifurone and DFA, expressed as flupyradifurone	No
	Animal products	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents	**EFSA (2015d):** Sum flupyradifurone and DFA, expressed as flupyradifurone	Yes
Conclusion/ comments	The enforcement residue definitions for plant and animal products derived by the JMPR evaluation are not fully compatible with the residue definitions established in the EU. In addition to the RD for enforcement as 'flupyradifurone', specific EU MRLs are also set for the metabolite difluoroacetic acid (DFA) in order to monitor DFA residues expected in rotational crops (EFSA, 2015d). Although the Codex MRLs for the parent compound could be taken over in the EU legislation, corresponding MRLs for DFA are not proposed by JMPR. Since detailed information on the DFA residues are reported in the JMPR evaluation, it would be possible to derive MRL proposals for DFA to be established in the EU. However, this needs to be discussed with risk managers. The risk assessment residue definition for plant products derived by the JMPR evaluation is wider than the respective EU residue definition, covering also the metabolite 6-chloropyridine-3-carboxylic acid (synonym: 6-chloronicotinic acid; 6-CNA), a metabolite that is not specific for flupyradifurone (this metabolite is also observed in metabolism of other neonicotinoids)			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.28.4. Codex MRL proposals – flupyradifurone (Table 132)

Table 132: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of cherries (includes all commodities in this subgroup)	**2**	Flupyradifurone: 0.01* Difluoroacetic acid (DFA): 0.02*	Critical GAP: USA 2 × 205 g/ha, interval 10 days, PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residues of flupyradifurone ranged from 0.014 to 0.94 mg/kg (STMR-Mo = 0.36 mg/kg). Total residues of flupyradifurone, DFA and 6-CNA expressed as parent equivalents ranged from 0.40 to 1.1 mg/kg (STMR-RA = 0.555 mg/kg). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs and how to precede for setting the MRL for DFA. In the JMPR evaluation, the results for DFA are reported separately, but it is not so obvious which of the 16 residue trials have been selected for deriving the MRL proposal
Subgroup of peaches (including nectarine and apricots) (includes all commodities in this subgroup)	**1.5**	Flupyradifurone: 0.01* Difluoroacetic acid (DFA): 0.02*	Critical GAP: USA 2 × 205 g/ha, interval 10 days, PHI 14 days Number of trials: 11 trials on peaches Sufficiently supported by data: Yes, according to JMPR rules. At EU level, in addition to the trials on peaches, trials on apricots would be required to extrapolate to the whole group. Specific comments/observations: Residues of flupyradifurone ranged from 0.13 to 0.73 mg/kg (STMR-Mo = 0.31 mg/kg). Total residues of flupyradifurone, DFA and 6-CNA expressed as parent equivalents ranged from 0.16 to 1.1 mg/kg (STMR-RA = 0.39 mg/kg). In the JMPR evaluation, the results for DFA are reported separately, but it is not so obvious which of the residue trials have been selected for deriving the MRL proposal. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs and how to precede for setting the MRL for DFA
Subgroup of plums (including fresh prunes) (includes all commodities in this subgroup)	**0.4**	Flupyradifurone: 0.01* Difluoroacetic acid (DFA): 0.02*	Critical GAP: USA 2 × 205 g/ha, interval 10 days, PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residues of flupyradifurone ranged from 0.037 to 0.26 mg/kg (STMR-Mo = 0.09 mg/kg). In the JMPR evaluation, the results for DFA are reported separately, but it is not so obvious which of the 16 residue trials have been selected for deriving the MRL proposal. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs and how to precede for setting the MRL for DFA

Commodity	Codex MRL proposal	EU MRL	Comment
Prunes, dried	**3**	–	The JMPR estimated a processing factor for flupyradifurone (parent only, i.e. the residue definition for enforcement) of 5.3 for prunes. Information on the number of processing studies is not provided in the available data. See also comments on plums
Canned peaches			Based on one processing study, a PF of 0.43 was derived for canned peaches (based on residue definition for risk assessment)
Cooked cherries			Based on one processing study, a PF of 0.35 was derived for cooked cherries (based on residue definition for risk assessment)
Conclusion/ comments	The use in the USA is for the stone fruit group; however, the JMPR recommended MRLs for the individual subgroups of stone fruit, as there are sufficient trials for each subgroup which is acceptable. The residue definition for enforcement in plant products derived by the JMPR evaluation is not fully compatible with the residue definitions established in the EU with regard to the metabolite DFA. The Codex MRL proposal is only 'Flupyradifurone' and the JMPR did not propose a specific Codex MRL for DFA. Specific information on DFA residues is not provided in the available residue trials data, but is probably reported in the JMPR evaluation		

MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.28.5. Consumer risk assessment – flupyradifurone (Table 133)

Table 133: Summary of the consumer risk assessment for flupyradifurone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for cherries, peaches and plums as outlined in Section 4.28.2. The EU ARfD was used. The HR values used for the crops under consideration are according to the RD-RA for plant products derived by the JMPR evaluation, which is wider than the respective EU residue definition, covering also the metabolite 6-CNA	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015d) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for cherries, peaches and plums. The EU ADI was used. The STMR values used for the crops under consideration are according to the RD-RA for plant products derived by the JMPR evaluation, which is wider than the respective EU residue definition, covering also the metabolite 6-CNA	**Specific comments** The JMPR exposure assessment is more comprehensive than the EU assessment because the JMPR RD-RA is wider than the respective EU residue definition, which results in a more conservative risk assessment
Results: No short-term exposure concern was identified (peaches: 44% of the ARfD; plums: 13% of the ARfD; cherries: 9% of the ARfD)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for up to 13% of the ADI (WHO Cluster diet B). The contributions of cherries, peaches and plums to the exposure were 0.3%, 0.3% and 0.1% of the ADI, respectively	**Results:** Long-term exposure: 6–20% of the ADI Short-term exposure: 0–30% of the ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; HR: highest residue; STMR: supervised trials median residue.

4.29. Quinclorac (287) (R)

4.29.1. Background information (Table 134)

Table 134: Background information on quinclorac

		Comments, references
Type of JMPR evaluation	New use	
RMS	–	
Approval status	Not approved	Commission Decision of 2004/129/EC[(a)]
EFSA conclusion	No	–
MRL review	No	–
MRL applications	No	–

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2004/19/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.

4.29.2. Toxicological reference values – quinclorac (Table 135)

Table 135: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.04 mg/kg bw per day	JMPR, 2015	–	–	N/A
ARfD	2 mg/kg bw	JMPR, 2015	–		N/A
Conclusion/ comment	No EU evaluation of the active substance. In 2015, JMPR assessed the active substance and its metabolites. JMPR concluded that the methyl ester is 10-fold more toxic than quinclorac and that a 10-fold potency factor should be applied to the residue levels for use in both the acute and chronic exposure assessments for quinclorac and that these should be added to the dietary exposures for quinclorac and compared with the ARfD and ADI for quinclorac, respectively				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.29.3. Residue definitions – quinclorac (Table 136)

Table 136: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Quinclorac plus quinclorac conjugates	Quinclorac	No
	Animal products	Quinclorac plus quinclorac conjugates The residue is fat soluble	Quinclorac	No
RD RA	Plant products	Quinclorac plus quinclorac conjugate plus quinclorac methyl ester expressed as quinclorac	Not established	N/A
	Animal products	Quinclorac plus quinclorac conjugates	Not established	N/A
Conclusion/ comments	In 2015, JMPR derived the above-reported residue definitions. They were based on metabolism studies in rice, wheat, rape seed, sorghum and strawberries. The metabolite quinclorac methyl ester was a significant residue in rape seeds (occurring in the same amount as parent compound) and was a minor residue in other primary and subsequent rotational crops; parent quinclorac was the major residue in all examined crops. In 2016, when Codex MRL proposals were discussed in CCPR for fruit crops, the EU expressed a reservation on the advancement of these proposed draft MRLs because of concerns as regards the residue definition for enforcement, since the more toxic metabolite was not included.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	In 2017, JMPR reassessed residue definitions; JMPR did not see a need to modify them. Considering that in 2017 JMPR assessed the setting of MRLs for rape seed, a crop where the methyl ester occurred in higher concentrations than expected from the metabolism studies, i.e. up to 400% of the parent compound, it would be more appropriate to include the more toxic metabolite in the residue definition. Parent quinclorac is considered to be not a good marker substance for rape seed. Since the metabolite quinclorac methyl ester has a toxicological potency up to 10 times higher than that of quinclorac, this potency factor needs to be taken into account when deriving the risk assessment values (STMR/HR value), i.e. calculating according to the following equation: (quinclorac + quinclorac conjugate, expressed as quinclorac) + 10 × quinclorac methyl ester, expressed as quinclorac). In 2017, JMPR reported several analytical methods that were used in the residue trials (rape seed) and were considered suitable for enforcement purpose. It needs to be verified whether routine enforcement methods are also covering quinclorac conjugates. Apparently, no hydrolysis step is included to release the conjugates. Without a routine enforcement method, the proposed Codex MRLs for the plant products are not acceptable. A method for animal commodities was reported in 2015 JMPR. The method foresees a hydrolysis step; thus, the quinclorac residues derived with this method seem to include quinclorac released from conjugates. However, in 2015, JMPR noted that it is not clear whether identified quinclorac represents quinclorac only or also includes quinclorac released from conjugates by the alkaline extraction method used. Thus, a confirmation needs to be provided that appropriate analytical methods are available to monitor residues in animal commodities complying with the enforcement residue definition. The results of the feeding studies do not provide any evidence that the residues in animal commodities should be considered as fat soluble			

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.29.4. Codex MRL proposals – quinclorac (Table 137)

Table 137: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (mammalian)	0.1		Specific comments/observations: From the presentation of the input values used for the dietary burden calculation, it is not so clear whether the calculations are based on the residue definition for risk assessment or for the residue definition for enforcement or a mixture, depending on the feed item. The critical dietary burden was calculated for Australia. It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Conclusion: The proposed Codex MRL is acceptable
Eggs	0.05*		Specific comments/observations: It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Conclusion: The proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	0.05*		Specific comments/observations: It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Conclusion: The proposed Codex MRL is acceptable
Meat (from mammals other than marine mammals)	0.05*(fat)		Specific comments/observations: It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Considering the results of the feeding study, the residues should not be classified as fat soluble. Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Milks	0.05*	–	Specific comments/observations: It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Conclusion: The proposed Codex MRL is acceptable
Poultry, Edible offal of	0.05*	–	Specific comments/observations: From the presentation of the input values used for the dietary burden calculation, it is not so clear whether the calculations are based on the residue definition for risk assessment or for the residue definition for enforcement or a mixture, depending on the feed item. The critical dietary burden was calculated for Australia. It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Conclusion: The proposed Codex MRL is acceptable
Poultry fats	0.05*	–	Specific comments/observations: It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Conclusion: The proposed Codex MRL is acceptable
Poultry meat	0.05* (fat)	–	Specific comments/observations: It should be confirmed that an analytical method suitable for the enforcement residue definition is available. Considering the results of the feeding study, the residues should not be classified as fat soluble. Conclusion: The proposed Codex MRL is acceptable.
Rape seed	**0.15**	0.02*	Critical GAP: CAN/USA, 0.1 kg ai/ha, PHI 60 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: The residue trials were analysed with a method that allowed a separate measurement of parent quinclorac and quinclorac methyl. These analyses demonstrate that the methyl ester occurred in higher concentrations than expected from the metabolism studies, i.e. up to 400% of the parent compound. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, taking into account the fact that the residue definition for enforcement has not been revised as suggested by the EU.
Rice	**10**		Critical GAP: USA, 1 × 0.5 kg/ha (from 2-leaf stage to before heading), PHI 40 days Number of trials: 12 Sufficiently supported by data: Yes, but see comments below. Specific comments/observations: The samples were only analysed for parent quinclorac and for quinclorac conjugate; to be verified in JMPR evaluation. To derive the risk assessment value (STMR), a conversion factor was used which was derived from metabolism studies in cereals (rice, wheat, sorghum). In addition, the toxicological potency factor of 10 was applied. Considering the high residues in rice, and the fact that there is only a slight reduction in residues during processing (husked rice, polished rice), the approach to use an indicative conversion factor from metabolism studies to estimate the residues of the more toxic metabolite is leading to a high uncertainty. Conclusion: The proposed Codex MRL is not acceptable because the samples of the supervised field trials were not analysed for the full residue definition. The approach used by JMPR to estimate the residues of quinclorac methyl is expected to lead to a high uncertainty. Considering that the dietary exposure to residues via rice is close to the ARfD, this high level of uncertainty is not acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Rice, husked	10	5	Sufficiently supported by data: No Specific comments/observations: Only 1 study is available which is not sufficient to derive a robust-processing factor. The samples of unprocessed and processed rice were analysed only for parent quinclorac. No reduction of residues occurred during the processing to produce husked rice. The proposed MRL for husked rice is not acceptable.
Rice, polished	8		Sufficiently supported by data: No Specific comments/observations: Only 1 study is available which is not sufficient to derive a robust-processing factor. Apparently, the reduction of residues during the processing to produce polished rice is low.
Rice straw and fodder, dry	8 (dw)		Specific comments/observations: The residue levels of quinclorac and quinclorac conjugates measured in rice straw was used to calculate the dietary burden of livestock. Quinclorac methyl was not taken into account. Metabolism studies do not allow concluding whether quinclorac methyl is an important component of the residue trials, since the extraction regime used did not allow a separate quantification of parent and methyl ester.
Rape seed oil, edible			Specific comments/observations: Based on 4 processing study, a PF of 1.3 was derived (applicable to the RD enforcement).
Rice bran, unprocessed			Specific comments/observations: Based on 1 trial, a PF of 1.3 was derived (applicable to the RD enforcement).

EU MRL: European Union maximum residue limit; PF: processing factor; PHI: preharvest interval; MRL: maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.29.5. Consumer risk assessment – quinclorac (Table 138)

Table 138: Summary of the consumer risk assessment for quinclorac

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A tentative short-term dietary risk assessment was performed for the commodities for which Codex MRL proposals were derived, using the approach as outlined in Section 4.29.2. The HR/STMR values derived by JMPR were used as input values. For rice, in addition, a scenario was calculated using the HR reported for the risk assessment residue definition (16 mg/kg) instead of the STMR (1.45 mg/kg). The JMPR ARfD was used, lacking a toxicological reference value derived in the EU	**RA assumptions:** The long-term risk assessment was performed using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the commodities under assessment. For the remaining commodities, the existing EU MRL was used. The JMPR ADI was used, since no EU reference value is available	**Specific comments**
Results: No short-term exposure concern was identified (0.9% of the ARfD for rice based on the STMR); Using the HR for rice (16 mg/kg), the acute exposure accounted for 10%	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.8% of the ADI. The contribution of rice to the exposure was 0.2% of the ADI	**Results:** Long-term exposure: 1% of the ADI Short-term exposure: 2% of the ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; HR: highest residue; STMR: supervised trials median residue.

4.30. Bicyclopyrone (295) (R/T)

4.30.1. Background information (Table 139)

Table 139: Background information on bicyclopyrone

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	–	
Approval status	Not approved	Not assessed in the EU
EFSA conclusion	No	–
MRL review	No	–
MRL applications	No	–

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.30.2. Toxicological reference values – bicyclopyrone (Table 140)

Table 140: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.003 mg/kg bw per day	JMPR, 2017	–	No EU assessment	–
ARfD	0.01 mg/kg bw (women of childbearing age)	JMPR, 2017	–		–
Conclusion/ comment	JMPR established an ADI on the basis of the effect of thyroid hyperplasia in the 2-year carcinogenicity study in rats, applying an overall safety factor of 100 (with decreased factor for toxicodynamic interspecies differences and increased factor for the use of a LOAEL). The refinements of the safety factor as presented might be considered differently at EU level on the basis of a more detailed assessment. According to JMPR, the ADI and ARfD for bicyclopyrone could be applied to all structurally related metabolites of SYN503780 and CSCD686480, the common moieties included in the residue definitions. EFSA is not in a position to derive a final position based on the available assessment				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.30.3. Residue definitions – bicyclopyrone (Table 141)

Table 141: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of bicyclopyrone and its structurally related metabolites determined as the sum of the common moieties 2-(2-methoxyethoxymethyl)-6-(trifluoromethyl) pyridine-3-carboxylic acid (SYN503780) and (2-(2-hydroxyethoxymethyl)-6-(trifluoromethyl)pyridine-3-carboxylic acid (CSCD686480), expressed as bicyclopyrone	–	N/A

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	Sum of bicyclopyrone and its structurally related metabolites determined as the sum of the common moieties 2-(2-methoxyethoxymethyl)-6-(trifluoromethyl) pyridine-3-carboxylic acid (SYN503780) and 2-(2-hydroxyethoxymethyl)-6-(trifluoromethyl)pyridine-3-carboxylic acid (CSCD686480), expressed as bicyclopyrone. The residue is not fat soluble	–	N/A
RD RA	Plant products	Sum of bicyclopyrone and its structurally related metabolites determined as the sum of the common moieties 2-(2-methoxyethoxymethyl)-6-(trifluoromethyl) pyridine-3-carboxylic acid (SYN503780) and (2-(2-hydroxyethoxymethyl)-6-(trifluoromethyl)pyridine-3-carboxylic acid (CSCD686480), expressed as bicyclopyrone	–	N/A
	Animal products	Sum of bicyclopyrone and its structurally related metabolites determined as the sum of the common moieties 2-(2-methoxyethoxymethyl)-6-(trifluoromethyl) pyridine-3-carboxylic acid (SYN503780) and 2-(2-hydroxyethoxymethyl)-6-(trifluoromethyl)pyridine-3-carboxylic acid (CSCD686480), expressed as bicyclopyrone	–	N/A
Conclusion/ comments	In the EU, no specific residue definition has been established. Thus, currently, the default enforcement residue definition is the parent compound. Residue definition for plant commodities: JMPR proposed a common moiety residue definition for plant commodities which would cover a number of metabolites which individually did not occurs in concentrations < 10%. RD for animal commodities: According to the metabolism in lactating goats, bicyclopyrone was found in all animal matrices; in addition, a metabolite was found in liver and milk in concentrations exceeding the parent compound that would be covered by the common moiety residue definition. In poultry, the parent compound was the main residue, but a number of metabolites occurred in low levels. Risk managers to decide whether a specific residue definition should be established under Regulation (EC) No 396/2005 for plant and animal commodities. The RD proposed by JMPR is more comprehensive and should be considered as an alternative to the default EU RD		

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.30.4. Codex MRL proposals – bicyclopyrone (Table 142)

Table 142: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Sweet corn (corn on the cob) (kernels plus cob with husk removed)	**0.03**	0.01*	Critical GAP: USA, preplant pre-emergence 50 g ai/ha, PHI 45 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	**0.04**	0.01*	Critical GAP: USA, foliar application, 50 g ai/ha, PHI 60 days Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Maize	**0.02***	0.01*	Critical GAP: Uruguay, 1 × 200 g ai/ha (pre-emergence) Number of trials: 26 trials from Brazil and USA Sufficiently supported by data: Yes Specific comments/observations: residue trials partially overdosed, but acceptable since residues were below LOQ Conclusion: The proposed Codex MRL is acceptable
Wheat	**0.04**	0.01*	Critical GAP: USA, CAN; 50 g ai/ha, PHI 60 days Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Sugar cane	**0.02***	0.01*	Critical GAP: Belize, 1 × 262.5 g ai/ha at BBCH 00 to BBCH 08 (pre-emergence) or at BBCH 11 to BBCH 14 (early post-emergence), PHI not required Number of trials: 17 Sufficiently supported by data: Yes Specific comments/observations: Additional overdosed residue trials (3-5N) were reported, all with residues below the LOQ. Conclusion: The proposed Codex MRL is acceptable
Edible offal (mammalian)	**3**	0.01*	In the feeding study in lactating dairy cows, residues were less than the LOQ in milk, fat and muscle. However, in kidney and liver, significant residues were found at 0.6N and 2N dose levels; residues were not dose dependent. The residue levels in the feeding study expected in liver and kidney (1N max. dietary burden) were in the same order of magnitude as the residues found in the metabolism study (lactating goats), which was performed at 25N dose rate of the maximum calculated dietary burden
Milk of cattle, goats and sheep	**0.02***	0.01*	The proposed Codex MRL is sufficiently supported by data and is acceptable
Mammalian fats (except milk fats)	**0.02***	0.01*	The proposed Codex MRL is sufficiently supported by data and is acceptable
Meat (from mammals other than marine mammals)	**0.02***	0.01*	The proposed Codex MRL is sufficiently supported by data and is acceptable
Wheat, bran processed	0.1		A PF of 2.3 was derived from two processing studies
Wheat, germ	0.06		A PF of 1.4 was derived from two processing studies
Barley bran, processed	0.1		The proposed Codex MRL for barley bran was derived by extrapolation from wheat bran. Considering morphological differences between wheat and barley, such an extrapolation, does not seem appropriate

GAP: Good Agricultural Practice; GAP: Good Agricultural Practice; PF: processing factor; MRL: maximum residue limit; PHI: preharvest interval.
*: Indicates that the input value is proposed at the limit of quantification.

4.30.5. Consumer risk assessment – bicyclopyrone (Table 143)

Table 143: Summary of the consumer risk assessment for bicyclopyrone

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for the commodities for which JMPR derived MRL proposals as outlined in Section 4.30.2. The HR values derived for ruminant liver was also used for other edible offal, except kidney (for kidney, a separate HR was reported by MPR which was used in the calculations). The JMPR ARfD was used for both children and adults. The risk assessment is tentative, as no EU reference values are available	**RA assumptions:** A tentative long-term risk assessment was performed, using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the commodities listed in the table above. For the remaining commodities, the default MRL of 0.01 mg/kg was used	**Specific comments** JMPR calculated the acute risk assessment only for women of childbearing age
Results: An exceedance of the ARfD was noted for children for bovine liver (221% of the ARfD) and edible offal of bovine (200% of the ARfD). For adults, the highest exposure was calculated for bovine edible offal and bovine liver (81% and 74% of the ARfD, respectively)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 42% of the ADI. The highest contributor was milk (26% of the ADI)	**Results:** Long-term exposure: 20% of the ADI Short-term exposure: 100% of the ARfD (for women of childbearing age)

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; HR: highest residue; STMR: supervised trials median residue.

4.31. Cyclaniliprole (296) (R/T)

4.31.1. Background information (Table 144)

Table 144: Background information on cyclaniliprole

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	AT	
Approval status	Not approved	Commission Implementing Regulation (EU) 2017/357[(a)]
EFSA conclusion	Yes, see comments	EFSA (2016g)
MRL review	No	
MRL applications	No	

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

(a): 2017/357: Commission Implementing Regulation (EU) 2017/357 of 28 February 2017 concerning the non-approval of the active substance cyclaniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 54, 1.3.2017, p. 4–5.

4.31.2. Toxicological reference values – cyclaniliprole (Table 145)

Table 145: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.04 mg/kg bw per day	JMPR, 2017 (90-day and 1-year dog study, uncertainty factor 100)	0.0043 mg/kg bw per day	EFSA (2016g) (1-year dog study, uncertainty factor 300)	No
ARfD	Unnecessary	JMPR, 2017	–	Not allocated	Yes
Conclusion/ comment	Regarding the ADI setting, the **JMPR** selected an overall NOAEL for the 90-day and 1-year dog studies of 4.07 mg/kg bw per day based on a consistent increase in alkaline phosphatase (ALP) activity, a slight but consistent decrease in albumin and increased liver weight at and above 1,000 ppm (equal to 26.8/27.2 mg/kg bw per day, respectively) and using a 100-fold safety factor. The JMPR considered that the ADI of the parent apply to the metabolites YT-1284, NSY-28 (present in the rat metabolism) and NK-1375 (based on an acute oral toxicity study, an Ames test and structural comparison with cyclaniliprole using Toxtree). In establishing the ADI for cyclaniliprole, the **EU** assessment interpreted differently the same effects observed on the same studies, identifying a LOAEL in both studies, and in the 1-year study, at 1.29 mg/kg bw per day for hepatotoxicity. In general, an increase in relative liver weights above 20% is considered to be adverse in the European peer review. The overall LOAEL was based on increases in liver weights (above 20% in both studies) in combination of induction of ALP and reduction of albumin in females. The basis of a LOAEL to set the ADI implied an additional uncertainty factor of 3 (overall 300). The ADI of the parent applies to metabolite NSY-28, since it was found to be a major rat metabolite. Additional metabolites were discussed for their toxicological relevance: i.e. NK-1375 which was found in significant levels in primary crops and YT-1327, BCPBA and BPQO which were found in processing studies, primarily under conditions representing sterilisation. The data provided on metabolites NK-1375, YT-1327, BCPBA and BPQO was considered insufficient by the peer review to conclude on their toxicity profile. In the EU, the acute oral toxicity study and the Ames test for NK-1375 were also assessed. In the acute oral study, there was no response to treatment at 2,000 mg/kg bw/day and the bacterial reverse mutation study showed no evidence of mutagenic activity in this bacterial system. QSAR analyses have been submitted as additional information but were considered not sufficient to finalise the complete genotoxicity package of NK-1375 including chromosome aberration and mammalian gene mutation				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union; NOAEL: no observed adverse effect level.

4.31.3. Residue definitions – cyclaniliprole (Table 146)

Table 146: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyclaniliprole	Reg. 396/2005: Default residue definition Peer review: Cyclaniliprole (for RAC; For processed commodities, assessment not finalised)	Yes
	Animal products	Cyclaniliprole The residue is fat soluble	Reg. 396/2005: Default residue definition Peer review: Cyclaniliprole The residue is fat soluble	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Cyclaniliprole + 3-bromo-2-((2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b]-[1,4]oxazin-4-ylidene)amino)-5-chloro-N-(1-cyclopropylethyl) benzamide (NK-1375), expressed as cyclaniliprole equivalents Note: The molecular weight conversion factor to express NK-1375 in cyclaniliprole equivalents = 1.064	Peer review: provisional RD for RAC: Cyclaniliprole and metabolite NK 1375 (pending information on the toxicity of metabolite NK-1375) Processed commodities: Assessment is not finalised; a separate residue definition for processed commodities may be proposed, possible inclusion of the compounds YT-1327, BCPBA and BPQO to be considered	N/A, since EU RD is only provisional
	Animal products	Cyclaniliprole	Cyclaniliprole and metabolites NSY-28 and NK-1375; provisionally and pending the submission of data to address the metabolism of NK-1375 in livestock and its toxicological properties. For NSY-28, reference values of parent may be used	No
Conclusion/ comments	In the EU Peer Review of cyclaniliprole, several data gaps were identified (e.g. toxicological assessment, including genotoxic potential of metabolites NK-1375, YT-1327, BCPBA and BPQO relevant to the consumer risk assessment; the occurrence of YT-1327, BCPBA and BPQO in processed commodities and finalisation of the residue definition for processed commodities). Thus, the residue definitions for consumer risk assessment, and consequently, the consumer risk assessment could not finalised because of the data gaps with regard to the toxicological relevance of metabolites NK-1375, YT-1327, BCPBA and BPQO in food commodities			

RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

4.31.4. Codex MRL proposals – cyclaniliprole (Table 147)

Table 147: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Subgroup of cherries (includes all commodities in this subgroup)	**0.9**	0.01	Critical GAP: USA, 1 × 60 + 3 × 80 g ai/ha (max. 300 g ai/ha per season), RTI 7 days, PHI 7 days Number of trials: 15 Sufficiently supported by data: No Specific comments/observations: The residue trials were performed with 3 × 100 g/ha, interval 6–8 days, PHI 7 days. Thus, the trials did not match with the critical GAP. JMPR used a new tool that was developed to model the residue behaviour and would allow to predict residue concentrations for a given GAP from residue trials that differ in terms of application rates, treatment intervals, PHI. Conclusion: Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable
Cherry tomato	**0.1**	0.01	See comments on tomatoes

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Subgroup of cucumbers and Summer squashes (includes all commodities in this subgroup)	**0.06**	0.01	Critical GAP for fruiting vegetables, cucurbits: USA, 4 × 60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 9 trials in cucumbers and 9 in summer squash. Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (cucumber trials: 3 × 76–84 g ai/ha, interval 6–8 days, PHI 1 day; summer squash: 3 × 77–83, interval 6–8 days, PHI 1 day). Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in fruiting vegetables. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Tomato, dried	**0.4**	0.01	The proposed MRL was derived from tomatoes, using processing factor of 3.3
Edible offal (mammalian)	0.01*	0.01	For the calculation of dietary burden, JMPR used the crops for which MRL proposals were derived, its by-products and crops where residues may be expected due to rotational crops. However, the calculations were modified, taking into account that in certain geographical regions, the use on certain crops is not approved. N this modified dietary burden calculation, Australian dietary burden was the basis for deriving MRL proposals for livestock. At the calculated dietary burden, residues were below 0.01 mg/kg in all matrices. Conclusion: The proposed Codex MRL is similar to the current default EU MRL
Subgroup of eggplants (includes all commodities in this subgroup)	**0.1**	0.01	Specific comments/observations: The proposed MRL was derived by extrapolation from tomatoes, see comments on tomatoes. Conclusion: Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Subgroup of flowerhead brassicas (includes all commodities in this subgroup)	**1**	0.01	Critical GAP: USA, 4 × 60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 10 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3×61–87 g ai/ha, interval 6 –8 days, PHI 1 day. Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in flower head brassica. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Subgroup of head brassicas (includes all commodities in this subgroup)	**0.7**	0.01	Critical GAP: USA, 4 × 60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 8 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3×61–102 g ai/ha, interval 6–8 days, PHI 1 day. Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in head brassicas. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Subgroup of leaves of *Brassicaceae Brassica* spp. (includes all commodities in this subgroup)	**15**	0.01	Critical GAP for mustard greens: USA, 4 × 60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 60–81 g ai/ha, interval 6–8 days, PHI 1 days. Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in peaches. Although the number of trials is sufficient for mustard greens (crop category 2), 5 trials are not sufficient to extrapolate to the whole group of leaves of Brassicaceae which comprises also major crops. Conclusion: Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. In addition, the number of trials is insufficient to extrapolate to the whole subgroup of Leaves of brassica. See also other general comments
Meat (from mammals other than marine mammals)	0.01* (fat)	0.01	See comments on Edible offal (mammalian)
Subgroup of melons, pumpkins and Winter squashes (includes all commodities in this group)	**0.15**	0.01	Critical GAP for fruiting vegetables, cucurbits: USA, 4 × 60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 10 trials in melons Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 76–85 g ai/ha, interval 6–8 days, PHI 1 day); summer squash: 3 × 77–83, interval 6–8 days, PHI 1 day). Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in melons and pumpkins. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Mammalian fats (except milk fats)	0.01*	0.01	See comments on Edible offal (mammalian)
Milks	0.01*	0.01	See comments on Edible offal (mammalian)
Milk fats	0.01*	0.01	See comments on Edible offal (mammalian)
Subgroup of peaches (including apricots and nectarines) (includes all commodities in this subgroup)	**0.3**	0.01	Critical GAP: USA, 1 × 60 + 3 × 80 g ai/ha (max. 300 g ai/ha per season), RTI 7 days, PHI 7 days Number of trials: 12 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 55–103 g ai/ha, interval 6–8 days, PHI 7 days. Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in peaches. Furthermore, residue trials in peaches would not be acceptable in the EU to extrapolate to apricots. Conclusion: Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Subgroup of peppers (except martynia, okra and roselle)	**0.2**	0.01	Critical GAP for sweet peppers: USA, 4×60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 9 trials in bell peppers, 3 trials in non-bell peppers Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 60–82 g ai/ha, interval 6–8 days, PHI 1 day). Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in peppers. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Peppers, Chili, dried	**2**	0.01	The proposed MRL was derived from peppers using the default dehydration factor of 10. See comments on peppers.
Group of pome fruits (includes all commodities in this group)	**0.3**	0.01	Critical GAP: USA, 1 × 60 + 3 × 80 g ai/ha (max. 300 g ai/ha per season), RTI 10 days, PHI 7 days Number of trials: 16 in apples, 9 in pears Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 59–107 g ai/ha, interval 13–15 days, PHI 7 days). Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in pome fruit. Conclusion: Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Subgroup of plums (includes all commodities in this subgroup)	**0.2**	0.01	Critical GAP: USA, 1 × 60 + 3 × 80 g ai/ha (max. 300 g ai/ha per season), RTI 7 days, PHI 7 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 40–102 g ai/ha, interval 6–8 days, PHI 7 days. Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in plums. Furthermore, for plums, being a major crop according to Codex rules, at least 8 trials would be required. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Prunes, dried	**0.8**	0.01	The proposed MRL was derived from plums using a processing factor that was derived from one processing study. See comments on plums
Grapes	**0.8**	0.01	Critical GAP: USA, 1 × 60 + 3 × 80 g ai/ha (max. 300 g ai/ha per season), RTI 7 days, PHI 7 days Number of trials: 15 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (3 × 97–105 g ai/ha, interval 6–8 days, PHI 7 days. Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in grapes. Conclusion: Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Tomato	**0.1**	0.01	Critical GAP for fruiting vegetables (covering tomatoes and eggplants): USA, 4 × 60 g ai/ha (max. 240 g ai/ha per season), RTI 5 days, PHI 1 days Number of trials: 22 Sufficiently supported by data: No Specific comments/observations: The conditions of the residue trials did not match with the critical GAP (tomatoes, including cherry tomatoes: 3 × 60–97 g ai/ha, interval 6–8 days, PHI 1 day). Thus, the trials did not match with the critical GAP. JMPR used the new tool (see general comments) to predict residue concentrations in tomatoes. Conclusion: The number of trials is insufficient. Since this model used by JMPR to predict the residues for the cGAP was never presented before, and no reliable validation of the tool is available, the proposed MRL is not acceptable. See also other general comments
Straw and fodder, dry of cereal grains	**0.45 (dw)**	0.01	No MRLs are established at EU level for straw and fodder of cereals
General comments	The tool used by JMPR to decide whether residue trials that differed with regard to the number of applications and the application rate from the critical GAP was reported under point 2.4 of the General Considerations. The validity of the calculation method has not been sufficiently demonstrated and therefore may lead to wrong MRLs. These data gaps and open issues identified in the EU peer review (see comments/conclusions on toxicological reference values and residue definitions) are also valid for the proposed Codex MRLs		

PHI: preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GAP: Good Agricultural Practice; EU: European Union.
*: Indicates that the input value is proposed at the limit of quantification.

4.31.5. Consumer risk assessment – cyclaniliprole (Table 148)

Table 148: Summary of the consumer risk assessment for cyclaniliprole

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was derived.	**RA assumptions:** A tentative short-term dietary risk assessment was performed for the commodities reported above as outlined in Section 4.31.2. The EU ADI was used. The calculation is tentative because of the data gaps as regards the toxicological relevance of metabolites/degradation products (see comments on toxicological reference values and residue definitions). Furthermore, the input values for risk assessment derived by JMPR are not reliable, since they were not based on residue trials matching the GAP. EFSA used the default EU MRLs and the STMR values derived by JMPR, noting the concerns raised in the previous sections	**Specific comments**
Results: –	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 48% of the ADI. The highest contributor was Chinese cabbage (20% of the ADI).	**Results:** Long-term exposure: 0–7% of the ADI Short-term exposure: Not relevant since no ARfD was derived

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GAP: Good Agricultural Practice; MRL: maximum residue limit.

4.32. Fenazaquin (297) (R/T)

4.32.1. Background information (Table 149)

Table 149: Background information on fenazaquin

		Comments, references
Type of JMPR evaluation	New compound evaluation	–
RMS	DE	–
Approval status	Approved	Commission Implementing Directive 2011/39/EU[(a)]
EFSA conclusion	Yes, see comments	EFSA (2010i) (approval restricted to use on ornamentals in greenhouses) EFSA (2013d) (application for amendment of approval conditions)
MRL review	No	Ongoing
MRL applications	Yes, see comments	EFSA (2010c) in tea (dried or fermented leaves and stalks of Camellia sinensis)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 2011/39/EU: Commission Implementing Directive 2011/39/EU of 11 April 2011 amending Council Directive 91/414/EEC to include fenazaquin as active substance and amending Commission Decision 2008/934/EC OJ L 97, 12.4.2011, p. 30–33.

4.32.2. Toxicological reference values – fenazaquin (Table 150)

Table 150: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR, 2017, (NOAEL combined chronic toxicity and carcinogenicity study in rats, UF 100)	0.005 mg/kg bw per day	EFSA (2010i) confirmed by EFSA (2013d) (2-year oral rat study, UF 100)	No
ARfD	0.1 mg/kg bw	JMPR, 2017 NOAEL of rat developmental toxicity study, UF 100)	0.1 mg/kg bw	EFSA (2010i) confirmed by EFSA (2013d) (rat developmental toxicity study, UF 100)	Yes
Conclusion/ comment	For fenazaquin, the EU and JMPR ADI are both derived from the same study, but using a different NOAEL, resulting in a 10 times lower EU ADI. In the EFSA conclusion, the increased incidence of focal hepatocellular atypia was considered adverse, whereas in the JMPR assessment, this effect was considered of uncertain significance as the incidence of this lesion is highly variable in this strain and no other pathological changes were observed. In the absence of a more detailed assessment justifying the non-relevance of this finding, EFSA is not in a position to change the NOAEL into a higher value. The RMS noted that, from a scientific point of view, the ADI derived from JMPR is supported. The existing EU value should be discussed considering the more recent evaluation by JMPR in a post annex I procedure or latest in the renewal procedure for fenazaquin. Metabolites: For the plant metabolite **TBPE**, in the EFSA conclusion (2013d), it was concluded that it is of higher toxicity than fenazaquin, based on its classification for reproductive toxicity (Repr 2) and repeated dose toxicity (STOT 2). Reference values were derived on the basis of a specific 4-week rat study and additional uncertainty factors to cover the extrapolation to chronic toxicity and the uncertainties over reproductive toxicity and damage after prolonged exposure (total UF 10 000), resulting in a value of 0.002 mg/kg bw (per day).				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	For the metabolite **M34** (2-[4-(carboxymethyl)phenyl]-2-methylpropanoic acid), insufficient data were available during the EU peer review to conclude on its toxicity profile (EFSA, 2013d). The metabolite **4-OHQ** (quinazolin-4-ol) was concluded of lower toxicity than fenazaquin, but no reference values were mentioned. The conclusion of JMPR that the reference values of fenazaquin can be applied seems reasonable. For the metabolite **2-oxy**-fenazaquin (identified in groundwater), no toxicological data were available. For the metabolite 2-hydroxyfenazaquin acid, a major metabolite in livestock, no toxicological data were available, neither to JMPR nor to EFSA. JMPR considered that its toxicological properties are covered by studies on parent compound since it was present as a major metabolite in faeces. In EU assessments, metabolites in faeces are not considered to be covered by the parent, since they might not have been absorbed (i.e. bioavailable). As a consequence, EFSA would not support the approach of JMPR for this metabolite				

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.32.3. Residue definitions – fenazaquin (Table 151)

Table 151: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fenazaquin	Reg. 396/2005: Fenazaquin Peer review: Fenazaquin (applicable to fruit);	Yes
	Animal products	Sum of fenazaquin and the metabolite 2-hydroxy-fenazaquin acid expressed as fenazaquin. The residue is fat soluble	Reg. 396/2005: Fenazaquin Peer review: Fenazaquin (ruminants) The residue is fat soluble	No
RD RA	Plant products	Fenazaquin	Peer review: Fenazaquin; TBPE These RD are applicable to unprocessed and processed fruit.	No
	Animal products	Sum of fenazaquin and the metabolite 2-hydroxy-fenazaquin acid expressed as fenazaquin.	Fenazaquin (ruminants)	No
Conclusion/ comments	The proposed enforcement RD for plants of JMPR is identical with the current EU residue definition established in the MRL legislation. The other residue definitions are not fully compatible. The difference in residue definition for animal products is currently of no relevance as regards the proposed Codex MRLs (MRL proposals only for plant products). For plants products, the peer review suggested two separate RA RDs (see above) based on a metabolism study in grapes. Rationale (EFSA, 2013d): For fenazaquin and metabolite TBPE, separate risk assessments are conducted due to the different toxicological reference values (TBPE is of higher toxicity than fenazaquin). JMPR assessed two metabolism studies in apples, one in oranges, grapes and maize. TBPE was not considered as a relevant metabolite by JMPR. It accounted for 2–5% of TRR in apples, < 6% of TRR in grapes (< 0.16 mg eq./kg): In oranges and maize, it was not identified. (This information should be verified in the JMPR evaluation). As regards the separate RD RA for plants (TBPE), the RMS noted that no further in-depth evaluation could be conducted on the continued need for setting of a 2nd RD for TBPE, and the EU position stands as it is. However, for benefits of aligning RD between JMPR and EU as much as possible it is strongly recommended to revisit this question as soon as possible, thereby taking into account potentially new data and new tools (QSAR) which were not available in the course of the peer review in order to decide whether such a high UF of 10 000 is further justified			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.32.4. Codex MRL proposals – fenazaquin (Table 152)

Table 152: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of cherries (inc	**2**	0.3	Critical GAP: USA, 1 × 504 g/ha, 3 days PHI Number of trials: 5 Sufficiently supported by data: For import tolerances in the EU at least 8 trials would be required. In Codex, cherries are also considered a major crop (crop for which refinement criteria applied). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU legislative system, considering the different RA RDs
Hops, dry	**30**	0.01*	Critical GAP: USA, 1 × 504 g/ha, PHI 7 days. Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU legislative system, considering the different RA RDs
General comment:	In the light of the outcome of the peer review, the existing EU MRL for fenazaquin in tea should be reconsidered. It has been established in 2010 following an import tolerance request. At that time, the risk assessment was only performed for fenazaquin. The second RD (TBPE) has been derived later in the framework of the peer review. The RMS proposed to perform an indicative risk assessment for TBPE, based on information on the expected proportion of this metabolite observed in metabolism studies. This type of tentative calculation could be performed by EFSA at a later stage. However, for the chronic risk assessment, the conclusions of an indicative risk assessment will be of low reliability, since currently no comprehensive information is available on all approved GAPs to decide whether the data from metabolism studies are sufficiently representative for all existing uses		

EU MRL: European Union maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.32.5. Consumer risk assessment – fenazaquin (Table 153)

Table 153: Summary of the consumer risk assessment for fenazaquin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions:	**RA assumptions:**	**Specific comments**
The risk assessment could be only performed for the parent compound. For the second EU RD (TBPE), no residue data are reported by JMPR. Thus, the outcome of the risk assessment is tentative.		–
The short-term dietary risk assessment was performed for the crops for which JMPR derived MRL proposals as outlined in Section 4.32.2.	The most recent long-term risk assessment (EFSA, 2010c in tea (dried or fermented leaves and stalks of Camellia sinensis)) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for hops and cherries. The EU ADI was used	
Results: The short-term exposure did not exceed the ARfD (cherries: 11.8% of the ARfD, hops: 1.6% of the ARfD)	**Results:** The calculated long-term consumer for fenazaquin did not exceed the ADI (90.2%). The contribution of cherries and hops was 4% and 1.1%, respectively	**Results:** Long-term exposure: 0.2% of the ADI Short-term exposure: 10% of the ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.33. Fenpyrazamine (298) (R/T)

4.33.1. Background information (Table 154)

Table 154: Background information on fenpyrazamine

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) No 2012/595[(a)]
EFSA conclusion	Yes, see comments	EFSA (2012a)
MRL review	Yes, see comments	EFSA (2017l)
MRL applications	Yes, see comments	EFSA (2018f) (in lettuce and salads plants, escarole, spinach and similar (leaves) group)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 595/2012/EU: Commission Implementing Regulation (EU) No 595/2012 of 5 July 2012 approving the active substance fenpyrazamine, 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 176, 6.7.2012, p. 46–49.

4.33.2. Toxicological reference values – fenpyrazamine (Table 155)

Table 155: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.3 mg/kg bw per day	JMPR, 2017 (Overall NOAEL of 25 mg/kg bw per day in dog studies)	0.13 mg/kg bw per day	EFSA (2012a) (2 years rat, uncertainty factor 100) as in European Commission (2012a)	No
ARfD	0.8 mg/kg bw	JMPR, 2017 (Acute neurotoxicity study in rats)	0.3 mg/kg bw	EFSA (2012a) (Developmental study rabbit, uncertainty factor 100) as in European Commission (2012a)	No
Conclusion/ comment	The JMPR and EFSA used a different study for setting the ADI. EFSA considered more appropriate to use the 2-year rat study than the dog studies. This was because EFSA set a lower NOAEL of 12.7 mg/kg bw per day in the 2-year rat study than JMPR (i.e. NOAEL of 52 mg/kg bw per day). JMPR identified decreased body weight as critical effect for setting the NOAEL of 52 mg/kg bw per day. It is not clear to EFSA why JMPR disregarded liver toxicity for setting the NOAEL, and therefore, EFSA still support the ADI as set during the peer review. The JMPR and EFSA used a different study for setting the ARfD. EFSA considered more appropriate to use the developmental rabbit study where a lower NOAEL was set compared to the acute neurotoxicity study. It is not clear to EFSA why JMPR disregarded the developmental rabbit study for setting the ARfD. As explained by the RMS dose-related premature deliveries/ abortions were observed, which might derive from complete food refusal of these dams for several days prior to the premature delivery. Since it is not clear why the dams refused to feed and at which time point of the pregnancy these effects might be induced, this was considered relevant for setting the ARfD. The data available indicated that the metabolite S-2188-OH is probably of comparable toxicity as the precursor S-2188-DC and parent compound fenpyrazamine. The toxicological profile of MPPZ and S-2188-CH_2-OH-DC was not discussed during the EFSA peer review. JMPR identified these metabolites in laying hen and goat, respectively, noting that these compounds occurred in the rat metabolism. EFSA would support that metabolites MPPZ and S-2188-CH_2-OH-DC can be considered covered by parent on the basis of rat metabolism studies			

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; NOAEL: no observed adverse effect level.

4.33.3. Residue definitions – fenpyrazamine (Table 156)

Table 156: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fenpyrazamine	Fenpyrazamine	Yes
	Animal products	Sum of fenpyrazamine and 5-amino-1,2-dihydro-2-isopropyl-4-(o-tolyl)pyrazol-3-one (S-2188-DC), expressed as fenpyrazamine The residue is not fat soluble	Reg. 396/2005: fenpyrazamine EFSA conclusion: Sum fenpyrazamine and S-2188-DC, expressed as fenpyrazamine The residue is not fat soluble	No, but JMPR RD is comparable proposed new EU RD
RD RA	Plant products	Sum of fenpyrazamine and 5-amino-1,2-dihydro-2-isopropyl-4-(o-tolyl)pyrazol-3-one (S-2188-DC), expressed as fenpyrazamine	Sum fenpyrazamine and S-2188-DC, expressed as fenpyrazamine	Yes
	Animal products	Sum of fenpyrazamine and 5-amino-1,2-dihydro-2-isopropyl-4-(o-tolyl)pyrazol-3-one (S-2188-DC), expressed as fenpyrazamine	Sum of fenpyrazamine, S-2188-DC, S-2188-CH_2OH-DC and MPPZ (provisional)	No
Conclusion/ comments	The residue definitions for plant commodities are comparable. MPPZ was found in metabolism study in poultry (15.9–34.1% TRR), while S-2188-CH_2OH-DC was a metabolite found in goat muscle, kidney and liver (12.7–29.2% TRR). According to JMPR, the two metabolites were found at low concentrations and were found in rats			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.33.4. Codex MRL proposals – fenpyrazamine (Table 157)

Table 157: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Subgroup of cherries (includes all commodities in this subgroup)	3	4	Critical GAP: Austria 3 × 600 g ai/ha, interval 7 days; PHI 1 day Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: The EU MRL is based on the same GAP and data (8 NEU and 4 SEU trials) (EFSA, 2017l). JMPR has merged the NEU and SEU data, while in the EU, the MRL was derived from the NEU data set only. Conclusion: Based on the NEU trials, an MRL of 4 mg/kg would be needed for NEU.
Subgroup of plums (includes all 2 commodities in this subgroup)	2	3	Critical GAP: Austria 3 × 600 g ai/ha, interval 7 days; PHI=1 day. Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The 16 trials are derived from 8 NEU and 8 SEU trials (2017l) Conclusion: The proposed Codex MRL should be reconsidered. Based on the NEU trials, an MRL of 3 mg/kg would be required.
Subgroup of peaches (includes all commodities in this subgroup)	4	4 Art 12 proposal (not yet implemented) 5 (peaches) 5 (apricots)	Critical GAP: Austria 3 × 600 g ai/ha, interval 7 days; PHI=1 day Number of trials: 6 on apricots (2 NEU + 4 SEU); 12 on peaches (4 NEU + 8 SEU) Sufficiently supported by data: Yes Specific comments/observations: –

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: Based on the SEU trials, an MRL proposal of 5 mg/kg was derived for peaches and apricots. Thus, the proposed Codex MRL should be reconsidered
Subgroup of cane berries (includes all commodities in this subgroup)	5	5	Critical GAP: USA 3 × 560 g ai/ha, interval 7 days; PHI = 0 day Number of trials: 4 trials on blackberries and raspberries Sufficiently supported by data: Yes Specific comments/observations: EU import tolerance was based on the same GAP. Conclusion: The proposed Codex MRL is acceptable
Subgroup of bush berries (includes all commodities in this subgroup)	**4**	0.01* Art. 12 proposals 4 blueberries; no proposals for other crops listed under 'bush berries', i.e. currants, gooseberries, rose hips, mulberries and elderberries	Critical GAP: USA 3 × 560 g ai/ha, interval 7 days; PHI = 0 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Same trials (7 GAP compliant and 1 overdosed trials on blueberries) as evaluated by EFSA (EFSA, 2017l). Conclusion: The proposed Codex MRL is acceptable for blueberries. According to the EU extrapolation rules, blueberry trials cannot be used for extrapolation to the other crops listed under the Codex group of bushberries. It is noted that the Codex group of bushberries does not comprise cranberries and azaroles
Grapes	**4**	3	Critical GAP: FR, foliar spray 3 × 560 g ai/ha, interval not specified; PHI = 3 days Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: the meeting used North American data set. It is noted that using the OECD calculator, an MRL of 3 mg/kg is derived. Conclusion: The proposed Codex MRL is should be aligned with the result of the OECD calculator (3 mg/kg)
Dried grapes	12		A processing factor was derived for dried grapes (best estimate 3.1) Sufficiently supported by data: Yes Conclusion: This proposal needs to be reconsidered, taking into account the conclusions on grapes. If the MRL for grapes is agreed to be set at a level of 3 mg/kg, the MRL for dried grapes would be 9 mg/kg.
Strawberry	3	3	Critical GAP: USA foliar spray 4 × 560 g ai/ha, interval 7–14 days; PHI = 0 days; in addition, EU indoor and outdoor GAP Number of trials: 7 for US GAP, 7 for EU indoor, 7 EU outdoor. Specific comments/observations: Although JMPR considered 1 trial less than EFSA, the overall MRL, HR and STMR are more or less the same. Conclusion: The proposed Codex MRL is acceptable
Cucumber	0.7	0.7	Critical GAP: France indoor 3 × 600 g ai/ha, interval 10 days; PHI = 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Same trials (8 GAP compliant on cucumber) were evaluated by EFSA. Conclusion: The proposed Codex MRL is acceptable
Peppers, sweet (including pimento or pimiento)	3	3	Critical GAP: France indoor 3 × 600 g ai/ha, interval 10 days; PHI = 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Same trials (8 GAP compliant on sweet peppers) as evaluated by EFSA. Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Tomato	3	3	Critical GAP: France indoor 3 × 600 g ai/ha, interval 10 days; PHI = 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Same trials (8 GAP compliant on cherry tomatoes) as evaluated by EFSA. Conclusion: The proposed Codex MRL is acceptable
Cherry tomato	3	3	Same GAP and trials as for tomatoes. Conclusion: The proposed Codex MRL is acceptable
Subgroup of eggplants (includes all commodities in this subgroup)	3	3	Critical GAP: France indoor 3 × 600 g ai/ha, interval 10 days; PHI = 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Same trials (8 GAP compliant on cherry tomatoes) as evaluated by EFSA were used to extrapolate to eggplants. Conclusion: The proposed Codex MRL is acceptable
Lettuce, Head	**1.5**	0.01*	Critical GAP: USA 3 × 560 g ai/ha, interval 7–10 days, PHI = 14 days Number of trials: 8 + 8 Sufficiently supported by data: Yes Specific comments/observations: Combined residues for head and leaf lettuce (n = 16) were pooled to derive the proposed MRL. Conclusion: The proposed Codex MRL is acceptable
Lettuce, Leaf	**1.5**	0.01*	Critical GAP: USA 3 × 560 g ai/ha, interval 7–10 days, PHI = 14 days Number of trials: 8 + 8 Sufficiently supported by data: Yes Specific comments/observations: Combined residues for head and leaf lettuce (n = 16) were pooled to derive the proposed MRL. Conclusion: The proposed Codex MRL is acceptable
Ginseng	**0.7**	0.01*	Critical GAP: USA 4 × 560 g ai/ha, interval 7–10 days, PHI = 2 days Number of trials: 3 Sufficiently supported by data: according to JMPR rules, 3 trials are sufficient. Specific comments/observations: HR of 3 trials compliant to US GAP was taken Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. It is noted that in the EU classification, ginger root is in the group of herbal infusions (dried roots). Thus, a dehydration factor would be required if the Codex MRL is taken over in the EU legislation
Almond	0.01*	0.01*	Critical GAP: USA GAP 3 × 420 g ai/ha, interval: not defined, PHI = 21 days Number of trials: 3 (1 GAP compliant, 2 with 2 applications) Sufficiently supported by data: No, at least 4 trials would be required according to JMPR rules. Specific comments/observations: A tentative EU MRL was derived from 5 GAP compliant trials (EFSA, 2017l). Conclusion: Considering that the proposed MRL is at the LOQ, the MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats (except milk fats)	**0.02***	0.01*	Maximum and mean dietary burden were calculated using the mean residues for grape wet pomace. No feeding study on cattle. MRL proposal was derived from goat metabolism study with 7.2 ppm in diet. Conclusion: The proposed Codex MRL is acceptable. It refers to the RD derived by JMPR
Meat (from mammals other than marine mammals)	**0.02***	0.01*	Maximum and mean dietary burden were calculated using the mean residues for grape wet pomace. No feeding study on cattle. MRL proposal was derived from goat metabolism study with 7.2 ppm in diet. Conclusion: The proposed Codex MRL is acceptable. It refers to the RD derived by JMPR
Milks	0.01*	0.01*	No feeding study on cattle (goat metabolism study). Conclusion: The proposed Codex MRL is acceptable
Edible offal (mammalian)	**0.05**	0.01*	Maximum and mean dietary burden were calculated using the mean residues for grape wet pomace. No feeding study on cattle. Residues in liver of goat metabolism study were scaled to the expected DB (AUS) Conclusion: The proposed Codex MRL is acceptable

MRL: maximum residue limit; PHI:preharvest interval; NEU: northern European Union; HR: highest residue; STMR: supervised trials median residue.
*: Indicates that the input value is proposed at the limit of quantification.

4.33.5. Consumer risk assessment – fenpyrazamine (Table 158)

Table 158: Summary of the consumer risk assessment for fenpyrazamine

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed with the PRIMO used for the Art. 12 review (EFSA, 2017l) by including higher JMPR proposals for blueberries, grapes, lettuces, ginseng and animal commodities. The EU ARfD was used.	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2017l) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for blueberries, grapes, lettuces, ginseng and animal commodities	**Specific comments** –
Results: No short-term exposure concern was identified (74.2% of the ARfD for table grapes)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 5.6% of the ADI (WHO Cluster diet B). The contribution of wine and table grapes to the exposure was 74.2% of the ADI	**Results:** Long-term exposure: 0.3% of the ADI Short-term exposure: 40% of the ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; EU: European Union.

4.34. Isoprothiolane (299) (R/T)

4.34.1. Background information (Table 159)

Table 159: Background information on isoprothiolane

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	–	
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[(a)]
EFSA conclusion	No	
MRL review	No	
MRL applications	Yes, see comments	EFSA (2012d)

(a): 2076/2002: 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. OJ L 319, 23.11.2002, p. 3–11.

4.34.2. Toxicological reference values – isoprothiolane (Table 160)

Table 160: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.1 mg/kg bw per day	JMPR, 2018, 2-year rat supported by 1-yr dog, safety factor 100	0.1 mg/kg bw per day	EFSA (2012d), 1-year and 2-year dog studies; 2-year rat, uncertainty factor 100	Yes
ARfD	Unnecessary	JMPR, 2018	0.12 mg/kg bw	EFSA (2012d), Rat developmental toxicity, uncertainty factor 100	No
Conclusion/ comment	During the EU evaluation of isoprothiolane, it was considered that an ARfD should be derived since adverse effects were observed during the early phases of several studies. It was agreed to set an ARfD of 0.12 mg/kg bw based on increased incidences of unossified vertebral bodies in foetuses in the rat developmental study. For the metabolites M3 (4-hydroxy isoprothiolane), M5 (1-hydroxypropan-2-yl propan-2-yl 1,3-dithiolan-2-ylidenemalonate) and M2 (monoester glucuronide conjugate), the JMPR assessment concluded that they are unlikely to be more toxic than the parent. During the EU evaluation (EFSA, 2012d), limited toxicological data (acute and/or genotoxicity studies, no repeated dose study) were provided for two metabolites (didehydro isoprothiolane (M-4) and 4-hydroxy-isoprothiolane (M-3)) and no conclusion was derived on the reference values that could be applicable to them. For metabolite M-2, EFSA cannot fully support the JMPR assessment based on the available data (considering that the genotoxic potential of the metabolite might be excluded on the basis of structural considerations, the extrapolation of the whole toxicity profile from the parent needs to be supported by more robust data)				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.34.3. Residue definitions – isoprothiolane (Table 161)

Table 161: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Isoprothiolane	Reg. 396/2005: Isoprothiolane	Yes
	Animal products	Sum of isoprothiolane and 2-(1,3-dithiolan-2-ylidene)-3-oxo-3-(propan-2-yloxy)propanoic acid (M-2), expressed as isoprothiolane The residue is not fat soluble	Reg. 396/2005: Isoprothiolane The residue is not fat soluble	No
RD RA	Plant products	Rice: isoprothiolane Plants other than rice: Sum of isoprothiolane, diisopropyl-4-hydroxy-1,3-dithiolan-2-ylidenemalonate (M-3); free and conjugated, and 1-hydroxypropan-2-yl propan-2-yl 1,3-dithiolan-2-ylidenemalonate (M-5); free and conjugated, expressed as isoprothiolane	EFSA (2012d): Isoprothiolane (residues in commodities of plant origin other than rice were not assessed in the framework of the EU import tolerance application)	Yes (for rice)
	Animal products	Sum of isoprothiolane and 2-(1,3-dithiolan-2-ylidene)-3-oxo-3-(propan-2-yloxy)propanoic acid (M-2), expressed as isoprothiolane	EFSA (2012d): Residues in livestock were not assessed in the framework of the EU import tolerance application	No
Conclusion/ comments	The paddy rice metabolism studies did not allow for the identification of potential metabolites due to the low application rate; no metabolites exceeded 0.01 mg eq/kg in rice grain at either 7 or 28 DALA. However, the potential contribution of isoprothiolane metabolites to the total consumer intake is covered by a wide safety margin of the calculated consumer exposure to isoprothiolane residues (EFSA, 2012d). JMPR noted that metabolites M-3 and M-5 did not occur in rice grain; however, since these metabolites were the major residue in rotational crops at the 30-day plant back interval, they were included in the residue definition for crops other than rice			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.34.4. Codex MRL proposals – isoprothiolane (Table 162)

Table 162: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Rice, husked	**6**	5	Critical GAP: Japan 9 g/box granule formulation application followed by 2 × 600 g/ha foliar application, PHI 14 days Number of trials: 8 Sufficiently supported by data: No Specific comments/observations: The EU import tolerance assessed the same Japanese GAP (granule formulation broadcast application 9 g a.s. to 5 L nursery box in combination with 2 × 600 g/ha ground spray application (EFSA, 2012d)). Two trials were rejected (dust application not matching the cGAP). These trials, however, were accepted by JMPR. The Codex MRL proposal refers to husked rice which corresponds to the part of the product to which the EU MRL applies for rice. Husked rice (stripped of the husk) is synonymous with brown rice, defined as rice after the removal of the hull from paddy rice. Conclusion: The proposed MRL is not acceptable, since only 6 GAP compliant trials were available. Two trials (the trails that were scaled by JMPR) do not reflect the GAP (dusting application instead of spray)

Commodity	Codex MRL proposal	EU MRL	Comment
Rice, polished	**1.5**	–	The JMPR derived a processing factor (PF) for polished rice of 0.25 on the basis of one study
Meat (from mammals other than marine mammals)	0.01*	0.01*	Only husked rice was considered as a livestock feed commodities by the JMPR, using the STMR of rice grain in the dietary burden calculation. For RD, see general comments below. Conclusion: The proposed Codex MRL is acceptable
Milks	0.01*	0.01*	For RD, see general comments below. Conclusion: The proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	0.01*	0.01*	For RD, see general comments below. Conclusion: The proposed Codex MRL is acceptable
Edible offal (mammalian)	0.01*	0.01*	For RD, see general comments below. Conclusion: The proposed Codex MRL is acceptable
General comments	Considering that an MRL proposal was derived only for rice, the residue definition covering also M-3 and M-5 is currently not relevant. For animal products, the residue definitions applicable in the EU and set by JMPR are different. A revision of the current EU residue definition should be considered, taking over the residue definition for animal products derived by JMPR. It is noted that in the livestock dietary burden calculation, rice bran and rice straw were not included (data insufficient for rice straw). However, without these by-products, the dietary burden might underestimate the actual dietary exposure		

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; STMR: supervised trials median residue.
*: Indicates that the input value is proposed at the limit of quantification.

4.34.5. Consumer risk assessment – isoprothiolane (Table 163)

Table 163: Summary of the consumer risk assessment for isoprothiolane

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was performed for rice as outlined in Section 4.34.2. The EU ARfD was used. The risk assessment assumes that no significant reduction of residues occurs during processing	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2012d) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for rice. The risk assessment assumes that no significant reduction of residues occurs during processing. For animal products, the existing/proposed Codex MRLs were used	**Specific comments** –
Results: No short-term exposure concern was identified (17% of the ARfD)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 1.7% of the ADI. The contribution of rice to the exposure was 1.0% of the ADI	**Results:** Long-term exposure: 2% of the ADI Short-term exposure: Not relevant

4.35. Natamycin (300) (R/T)

4.35.1. Background information (Table 164)

Table 164: Background information on natamycin

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	–	
Approval status	–	Not assessed in the EU
EFSA conclusion	No	
MRL review	No	
MRL applications	No	
Other EFSA assessment	Yes, assessment as food additive	EFSA ANS Panel (2009)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.35.2. Toxicological reference values – natamycin (Table 165)

Table 165: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	Not established	JMPR, 2017	–	–	N/A
ARfD	Not established	JMPR, 2017	–	–	N/A
Conclusion/ comment	No EU evaluation as pesticide. As food additive, the EFSA Panel on Food Additives and Nutrient Sources added to Food (EFSA ANS Panel, 2009) considered that the available data are not sufficiently robust for the purpose of deriving an ADI because of the limitations of the present database on natamycin (design of the animal studies, limited number of animals, lack of a carcinogenicity study) and in view of the inadequate description of the human data. This is line with JMPR assessment as a pesticide				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.35.3. Residue definitions – natamycin (Table 166)

Table 166: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Natamycin (for plant commodities and fungi)	–	N/A
	Animal products	–	–	N/A
RD RA	Plant products	Natamycin (for plant commodities and fungi)	–	N/A
	Animal products	–	–	N/A
Conclusion/ comments	At EU level, natamycin has not been assessed for use in PPPs and no residue definition for use on plants has been set. Natamycin is not listed in any Annex of Regulation (EC) No 396/2005. Natamycin is listed in the veterinary MRL Regulation (EU) No 37/2010[(a)]. Its use is restricted to topical application on bovine and equidae and does not require setting of an MRL and residue marker. In 2009, EFSA assessed natamycin as food additive. The highest potential exposure to natamycin was estimated to be below 0.1 mg/kg bw/day for children (97.5th percentile). Considering that this conservative estimate would provide an adequate margin of safety from the effect level seen from the long-term animal studies and the human study used by JECFA to establish an ADI, the Panel considered that the proposed use levels of natamycin are not of safety concern if it is only used for the surface treatment of the rind of semihard and semisoft cheese and on the casings of certain sausages.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	The residue definition as parent natamycin of JMPR is not based on metabolism studies in plants, but was derived based considerations that for the GAPs under consideration (post-harvest uses in citrus and pineapples and uses in mushrooms) no degradation is expected. EFSA is of the opinion that the residue definition is not sufficiently supported by experimental data. Considering that the residue trials show a transfer from the peel to the pulp in citrus, the theoretical conditions on the residue behaviour on the surface are not sufficient. The nature of residues needs to be investigated in metabolism studies in representative crops for the intended uses. Furthermore, the possible development and/or transfer of resistance may need to be addressed			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.
(a): 37/2010: Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 015 20.1.2010, p. 1.

4.35.4. Codex MRL proposals – natamycin (Table 167)

Table 167: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Group of Citrus fruit (includes all commodities in this group)	5(Po)	–	A Codex MRL proposal was reported (5 mg/kg) only in the JMPR report (p. 307), but this MRL proposal is not mentioned in the Annex 1 (p. 440). On p. 307, JMPR concluded that the residue trials are suitable for establishing an MRL. However, since no toxicological reference values were derived, the dietary risk assessment could not be completed. EFSA noted a number of deficiencies related to the MRL proposal (e.g. lack of storage stability data, nature of residues in edible part of the crop is expected to be different due to hydrolytic degradation under acidic conditions, method to calculate the MRL for post-harvest uses is 'mean + 4 SD' for Po, which leads to a MRL proposal of 4 mg/kg; lack of toxicological reference values to perform a risk assessment) Conclusion: The proposed Codex MRL is not acceptable due to the deficiencies listed above and due to the residue definition that is not sufficiently supported by data

MRL: maximum residue limit.

4.35.5. Consumer risk assessment – natamycin (Table 168)

Table 168: Summary of the consumer risk assessment for natamycin

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: –	**RA assumptions:** –	**Specific comments** JMPR has not conducted a consumer risk assessment
Results: N/A	**Results:** N/A	**Results:** –

RA: risk assessment.

4.36. Phosphonic acid (301) (R/T)

4.36.1. Background information (Table 169)

Table 169: Background information on phosphonic acid

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	FR	
Approval status	Not approved	Assessed as metabolite of fosetyl, potassium phosphonate and disodium phosphonate
EFSA conclusion	Yes, see comments	Fosetyl (EFSA, 2005b – corrigendum 2013), Disodium phoshonate (EFSA, 2013e), Potassium phosphonate (EFSA, 2012h, corrigendum 2013)
MRL review	–	See fosetyl
MRL applications	–	See fosetyl

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.36.2. Toxicological reference values – phosphonic acid (Table 170)

Table 170: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	1 mg/kg bw per day (Applies to fosetyl-aluminium and phosphonic acid, expressed as fosetyl-aluminium)	JMPR, 2017	2.25 mg/kg bw per day	EFSA (2012h–2013e)	No
ARfD	Unnecessary	JMPR, 2017	Unnecessary	EFSA (2012h–2013e)	Yes
Conclusion/ comment	For the ADI of phosphonic acid, considered as the major metabolite of fosetyl-Al and fosetyl, JMPR has proposed to use the ADI of fosetyl-Al. During the EU evaluations, it has been considered more relevant to use the 2-year rat study performed with the hydrated monosodium phosphonate, with a correction for the content of water (25.9%) and for the molecular weight of monosodium phosphonate vs. phosphonic acid. The resulting ADI is 2.25 mg/kg bw per day (UF 100). In the renewal dossier for Fosetyl-Al, no change has been proposed (to be confirmed in an experts' meeting in February 2018)				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.36.3. Residue definitions – phosphonic acid (Table 171)

Table 171: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	See fosetyl Al	No
	Animal products	Phosphonic acid The residue is not fat soluble	See fosetyl Al	No
RD RA	Plant products	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	See fosetyl Al	Yes
	Animal products	Phosphonic acid	See fosetyl Al	Yes
Conclusion/ comments				

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.36.4. Codex MRL proposals – phosphonic acid

See fosetyl.

4.36.5. Consumer risk assessment – phosphonic acid

See fosetyl.

4.37. Fosetyl Al (302) (R/T)

4.37.1. Background information (Table 172)

Table 172: Background information on fosetyl Al

		Comments, references
Type of JMPR evaluation	New compound evaluation	–
RMS	FR	–
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 678/2014[(a)]
EFSA conclusion	Yes, see comments	EFSA (2005b) (corrigendum 2013) EFSA (2014g) (Statement dietary RA proposed temporary MRLs) • EFSA conclusions ongoing (AIR III)
MRL review	Yes, see comments	EFSA (2012g)
MRL applications	Yes, see comments	
		EFSA (2015m) (various crop) EFSA (2012i) (potato, kiwi) EFSA (2018d) (tree nuts, peaches, potatoes)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.
(a): 678/2014/EU: Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac. OJ L 180, 20.6.2014, p. 11–12.

4.37.2. Toxicological reference values – fosetyl Al (Table 173)

Table 173: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	1 mg/kg bw per day (Applies to fosetyl-aluminium and phosphonic acid, expressed as fosetyl-aluminium)	JMPR, 2017	3 mg/kg bw per day	European Commission (2012c) confirmed in EFSA (2005b) (corrigendum 2013) (2-year dog and 2-year rat, safety factor of 100)	No
ARfD	Unnecessary	JMPR, 2017	Unnecessary as low acute toxicity and lack of severe acute effects	–	Yes

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
Conclusion/ comment	For **fosetyl**, a new ADI of 1 mg/kg bw per day based on the rabbit developmental toxicity study is proposed in the RAR and will be discussed in the pesticide peer review meeting in February 2018. An ARfD for fosetyl of 1 mg/kg bw based on the rabbit developmental toxicity study is proposed in the RAR considering the developmental NOAEL of 100 mg/kg bw per day based on increased incidence of dilated ureter at the high dose and an uncertainty factor of 100. This proposal will be discussed in the pesticide peer review meeting in February 2018. Concerning **phosphonic acid**, a specific ADI was proposed in the EFSA Conclusion in corrigendum 2013 at 2.25 mg/kg per day based on the 2-year rat study with an uncertainty factor of 100 and the same is proposed in the RAR (to be confirmed in February 2018). For phosphonic acid, no ARfD has been established and no proposal is made in the RAR. For details on **phosphonic acid**, see section above				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.37.3. Residue definitions – fosetyl Al (Table 174)

Table 174: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	EU Reg. 365/2005: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) MRL review: Phosphonic acid; risk managers to decide whether a separate residue definition for fosetyl should be established (EFSA, 2012h) Peer review: Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid (not enforced) (EFSA corrigendum 2013), confirmed in expert meeting (February 2018)	No
	Animal products	Phosphonic acid The residue is not fat soluble	EU Reg. 365/2005: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) Peer review: Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid (not enforced) (EFSA corrigendum 2013) The residue is not fat soluble	No
RD RA	Plant products	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid MRL review: Phosphonic acid; risk managers to decide whether a separate residue definition for fosetyl should be established (EFSA, 2012h), confirmed by expert meeting (February 2018)	Yes
	Animal products	Phosphonic acid	Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid MRL review: Phosphonic acid; risk managers to decide whether a separate residue definition for fosetyl should be established (EFSA, 2012h)	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion/ comments	The residue definitions for enforcement in plant and animal commodities are expressed differently, i.e., as fosetyl or as phosphonic acid. The conversions between both compounds using conversion factors derived from molecular weights are possible. For animal products, different residue definitions for enforcement are established. In the EU RD, fosetyl is included while JMPR restricted the RD to phosphonic acid. However, fosetyl is rapidly degrading to phosphonic acid in plants and in animals. Thus, the difference of the enforcement residue definitions for animal products is of low practical relevance. The RMS noted that in the RAR the same residue definition as the one set by JMPR was proposed. The proposal to set the residue definitions for both risk assessment and monitoring as phosphonic acid only and to let risk managers decide to set a separate residue definition for fosetyl was discussed during the Standing Committee on the food chain and animal health held in Brussels on February 2014. Member States agreed to the proposal to set the residue definition as 'phosphonic acid'. Nevertheless, pending modification of the existing enforcement residue definition (set in Regulation (EC) No 396/2005), the Article 10 MRL applications submitted to EFSA have been assessed in a way to accommodate various residue definitions. The renewal of the approval of fosetyl-Al at the European level is currently ongoing where the residue definitions for fosetyl-Al in plant and animal matrices will be agreed. When CXLs for plant and animal commodities are taken over in the EU MRL legislation, they need to be converted to fosetyl by applying the molecular weight conversion factor of 1.34. Alternatively, if the EU residue definition is amended as proposed in the peer review, the CXLs can be taken over without recalculation, with a minor discrepancy for the MRLs for animal products			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.37.4. Codex MRL proposals – fosetyl Al (Table 175)

Table 175: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Avocado	20	50	Critical GAP: ES (fosetyl-Al): 3 × 0.24 kg/hL, PHI 14 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: 1 trial matching GAP, rest of trials scaled down. Values ranging from 2.7 to 3.4 mg/kg, except one value at 10 mg/kg. MRL expressed as fosetyl would be 30 mg/kg. Conclusion: The proposed Codex MRL is acceptable.
Cucumber	60 (**80** expressed as fosetyl)	75	Critical GAP: EL (fosetyl-Al): 4 × 4.8 kg/ha, PHI 1 days Number of trials: 7 (indoor) Sufficiently supported by data: No; cucumbers are considered a major crop both by JMPR and at EU level. Thus, at least 8 trials would be required. Specific comments/observations: It is not reported whether the GAP is indoor or outdoor. The MRL expressed as fosetyl would be 80 mg/kg. Conclusion: The proposed Codex MRL is not supported by a sufficient number of trials. However, the EU MRL is established at a similar level, which is based on a sufficient number of trials (MRL proposal under Art. 12: 70 mg/kg for cucumbers and courgette for phosphonic acid for the indoor use (not yet enforced)

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (mammalian)	0.5	0.5*	Based on the mean/max DB calculated for dairy and beef cattle in Australia (31 mg/kg DM) following the intake of grape wet pomace, apple wet pomace and dried citrus pulp. Residues determined in kidney and liver based on the feeding study performed with lactating cows at the dose level 32 mg/kg DM phosphonic acid. The Codex MRL refers to phosphonic acid
Grapes	60	100	Critical GAP: CZ (fosetyl-Al): 3 × 2 kg/ha, PHI 21 days Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: The MRL expressed as fosetyl would be 80 mg/kg. Conclusion: The proposed Codex MRL is acceptable
Group of pome fruits (includes all commodities in this group)	50	75 pome fruit; 2*kaki/ Japanese persimmon, 2* azaroles	Critical GAP: FR (fosetyl-Al): 3 × 3 kg/ha, PHI 28 days Number of trials: 15 (7 apples + 8 pears) Sufficiently supported by data: Yes Specific comments/observations: MRL expressed as fosetyl would be 60 mg/kg. The Codex MRL would apply also to kaki/Japanese persimmon and azaroles, which according to EU food classification is included in the group 'Miscellaneous fruit (edible peel)' and 'Other small fruit and berries'. An extrapolation from apple/ pear trials to Japanese persimmon is acceptable (the existing EU MRL for persimmon is 2* mg/kg). Conclusion: The proposed Codex MRL is acceptable
Hops (dry)	1500 (**2000** expressed as fosetyl)	1500	Critical GAP: DE (fosetyl-Al): 8 × 8 kg/ha, PHI 14 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: The MRL expressed as fosetyl would be 2,000 mg/kg. Conclusion: The proposed Codex MRL is acceptable
Lettuce, head	**200**	75	Critical GAP: FI (fosetyl-Al): 4 × 2.4 kg/ha, PHI 14 days Number of trials: 7 indoor, Sufficiently supported by data: Yes (according the JMPR rules); at EU level lettuce the trials on head and leaf lettuce would be combined. Thus, overall, the number of trials would be sufficient. Specific comments/observations: The MRL expressed as fosetyl would be 300 mg/kg. Conclusion: Due to a different policy of pooling data on leaf and head lettuce, and considering indoor and outdoor trials separately, a different MRL would be derived
Lettuce, leaf	40	75	Critical GAP: FI (fosetyl-Al): 4 × 2.4 kg/ha, PHI 14 days Number of trials: 18 (8 indoor + 10 outdoor) Sufficiently supported by data: Yes Specific comments/observations: The indoor and outdoor residue trials were combined to derive CXL. The Codex MRL for the indoor use alone would be 60 mg/kg (or 70 mg/kg, expressed as fosetyl) and 30 mg/kg for the outdoor use (or 40 mg/kg expressed as fosetyl). Conclusion: See conclusion on lettuce, head

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats (except milk fats)	0.2	0.5*	Based on the mean/max DB calculated for dairy and beef cattle in Australia (31 mg/kg DM) following the intake of grape wet pomace, apple wet pomace and dried citrus pulp. Residues determined in fat based on the feeding study performed with lactating cows at the dose level 32 mg/kg DM phosphonic acid. The Codex MRL refers to phosphonic acid
Meat (from mammals other than marine mammals)	0.15	0.5* (muscle)	Based on the mean/max DB calculated for dairy and beef cattle in Australia (31 mg/kg DM) following the intake of grape wet pomace, apple wet pomace and dried citrus pulp. Residues determined in meat based on the feeding study performed with lactating cows at the dose level 32 mg/kg DM phosphonic acid. The Codex MRL refers to phosphonic acid
Melon (except water melon)	60	75	Critical GAP: FR (fosetyl-Al): 2 × 3.2 kg/ha, PHI 3 days Number of trials: 14 (8 indoor + 6 outdoor) Sufficiently supported by data: Yes for indoor, no for outdoor Specific comments/observations: Indoor and outdoor residue trials were combined. The Codex MRL for indoor use alone would be 50 mg/kg (and 70 mg/kg, expressed as fosetyl); the outdoor use is not sufficiently supported by residue data (additional 2 trials would be required). Conclusion: Although at EU level, the indoor and outdoor trials would not be combined, the proposed Codex MRL might be acceptable to risk managers
Milks	0.1	0.1*	Based on the mean/max DB calculated for dairy and beef cattle in Australia (31 mg/kg DM) following the intake of grape wet pomace, apple wet pomace and dried citrus pulp. Residues determined in meat based on the feeding study performed with lactating cows at the dose level 32 mg/kg DM phosphonic acid. The Codex MRL refers to phosphonic acid
Peppers, sweet, (including pimento or pimiento)	7	130	Critical GAP: HU (fosetyl): indoor 18.6 kg/ha + 9.3 kg/ha (seeding drench) + 4 × 0.93 kg/ha (drip irrigation), PHI 3 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: The MRL expressed as fosetyl would be 9 mg/kg. Conclusion: The proposed Codex MRL is acceptable. The manufacturer should be encouraged to submit the EU GAP and residue trials to JMPR set a Codex MRL that covers the EU uses
Spinach	20	75	Critical GAP: BE (fosetyl): outdoor 1 × 0.775 kg/ha, PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The MRL expressed as fosetyl would be 30 mg/kg. Conclusion: The proposed Codex MRL is acceptable. The proposed Codex MRL is acceptable. The manufacturer should be encouraged to submit the EU GAP and residue trials to JMPR set a Codex MRL that covers the EU uses

Commodity	Codex MRL proposal	EU MRL	Comment
Strawberries	70 (**100** expressed as fosetyl)	75	Critical GAP: FR (fosetyl-Al): 3 × 4 kg/ha, PHI 14 days Number of trials: 16 (8 indoor + 8 outdoor) Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL for the outdoor use alone would be 80 mg/kg (150 mg/kg, expressed as fosetyl) and 60 mg/kg for indoor use (80 mg/kg, expressed as fosetyl). Conclusion: Although at EU level, indoor and outdoor trials would not be combined, the proposed Codex MRL may be acceptable for risk managers
Subgroup of Mandarins (includes all commodities in this subgroup)	50	75	Critical GAP: USA (fosetyl-Al): 4 × 4.48 kg/ha, PHI 12 h Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations:.JMPR used EU trials on mandarins scaled down for USA GAP. The MRL expressed as fosetyl would be 60 mg/kg. In the Art. 12 review, an MRL of 50 mg/kg for phosphonic acid for mandarins was proposed for an EU use (not yet enforced). Conclusion: To be discussed, whether the proposed Codex MRL is not acceptable since it is based on EU trials to support US GAP
Subgroup of oranges, sweet, sour (includes all commodities in this subgroup)	20	75	Critical GAP: USA (fosetyl-Al): 4 × 4.48 kg/ha, PHI 12 h Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: EU trials on oranges were scaled down for USA GAP. The MRL expressed as fosetyl would be 30 mg/kg. In the Art. 12 review, an MRL of 20 mg/kg for phosphonic acid for oranges was proposed for an EU use (not yet enforced). Conclusion: To be discussed, whether the proposed Codex MRL is not acceptable since it is based on EU trials to support US GAP
Summer squash	70 (**100** expressed as fosetyl)	75	Critical GAP: EL (fosetyl-Al): 4 × 4.8 kg/ha, PHI 3 days Number of trials: 6 Sufficiently supported by data: Yes (according to JMPR rules); at EU level, 2 additional trials would be required. Specific comments/observations: Trials were scaled up for the GAP. The MRL expressed as fosetyl would be 100 mg/kg. Conclusion: The proposed Codex MRL is not acceptable because 2 more trials would be required. However, the Art. 12 review, an MRL of 70 mg/kg for phosphonic acid was proposed based on indoor GAP for EU uses (not yet enforced)
Tomato	8	100	Critical GAP: HU (fosetyl): indoor 2 × 9.3 kg/ha (seedling drench)+ 4 × 0.93 kg/ha (drip irrigation); PHI 3 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The residue values range from 0.21 to 0.47, apart from a single value at 5.2 mg/kg. The MRL expressed as fosetyl would be 10 mg/kg. Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Tree nuts (includes all 400 commodities in this group)	**400** (**500** expressed as fosetyl)	2* for Brazil nuts, chestnuts, coconuts, pecans, pine nut kernels 75 for almonds, cashew nuts, hazelnuts, macadamias, pistachios, walnuts	Critical GAP: USA (phosphonic acid): 6 × 1.9 kg/ha Number of trials: 15 (5 almonds + 5 pistachio + 5 walnuts) Sufficiently supported by data: Yes Specific comments/observations: The MRL expressed as fosetyl would be 500 mg/kg and according to EU extrapolation rules would not apply to coconuts. Recent EU assessment of the same US trials was performed where 2 trials (almond/walnuts) were disregarded (deviations in number of appl.), but the MRL proposal derived was 500 mg/kg (tree nuts except coconuts). Conclusion: The proposed Codex MRL is acceptable

GAP: Good Agricultural Practice; MRL: maximum residue limit; CXL: Codex Maximum Residue Limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.37.5. Consumer risk assessment – fosetyl Al (Table 176)

Table 176: Summary of the consumer risk assessment for fosetyl Al

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The short-term dietary risk assessment was not performed as ARfD is established neither for fosetyl nor for phosphonic acid	**RA assumptions:** The most recent long-term risk assessment performed for total residues expressed as fosetyl (scenario1) and separately for total residues expressed as phosphonic acid (scenario 2) (EFSA, 2018d) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for those crops for which Codex MRL proposal is higher than the existing corresponding EU MRL (cucumber, hops, strawberries, courgettes (summer squash), tree nuts, persimmon, lettuce). For animal commodities, only those Codex MRL proposals were included in the RA, which were at the same level (or higher) than the corresponding EU MRL (ruminant kidney, liver, edible offal and milk). For tree nuts, the STMR values derived under EU assessment were higher and thus used in the RA. To assess consumer exposure to phosphonic acid residues, the existing EU MRLs were expressed as phosphonic acid by applying the molecular weight conversion factor of 0.75 where the risk assessment values for phosphonic acid were not available.	**Specific comments** The ADI values set at EU level and CCPR are different
Results:	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 43% of the ADI for fosetyl (scenario 1) and for 40% of the ADI for phosphonic acid (scenario 2)	**Results:** Long-term exposure: 30% of the ADI for fosetyl-Al (applicable also to phosphonic acid) Short-term exposure: not calculated, not necessary

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; ADI: acceptable daily intake; ARfD: acute reference dose; EU: European Union.

4.38. Triflumezopyrim (303) (R/T)

4.38.1. Background information (Table 177)

Table 177: Background information on triflumezopyrim

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	–	
Approval status	Approval status	–
EFSA conclusion	EFSA conclusion	No
MRL review	MRL review	No
MRL applications	MRL applications	No

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RMS: rapporteur Member State.

4.38.2. Toxicological reference values – triflumezopyrim (Table 178)

Table 178: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.2 mg/kg bw per day	JMPR, 2017; Rat 2-year study	–	No EU assessment	Not applicable
ARfD	1 mg/kg bw	JMPR, 2017; Rat acute neurotoxicity study	–		Not applicable
Conclusion/ comment	Considering the data presented in the JMPR assessment, different conclusions might be derived during an EU peer review on the basis of a more detailed evaluation (also taking into account the carcinogenic potential and the identified endocrine-mediated effects against the approval criteria). However, for the time being, no application for EU approval has been submitted. Metabolites IN-Y2186 and IN-RPD47: in the absence of toxicological data, and considering that they are not major rat metabolites, the considerations given to structural similarities are not sufficient to conclude on their overall toxicity profile.				

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values; EU: European Union.

4.38.3. Residue definitions – triflumezopyrim (Table 179)

Table 179: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Triflumezopyrim	–	N/A
	Animal products	Triflumezopyrim The residue is not fat soluble	–	N/A
RD RA	Plant products	Sum of triflumezopyrim and 3-(trifluoromethyl)benzoic acid (IN-Y2186), expressed as triflumezopyrim	–	N/A
	Animal products	Triflumezopyrim	–	N/A
Conclusion/ comments	Since the substance is not specifically mentioned in Regulation (EC) No 396/2005, the default residue definition (parent compound) is currently applicable. For the tentative risk assessment, the residue definitions derived by JMPR for risk assessment can be used			

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; RD RA: residue definition for risk assessment; RD enf: residue definition for enforcement practice; EU: European Union.

4.38.4. Codex MRL proposals – triflumezopyrim (Table 180)

Table 180: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Rice	**0.2**	0.01*	Critical GAP: China, India, Thailand: 2 × 25 g ai/ha, PHI 21 days Number of trials: 23 Sufficiently supported by data: Yes Specific comments/observations: The samples were analysed only for the parent compound, but not for the full-residue definition for risk assessment which comprises also metabolite IN-Y2186. Conclusion: At EU level, no MRLs are established for rice grain (rice including the husk)
Rice, husked	0.01	0.01*	Critical GAP: see 'Rice' Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: 6 slightly overdosed residue trials (2 × 37.5 g ai/ha) with husked rice were available. In none of the samples, quantifiable residues were found. For risk assessment, 8 residue trials from Thailand were mentioned, that were analysed for parent triflumezopyrim and the metabolite IN-2186. Using molecular weight conversion factors, the corresponding residue concentrations for the sum of parent + IN-2186, expressed as parent were determined. The resulting residues were significantly higher than the residues reported for parent compound (i.e. up to 0.098 mg/kg). Conclusion: In the EU MRL legislation, an MRL should be established for husked rice. Although only 6 trials are available, the MRL proposal of 0.01 mg/kg should be acceptable, considering that this value is similar to the current default MRL
Rice, polished	0.01	0.01*	Specific comments/observations: No specific processing studies for polished rice are available. The results from husked rice gave an indication that no quantifiable residues are likely to occur in polished rice
Meat (from mammals other than marine mammals)	0.01*	0.01*	Specific comments/observations: The calculation of the dietary burden of livestock is based on residues of parent triflumezopyrim in feed (i.e. rice straw, rice hulls, rice grain and rice bran). The contribution of residues on IN-2186 was neglected (e.g. for rice grain, the STMR value of 0.025 mg/kg derived for parent compound was used, instead of the STMR value calculated for the risk assessment residue definition (0.053 mg/kg). The highest dietary burden was identified for the Australian livestock diet. In the feeding studies, residues were below the LOQ in all animal commodities. Conclusion: Although the calculation of the dietary burden is likely to underestimate the actual exposure, the proposed MRLs is acceptable, considering that no quantifiable residues were found in animal products even at significantly higher feeding levels. However, the calculation of the dietary burden calculation should be reconsidered (including all components of the risk assessment residue definition)
Mammalian fats (except milk fats)	0.01*	0.01*	See comments on meat (mammals)
Edible offal (mammalian)	0.01*	0.01*	See comments on meat (mammals)
Milks	0.01*	0.01*	See comments on meat (mammals)

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Poultry meat	0.01*	0.01*	Specific comments/observations: For dietary burden calculation, see comments on meat (from mammals). No poultry feeding study was available. The proposed MRLs were derived from the metabolism study in poultry which was performed with a significantly higher dose rate (at least 824 times higher). Conclusion: Although the dietary burden was calculated wrongly, the MRL proposal might be acceptable, considering the evidence that even at significantly higher feeding levels no quantifiable residues were found
Poultry fats	0.01*	0.01*	See comment on poultry meat
Poultry, edible offal of	0.01*	0.01*	See comment on poultry meat
Eggs	0.01*	0.01*	See comment on poultry meat

MRL: maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.

4.38.5. Consumer risk assessment – triflumezopyrim (Table 181)

Table 181: Summary of the consumer risk assessment for triflumezopyrim

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions:A tentative short-term dietary risk assessment was performed for rape seed as outlined in Section 4.38.2. The JMPR ARfD was used	**RA assumptions:** A tentative long-term risk assessment was performed, based on the existing EU MRLs and the including the STMR values derived by JMPR for the commodities under assessment	**Specific comments**
Results: No short-term exposure concern was identified (0.1% of the ARfD for milk and rice)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.4% of the ADI	**Results:** Long-term exposure: 0.2% of the ADI Short-term exposure: 0% of the ARfD

ADI: acceptable daily intake; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRV: toxicological reference values.

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Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DM	dry matter
DMS	document management system
dw	dry weight
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
ha	hectare
hL	hectolitre
HR	highest residue
IESTI	International estimated of short-term intake
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
MW	Molecular weight
NEU	northern European Union
NOAEL	no observed adverse effect level
n.n	not necessary
n.a	not applicable
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
ppm	parts per million (10^{-6})
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
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
TTC	threshold of toxicological concern
TRR	total radioactive residues
UF	Uncertainty factor
VF	variation factor
WHO	World Health Organization

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

Chlormequat			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	0.09
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
0 40

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)
40.4	DK child	16.3	Wheat	15.7	Rye	5.1	Milk and cream	
28.4	WHO Cluster diet B	25.3	Wheat	1.3	Milk and cream	0.5	Barley	
28.2	NL child	14.1	Wheat	11.7	Milk and cream	0.8	Oats	
25.5	UK Infant	15.5	Milk and cream	7.8	Wheat	2.0	Oats	
24.1	FR toddler	15.8	Milk and cream	7.8	Wheat	0.2	Bovine: Meat	
24.1	WHO cluster diet D	19.3	Wheat	2.0	Milk and cream	1.4	Rye	
23.0	DE child	12.2	Wheat	5.7	Milk and cream	2.8	Rye	
21.2	WHO cluster diet E	11.7	Wheat	3.9	Rape seed	1.5	Rye	
20.5	UK Toddler	11.6	Wheat	8.3	Milk and cream	0.4	Oats	
19.8	IT kids/toddler	19.7	Wheat	0.0	Pears	0.0	Cultivated fungi	
19.7	WHO Cluster diet F	10.7	Wheat	2.7	Rye	2.1	Rape seed	
18.9	ES child	13.2	Wheat	5.0	Milk and cream	0.2	Bovine: Meat	
15.7	SE general population 90th percentile	9.5	Wheat	5.0	Milk and cream	1.0	Rye	
13.1	WHO regional European diet	8.8	Wheat	1.9	Milk and cream	0.8	Rape seed	
13.1	FR infant	10.3	Milk and cream	2.5	Wheat	0.1	Bovine: Meat	
12.8	PT General population	11.6	Wheat	0.5	Rye	0.3	Wine grapes	
12.7	IE adult	6.8	Wheat	2.1	Barley	1.4	Oats	
12.4	IT adult	12.3	Wheat	0.0	Pears	0.0	Cultivated fungi	
11.8	DK adult	6.0	Wheat	2.4	Rye	2.1	Milk and cream	
11.7	FR all population	9.8	Wheat	1.1	Milk and cream	0.5	Wine grapes	
10.4	NL general	6.2	Wheat	2.6	Milk and cream	0.6	Barley	
10.3	ES adult	7.0	Wheat	2.0	Milk and cream	0.8	Barley	
9.6	LT adult	3.8	Rye	3.1	Wheat	1.6	Milk and cream	
8.4	FI adult	2.9	Wheat	2.4	Rye	2.3	Milk and cream	
8.1	UK vegetarian	6.1	Wheat	1.3	Milk and cream	0.4	Oats	
6.6	UK Adult	5.0	Wheat	1.2	Milk and cream	0.1	Wine grapes	
0.1	PL general population	0.1	Cultivated fungi	0.0	Table grapes	0.0	Pears	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of chlormequat 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)
40.0	Milk and milk products:	0.29/-	40.0	Milk and milk	0.29/-	10.3	Wheat	1.1868/-	10.3	Wheat	1.1868/-
28.1	Cultivated fungi	3/-	28.1	Cultivated fungi	3/-	9.7	Cultivated fungi	3/-	9.7	Cultivated fungi	3/-
19.1	Wheat	1.1868/-	19.1	Wheat	1.1868/-	7.7	Rye	1.419/-	7.7	Rye	1.419/-
13.7	Oats	3.1/-	13.7	Oats	3.1/-	5.6	Milk and milk	0.29/-	5.6	Milk and milk products: Cattle	0.29/-
10.0	Rye	1.419/-	10.0	Rye	1.419/-	5.5	Barley	0.68/-	5.5	Barley	0.68/-
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)			
15.6	Wheat flour	1.1868/-				5.8	Bread/pizza	1.1868/-			
1.9	Grape juice	0.0516/-				0.2	Wine	0.0516/-			
1.4	Pear juice	0.07/-				0.0	Raisins	0.0516/-			
0.0	Wine	0.0516/-									
0.0	Grapes (raisins)	0.0516/-									

*) 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 chlormequat, 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.

Chlormequat

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.05**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2018**	Year of evaluation:	**2018**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	0 – 32
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)
32.3	DK child	13.1	Wheat	12.5	Rye	4.0	Milk and cream	
22.7	WHO Cluster diet B	20.3	Wheat	1.0	Milk and cream	0.4	Barley	
22.5	NL child	11.3	Wheat	9.4	Milk and cream	0.7	Oats	
20.4	UK Infant	12.4	Milk and cream	6.2	Wheat	1.6	Oats	
19.3	FR toddler	12.7	Milk and cream	6.2	Wheat	0.1	Bovine: Meat	
19.3	WHO cluster diet D	15.4	Wheat	1.6	Milk and cream	1.1	Rye	
18.4	DE child	9.8	Wheat	4.6	Milk and cream	2.2	Rye	
17.0	WHO cluster diet E	9.4	Wheat	3.1	Rape seed	1.2	Rye	
16.4	UK Toddler	9.3	Wheat	6.6	Milk and cream	0.3	Oats	
15.9	IT kids/toddler	15.8	Wheat	0.0	Pears	0.0	Cultivated fungi	
15.8	WHO Cluster diet F	8.5	Wheat	2.2	Rye	1.6	Rape seed	
15.1	ES child	10.5	Wheat	4.0	Milk and cream	0.1	Bovine: Meat	
12.5	SE general population 90th percentile	7.6	Wheat	4.0	Milk and cream	0.8	Rye	
10.5	WHO regional European diet	7.0	Wheat	1.5	Milk and cream	0.6	Rape seed	
10.4	FR infant	8.2	Milk and cream	2.0	Wheat	0.1	Bovine: Meat	
10.2	PT General population	9.3	Wheat	0.4	Rye	0.3	Wine grapes	
10.1	IE adult	5.4	Wheat	1.7	Barley	1.1	Oats	
9.9	IT adult	9.8	Wheat	0.0	Pears	0.0	Cultivated fungi	
9.4	DK adult	4.8	Wheat	1.9	Rye	1.7	Milk and cream	
9.4	FR all population	7.8	Wheat	0.9	Milk and cream	0.4	Wine grapes	
8.3	NL general	4.9	Wheat	2.1	Milk and cream	0.5	Barley	
8.2	ES adult	5.6	Wheat	1.6	Milk and cream	0.7	Barley	
7.7	LT adult	3.1	Rye	2.5	Wheat	1.3	Milk and cream	
6.7	FI adult	2.3	Wheat	1.9	Rye	1.8	Milk and cream	
6.5	UK vegetarian	4.9	Wheat	1.0	Milk and cream	0.3	Oats	
5.3	UK Adult	4.0	Wheat	1.0	Milk and cream	0.1	Wine grapes	
0.1	PL general population	0.1	Cultivated fungi	0.0	Table grapes	0.0	Pears	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of chlormequat 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)
72.0	Milk and milk products:	0.29/-	72.0	Milk and milk	0.29/-	18.6	Wheat	1.1868/-	18.6	Wheat	1.1868/-
50.7	Cultivated fungi	3/-	50.7	Cultivated fungi	3/-	17.5	Cultivated fungi	3/-	17.5	Cultivated fungi	3/-
34.3	Wheat	1.1868/-	34.3	Wheat	1.1868/-	13.8	Rye	1.419/-	13.8	Rye	1.419/-
24.7	Oats	3.1/-	24.7	Oats	3.1/-	10.0	Milk and milk	0.29/-	10.0	Milk and milk products: Cattle	0.29/-
17.9	Rye	1.419/-	17.9	Rye	1.419/-	9.8	Barley	0.68/-	9.8	Barley	0.68/-
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)	
28.1	Wheat flour	1.1868/-		10.4	Bread/pizza	1.1868/-	
3.4	Grape juice	0.0516/-		0.4	Wine	0.0516/-	
2.5	Pear juice	0.07/-		0.0	Raisins	0.0516/-	
0.0	Wine	0.0516/-					
0.0	Grapes (raisins)	0.0516/-					

*) 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 chlormequat, 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.

Oxamyl

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.001**	ARfD (mg/kg bw):	**0.001**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
2	28

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)
28.2	UK Toddler	22.9	Sugar beet (root)	1.7	Potatoes	1.1	Bananas	
15.7	UK Infant	10.1	Sugar beet (root)	1.6	Potatoes	1.5	Bananas	
8.8	FR toddler	2.5	Potatoes	2.4	Carrots	1.3	Bananas	
8.3	WHO Cluster diet B	3.1	Tomatoes	1.3	Potatoes	0.7	Sugar beet (root)	
8.2	NL child	2.9	Potatoes	1.7	Bananas	1.6	Oranges	
8.0	DE child	1.9	Oranges	1.5	Bananas	1.3	Potatoes	
7.2	SE general population 90th percentile	2.1	Potatoes	1.8	Bananas	0.8	Carrots	
6.8	FR infant	2.6	Carrots	2.1	Potatoes	0.7	Bananas	
6.5	UK vegetarian	3.8	Sugar beet (root)	0.7	Potatoes	0.6	Tomatoes	
6.4	DK child	1.6	Cucumbers	1.4	Carrots	1.2	Potatoes	
6.2	UK Adult	4.0	Sugar beet (root)	0.7	Potatoes	0.4	Tomatoes	
5.4	IE adult	1.1	Potatoes	0.8	Bananas	0.6	Parsnips	
5.2	PT General population	2.7	Potatoes	0.9	Tomatoes	0.7	Carrots	
4.9	WHO regional European diet	2.0	Potatoes	1.1	Tomatoes	0.4	Bananas	
4.6	ES child	1.1	Oranges	1.0	Bananas	1.0	Tomatoes	
4.6	WHO cluster diet D	2.0	Potatoes	1.0	Tomatoes	0.2	Carrots	
4.4	WHO Cluster diet F	1.7	Potatoes	0.7	Tomatoes	0.6	Bananas	
4.2	WHO cluster diet E	1.9	Potatoes	0.5	Tomatoes	0.5	Carrots	
3.5	NL general	1.4	Potatoes	0.7	Oranges	0.4	Tomatoes	
3.4	IT kids/toddler	1.4	Tomatoes	0.5	Bananas	0.4	Potatoes	
3.3	PL general population	1.7	Potatoes	0.9	Tomatoes	0.3	Carrots	
3.0	LT adult	1.6	Potatoes	0.6	Tomatoes	0.4	Cucumbers	
2.9	ES adult	0.8	Tomatoes	0.6	Oranges	0.5	Potatoes	
2.6	IT adult	1.2	Tomatoes	0.3	Potatoes	0.2	Bananas	
2.5	DK adult	0.7	Potatoes	0.4	Carrots	0.4	Tomatoes	
2.3	FI adult	0.6	Potatoes	0.5	Oranges	0.4	Tomatoes	
2.2	FR all population	0.6	Potatoes	0.4	Tomatoes	0.3	Carrots	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Oxamyl 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):**		**1**	**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)
128.7	Cucumbers	0.022/0.01	128.7	Cucumbers	0.022/0.01	59.4	Courgettes	0.022/-	44.7	Courgettes	0.022/-
102.3	Courgettes	0.022/0.02	75.8	Melons	0.005/-	43.3	Cucumbers	0.022/-	43.3	Cucumbers	0.022/-
75.8	Melons	0.005/-	73.1	Courgettes	0.022/-	24.9	Aubergines (egg	0.01/-	24.9	Aubergines (egg plants)	0.01/-
63.0	Peppers	0.01/-	61.1	Watermelons	0.005/-	20.3	Watermelons	0.005/-	20.3	Watermelons	0.005/-
61.1	Watermelons	0.005/-	45.0	Peppers	0.01/-	19.7	Melons	0.005/-	19.7	Melons	0.005/-
No of critical MRLs (IESTI 1)		2				**No of critical MRLs (IESTI 2)**		1			

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)	
42.9	Carrot, juice	0.01/-		5.5	Orange juice	0.0055/-	
27.2	Orange juice	0.0055/-		1.9	Tomato (preserved-fresh)	0.01/-	
17.4	Tomato juice	0.01/-		0.4	Potato uree (flakes)	0.005/-	
6.8	Potato puree (flakes)	0.005/-		0.4	Fried potatoes	0.005/-	
0.7	Fried potatoes	0.005/-					

*) 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 Oxamyl, 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 1 commodities.

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

Propiconazole

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.04**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	2 – 12
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)
11.9	WHO Cluster diet B	5.6	Tomatoes	1.3	Wheat	0.9	Maize	0.0
11.2	UK Toddler	6.3	Sugar beet (root)	1.1	Oranges	1.1	Tomatoes	0.0
11.1	DE child	3.3	Apples	2.1	Oranges	1.7	Tomatoes	0.0
7.8	NL child	1.7	Apples	1.7	Oranges	1.1	Tomatoes	0.0
7.2	UK Infant	2.8	Sugar beet (root)	1.0	Rice	0.7	Oranges	0.0
6.0	IE adult	0.9	Maize	0.8	Peaches	0.7	Tomatoes	0.0
6.0	PT General population	1.6	Tomatoes	1.3	Rice	0.7	Wine grapes	
5.7	ES child	1.8	Tomatoes	1.2	Oranges	0.8	Rice	0.0
5.5	IT kids/toddler	2.6	Tomatoes	1.0	Wheat	0.5	Peaches	
5.2	WHO cluster diet D	1.8	Tomatoes	1.0	Wheat	0.9	Rice	0.0
4.8	FR toddler	1.4	Tomatoes	1.1	Oranges	0.7	Apples	0.0
4.4	IT adult	2.1	Tomatoes	0.6	Wheat	0.6	Peaches	
4.4	WHO cluster diet E	0.9	Tomatoes	0.6	Wheat	0.5	Wine grapes	0.0
4.4	WHO regional European diet	2.0	Tomatoes	0.4	Wheat	0.3	Rice	0.0
4.4	SE general population 90th percentile	1.4	Tomatoes	0.7	Rice	0.5	Wheat	0.0
4.3	UK vegetarian	1.1	Tomatoes	1.0	Sugar beet (root)	0.6	Rice	0.0
4.1	DK child	1.0	Tomatoes	0.8	Wheat	0.7	Rye	0.0
4.1	ES adult	1.4	Tomatoes	0.7	Oranges	0.4	Rice	0.0
4.0	WHO Cluster diet F	1.2	Tomatoes	0.5	Wheat	0.5	Oranges	0.0
3.8	UK Adult	1.1	Sugar beet (root)	0.8	Tomatoes	0.6	Rice	0.0
3.5	FR all population	1.2	Wine grapes	0.8	Tomatoes	0.5	Wheat	0.0
3.4	NL general	0.8	Oranges	0.8	Tomatoes	0.3	Apples	0.0
2.7	PL general population	1.6	Tomatoes	0.6	Apples	0.2	Cherries	
2.5	LT adult	1.1	Tomatoes	0.5	Apples	0.4	Rice	0.0
2.4	DK adult	0.7	Tomatoes	0.4	Wine grapes	0.3	Wheat	0.0
2.2	FI adult	0.8	Tomatoes	0.5	Oranges	0.2	Rice	0.0
2.1	FR infant	0.7	Apples	0.5	Oranges	0.3	Tomatoes	0.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Propiconazole 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)
57.0	Oranges	0.43/-	41.2	Oranges	0.43/-	11.0	Oranges	0.43/-	8.9	Oranges	0.43/-
35.6	Peaches	0.6/-	26.1	Peaches	0.6/-	10.5	Peaches	0.6/-	8.1	Peaches	0.6/-
23.9	Mandarins	0.43/-	22.0	Cherries	1.8/-	7.6	Cherries	1.8/-	7.6	Cherries	1.8/-
22.0	Cherries	1.8/-	19.2	Pineapples	0.19/-	5.8	Mandarins	0.43/-	4.5	Mandarins	0.43/-
19.2	Pineapples	0.19/-	18.0	Mandarins	0.43/-	4.3	Pineapples	0.19/-	4.3	Pineapples	0.19/-
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)	
12.6	Tomato juice	0.72/-		2.2	Orange juice	0.22/-	
10.9	Orange juice	0.22/-		1.4	Tomato (preserved-fresh)	0.72/-	
10.6	Peach juice	0.59/-		1.2	Peach preserved with	0.59/-	
5.6	Apple juice	0.11/-		0.7	Apple juice	0.11/-	
3.9	Grape juice	0.12/-		0.5	Wine	0.12/-	

*) 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 Propiconazole, 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.

Fenpropimorph

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.003**	ARfD (mg/kg bw):	**0.03**
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
	3 – 33
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)
33.1	UK Toddler	9.9	Sugar beet (root)	6.5	Wheat	6.3	Currants (red, black and white)	
28.3	NL child	7.9	Wheat	6.4	Currants (red, black and white)	4.5	Bananas	
27.0	WHO Cluster diet B	14.2	Wheat	9.7	Gooseberries	0.8	Bananas	
23.8	UK Infant	4.4	Sugar beet (root)	4.4	Wheat	3.9	Bananas	
23.7	DK child	9.2	Wheat	7.4	Rye	3.0	Bananas	
23.0	DE child	6.9	Wheat	4.1	Bananas	3.9	Currants (red, black and white)	
17.7	WHO cluster diet D	10.8	Wheat	1.8	Currants (red, black and white)	1.0	Raspberries	
17.7	IE adult	5.7	Currants (red, black and white)	3.8	Wheat	3.7	Barley	
17.1	SE general population 90th percentile	5.3	Wheat	4.8	Bananas	1.2	Milk and cream	
16.2	WHO cluster diet E	6.6	Wheat	2.5	Currants (red, black and white)	2.4	Barley	
15.7	FR toddler	4.4	Wheat	4.0	Milk and cream	3.4	Bananas	
15.5	WHO Cluster diet F	6.0	Wheat	1.8	Barley	1.6	Currants (red, black and white)	
12.9	IT kids/toddler	11.1	Wheat	1.4	Bananas	0.2	Carrots	
11.8	ES child	7.4	Wheat	2.7	Bananas	1.3	Milk and cream	
10.1	FI adult	3.7	Currants (red, black and white)	1.6	Wheat	1.4	Blueberries	
9.8	WHO regional European diet	4.9	Wheat	1.0	Bananas	1.0	Barley	
9.0	FR infant	2.6	Carrots	2.6	Milk and cream	1.9	Bananas	
8.8	NL general	3.5	Wheat	1.2	Currants (red, black and white)	1.1	Barley	
8.5	PT General population	6.5	Wheat	0.9	Bananas	0.7	Carrots	
8.4	UK vegetarian	3.4	Wheat	1.6	Sugar beet (root)	1.0	Bananas	
7.7	IT adult	6.9	Wheat	0.5	Bananas	0.1	Carrots	
7.4	UK Adult	2.8	Wheat	1.7	Sugar beet (root)	0.9	Bananas	
7.2	ES adult	3.9	Wheat	1.5	Barley	1.0	Bananas	
7.1	FR all population	5.5	Wheat	0.7	Bananas	0.3	Carrots	
7.0	DK adult	3.4	Wheat	1.1	Rye	1.0	Bananas	
6.2	LT adult	1.8	Rye	1.8	Wheat	1.0	Currants (red, black and white)	
3.4	PL general population	2.1	Gooseberries	0.5	Bananas	0.3	Carrots	

Conclusion:

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

Acute risk assessment /children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**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)
	119.8	Bananas	0.43/0.35	86.9	Bananas	0.43/-	39.7	Raspberries	3/-	39.7	Raspberries	3/-
	67.9	Bovine: Liver	2.524/-	67.9	Bovine: Liver	2.524/-	22.7	Bovine: Liver	2.524/-	22.7	Bovine: Liver	2.524/-
	56.1	Raspberries	3/-	56.1	Raspberries	3/-	19.6	Bananas	0.43/-	16.8	Blueberries	1.59/-
	49.2	Currants (red, black	1.59/-	49.2	Currants (red,	1.59/-	16.8	Blueberries	1.59/-	15.0	Bananas	0.43/-
	32.8	Gooseberries	1.59/-	32.8	Gooseberries	1.59/-	14.5	Dewberries	3/-	14.5	Dewberries	3/-
	No of critical MRLs (IESTI 1)		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)			
	49.2	Cuurant juice	1.46/-				0.7	Bread/pizza	0.05/-			
	41.6	Raspberries juice	1.04/-									
	35.3	Blueberries	1.46/-									
	4.3	Carrot, juice	0.03/-									
	2.0	Wheat flour	0.05/-									

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.

*) 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 Fenpropimorph, 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 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 0 commodities.

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

Tebuconazole

Status of the active substance:	**Approved**	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:	**2008**	Year of evaluation:	**2008**

MRLs according to Reg. (EU) 2017/626, exept for beans with pods (crop under assessment) using HR proposed by JMPR 2018.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	3 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	WHO Cluster diet B	2.4	Tomatoes	2.2	Wine grapes	1.7	Beans (without pods)	
14.6	DE child	5.2	Apples	1.0	Milk and milk products: Cattle	0.7	Tomatoes	
14.5	IE adult	2.8	Barley	1.5	Wine grapes	1.2	Beans (without pods)	
13.1	NL child	2.7	Apples	2.0	Milk and milk products: Cattle	0.8	Wheat	
12.3	WHO cluster diet E	2.0	Wine grapes	1.8	Barley	1.5	Beans (without pods)	
9.0	PT General population	3.1	Wine grapes	1.7	Beans (without pods)	0.7	Rice	
8.7	WHO regional European diet	1.6	Peas (with pods)	0.8	Tomatoes	0.7	Barley	
8.4	FR all population	4.9	Wine grapes	0.5	Wheat	0.3	Tomatoes	
8.4	FR toddler	1.2	Carrots	1.2	Beans (with pods)	1.1	Apples	
8.0	WHO Cluster diet F	1.4	Barley	0.7	Wine grapes	0.6	Wheat	
7.3	FR infant	1.7	Milk and milk products: Cattle	1.3	Carrots	1.1	Apples	
7.1	ES child	0.8	Milk and milk products: Cattle	0.8	Tomatoes	0.7	Wheat	
7.0	SE general population 90th percentile	0.8	Milk and milk products: Cattle	0.6	Tomatoes	0.6	Beans (without pods)	
6.8	WHO cluster diet D	1.1	Wheat	0.8	Tomatoes	0.5	Rice	
6.6	DK child	1.0	Apples	0.9	Wheat	0.9	Oats	
6.5	NL general	0.8	Barley	0.8	Wine grapes	0.5	Apples	
6.3	ES adult	1.1	Barley	0.6	Tomatoes	0.5	Wine grapes	
4.8	UK Toddler	0.7	Apples	0.7	Wheat	0.5	Rice	
4.7	UK Infant	0.7	Apples	0.7	Carrots	0.6	Rice	
4.3	IT kids/toddler	1.1	Wheat	1.1	Tomatoes	0.4	Apples	
4.3	DK adult	1.7	Wine grapes	0.3	Apples	0.3	Wheat	
4.0	UK vegetarian	1.0	Wine grapes	0.5	Tomatoes	0.4	Rice	
3.8	LT adult	0.8	Apples	0.5	Tomatoes	0.3	Swine: Meat	
3.7	UK Adult	1.3	Wine grapes	0.3	Rice	0.3	Tomatoes	
3.6	IT adult	0.9	Tomatoes	0.7	Wheat	0.3	Apples	
3.2	PL general population	0.9	Apples	0.7	Tomatoes	0.4	Beans (without pods)	
2.5	FI adult	0.4	Wine grapes	0.3	Tomatoes	0.2	Oats	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Tebuconazole 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)
71.9	Beans (with pods)	1.9/-	71.9	Beans (with pods)	1.9/-	33.6	Beans (with pods)	1.9/-	33.6	Beans (with pods)	1.9/-
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 Tebuconazole, 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.

Fenpyroximate

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):	**0.02**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	5 28
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)
27.6	DE child	10.1	Apples	6.1	Oranges	2.1	Cherries	
21.7	NL child	5.3	Apples	5.0	Oranges	2.9	Potatoes	
16.6	WHO Cluster diet B	3.1	Tomatoes	1.9	Wine grapes	1.4	Oranges	
15.7	IE adult	1.8	Tea (dried leaves and stalks	1.7	Oranges	1.3	Wine grapes	
13.0	FR toddler	3.2	Oranges	2.5	Potatoes	2.2	Apples	
10.1	PT General population	2.7	Potatoes	2.6	Wine grapes	1.0	Oranges	
9.7	UK Toddler	3.2	Oranges	1.7	Potatoes	1.4	Apples	
9.7	ES child	3.5	Oranges	1.0	Tomatoes	1.0	Apples	
9.5	WHO cluster diet E	1.9	Potatoes	1.7	Wine grapes	0.7	Oranges	
8.8	FR infant	2.1	Apples	2.1	Potatoes	1.5	Oranges	
8.6	UK Infant	2.1	Oranges	1.6	Potatoes	1.3	Apples	
8.6	NL general	2.4	Oranges	1.4	Potatoes	1.0	Apples	
8.5	DK child	2.1	Cucumbers	2.0	Apples	1.2	Potatoes	
8.5	WHO regional European diet	2.0	Potatoes	1.1	Tomatoes	0.8	Oranges	
8.3	WHO cluster diet D	2.0	Potatoes	1.0	Tomatoes	0.6	Cherries	
8.3	FR all population	4.2	Wine grapes	0.6	Potatoes	0.5	Oranges	
8.2	SE general population 90th percentile	2.1	Potatoes	1.2	Oranges	0.9	Apples	
7.2	WHO Cluster diet F	1.7	Potatoes	1.4	Oranges	0.7	Tomatoes	
7.0	ES adult	2.1	Oranges	0.8	Tomatoes	0.6	Apples	
6.3	PL general population	1.7	Potatoes	1.7	Apples	0.9	Tomatoes	
6.2	IT kids/toddler	1.4	Tomatoes	0.8	Oranges	0.7	Apples	
6.1	UK vegetarian	1.4	Oranges	0.8	Wine grapes	0.7	Tea (dried leaves and stalks	
5.5	UK Adult	1.1	Wine grapes	0.9	Oranges	0.8	Tea (dried leaves and stalks	
5.4	IT adult	1.2	Tomatoes	0.7	Apples	0.6	Peaches	
5.3	LT adult	1.6	Potatoes	1.6	Apples	0.6	Tomatoes	
5.2	DK adult	1.4	Wine grapes	0.7	Potatoes	0.7	Apples	
4.7	FI adult	1.6	Oranges	0.6	Potatoes	0.4	Tomatoes	

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

Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
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):**		**---**	**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)
179.0	Oranges	0.27/0.15	129.4	Oranges	0.27/0.2	34.5	Oranges	0.27/-	28.1	Oranges	0.27/-
120.4	Grapefruit	0.27/0.22	120.4	Grapefruit	0.27/0.22	27.0	Grapefruit	0.27/-	23.6	Cucumbers	0.24/-
75.1	Mandarins	0.27/-	70.2	Cucumbers	0.24/-	23.6	Cucumbers	0.24/-	21.2	Aubergines (egg plants)	0.17/-
74.2	Peaches	0.25/-	68.3	Melons	0.09/-	21.8	Peaches	0.25/-	21.0	Cherries	0.99/-
70.2	Cucumbers	0.24/-	61.1	Watermelons	0.1/-	21.2	Aubergines (egg	0.17/-	20.3	Watermelons	0.1/-
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)			
38.2	Apple juice	0.15/-				4.9	Apple juice	0.15/-			
23.0	Plums juice	0.33/-				2.5	Peach preserved with syrup	0.25/-			
22.4	Peach juice	0.25/-				1.8	Orange juice	0.0364/-			
14.8	Tomato juice	0.17/-				1.6	Tomato (preserved-	0.17/-			
13.1	Pear juice	0.15/-				1.2	Wine	0.06/-			

*) 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.

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.

Conclusion:
For Fenpyroximate, 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.

Fenpyroximate

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):	**0.01**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
5 28

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)
27.6	DE child	10.1	Apples	6.1	Oranges	2.1	Cherries	
21.7	NL child	5.3	Apples	5.0	Oranges	2.9	Potatoes	
16.6	WHO Cluster diet B	3.1	Tomatoes	1.9	Wine grapes	1.4	Oranges	
15.7	IE adult	1.8	Tea (dried leaves and stalks	1.7	Oranges	1.3	Wine grapes	
13.0	FR toddler	3.2	Oranges	2.5	Potatoes	2.2	Apples	
10.1	PT General population	2.7	Potatoes	2.6	Wine grapes	1.0	Oranges	
9.7	UK Toddler	3.2	Oranges	1.7	Potatoes	1.4	Apples	
9.7	ES child	3.5	Oranges	1.0	Tomatoes	1.0	Apples	
9.5	WHO cluster diet E	1.9	Potatoes	1.7	Wine grapes	0.7	Oranges	
8.8	FR infant	2.1	Apples	2.1	Potatoes	1.5	Oranges	
8.6	UK Infant	2.1	Oranges	1.6	Potatoes	1.3	Apples	
8.6	NL general	2.4	Oranges	1.4	Potatoes	1.0	Apples	
8.5	DK child	2.1	Cucumbers	2.0	Apples	1.2	Potatoes	
8.5	WHO regional European diet	2.0	Potatoes	1.1	Tomatoes	0.8	Oranges	
8.3	WHO cluster diet D	2.0	Potatoes	1.0	Tomatoes	0.6	Cherries	
8.3	FR all population	4.2	Wine grapes	0.6	Potatoes	0.5	Oranges	
8.2	SE general population 90th percentile	2.1	Potatoes	1.2	Oranges	0.9	Apples	
7.2	WHO Cluster diet F	1.7	Potatoes	1.4	Oranges	0.7	Tomatoes	
7.0	ES adult	2.1	Oranges	0.8	Tomatoes	0.6	Apples	
6.3	PL general population	1.7	Potatoes	1.7	Apples	0.9	Tomatoes	
6.2	IT kids/toddler	1.4	Tomatoes	0.8	Oranges	0.7	Apples	
6.1	UK vegetarian	1.4	Oranges	0.8	Wine grapes	0.7	Tea (dried leaves and stalks	
5.5	UK Adult	1.1	Wine grapes	0.9	Oranges	0.8	Tea (dried leaves and stalks	
5.4	IT adult	1.2	Tomatoes	0.7	Apples	0.6	Peaches	
5.3	LT adult	1.6	Potatoes	1.6	Apples	0.6	Tomatoes	
5.2	DK adult	1.4	Wine grapes	0.7	Potatoes	0.7	Apples	
4.7	FI adult	1.6	Oranges	0.6	Potatoes	0.4	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fenpyroximate 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): 8			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)
358.1	Oranges	0.27/0.07	258.8	Oranges	0.27/0.1	69.1	Oranges	0.27/-	56.1	Oranges	0.27/-
240.8	Grapefruit	0.27/0.11	240.8	Grapefruit	0.27/0.11	54.0	Grapefruit	0.27/-	47.2	Cucumbers	0.24/-
150.3	Mandarins	0.27/0.17	140.4	Cucumbers	0.24/0.17	47.2	Cucumbers	0.24/-	42.3	Aubergines (egg plants)	0.17/-
148.3	Peaches	0.25/0.16	136.5	Melons	0.09/0.06	43.7	Peaches	0.25/-	42.0	Cherries	0.99/-
140.4	Cucumbers	0.24/0.17	122.3	Watermelons	0.1/0.08	42.3	Aubergines (egg	0.17/-	40.6	Watermelons	0.1/-
136.6	Pears	0.15/0.1	121.1	Cherries	0.99/0.81						
136.5	Melons	0.09/0.06	113.0	Mandarins	0.27/0.23						
122.3	Watermelons	0.1/0.08	108.8	Peaches	0.25/0.22						
121.1	Cherries	0.99/0.81	98.2	Pears	0.15/-						
108.6	Plums	0.33/0.3									
98.8	Tomatoes	0.17/-									
93.0	Lemons	0.27/-									
No of critical MRLs (IESTI 1)		10				**No of critical MRLs (IESTI 2)**		8			

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)
76.4	Apple juice	0.15/-		9.9	Apple juice	0.15/-
46.0	Plums juice	0.33/-		5.0	Peach preserved with syrup	0.25/-
44.8	Peach juice	0.25/-		3.7	Orange juice	0.0364/-
29.6	Tomato juice	0.17/-		3.2	Tomato (preserved-	0.17/-
26.3	Pear juice	0.15/-		2.3	Wine	0.06/-

*) 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 Fenpyroximate, 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 8 commodities.

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

Cyprodinil

Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.03	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2005

MRL according to Reg. (EU) 2017/626, except CXL proposal (CCP report 2018) in red.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	5 – 40
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)
39.7	DE child	19.7	Apples	2.9	Table grapes	2.1	Spinach	
32.2	NL child	10.3	Apples	3.8	Spinach	2.1	Scarole (broad-leaf endive)	
27.4	WHO Cluster diet B	4.0	Wine grapes	3.7	Lettuce	3.7	Wheat	
24.7	IE adult	3.6	Celery	3.1	Barley	2.8	Wine grapes	
24.6	FR toddler	7.3	Spinach	4.3	Apples	3.6	Carrots	
20.2	FR infant	4.6	Spinach	4.1	Apples	3.9	Carrots	
18.3	FR all population	8.9	Wine grapes	2.0	Other lettuce and other salad plants	1.4	Wheat	
18.2	WHO cluster diet E	3.6	Wine grapes	2.0	Barley	1.7	Wheat	
16.7	DK child	3.8	Apples	2.4	Wheat	2.0	Carrots	
16.1	IT adult	3.9	Lettuce	1.8	Wheat	1.6	Other lettuce and other salad	
16.0	WHO regional European diet	3.9	Lettuce	1.3	Wheat	1.1	Apples	
15.9	ES adult	5.5	Lettuce	1.3	Apples	1.2	Barley	
15.7	IT kids/toddler	3.0	Lettuce	2.9	Wheat	1.4	Apples	
15.1	ES child	4.3	Lettuce	1.9	Wheat	1.9	Apples	
13.8	PT General population	5.6	Wine grapes	1.7	Apples	1.7	Wheat	
13.8	NL general	1.9	Apples	1.5	Spinach	1.4	Wine grapes	
12.8	WHO Cluster diet F	3.1	Lettuce	1.6	Wheat	1.5	Barley	
12.2	WHO cluster diet D	2.8	Wheat	1.1	Apples	0.9	Celery	
10.9	SE general population 90th percentile	1.7	Apples	1.4	Wheat	1.3	Carrots	
10.8	UK Toddler	2.8	Apples	1.7	Wheat	1.2	Celery	
10.5	UK Infant	2.6	Apples	2.0	Carrots	1.1	Wheat	
9.2	UK vegetarian	1.8	Wine grapes	1.5	Lettuce	1.0	Celery	
8.5	DK adult	3.1	Wine grapes	1.3	Apples	0.9	Wheat	
7.8	PL general population	3.3	Apples	0.7	Table grapes	0.5	Tomatoes	
7.5	UK Adult	2.4	Wine grapes	1.2	Lettuce	0.7	Wheat	
7.3	LT adult	3.0	Apples	0.7	Lettuce	0.5	Rye	
5.0	FI adult	0.8	Lettuce	0.7	Wine grapes	0.7	Apples	

Conclusion:

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

Trifloxystrobin

Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.1**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EU**	Source of ARfD:	**EFSA**
Year of evaluation:	**2003**	Year of evaluation:	**2017**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
1 8

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)
8.4	FR toddler	5.4	Spinach	0.8	Milk and cream	0.4	Beans (with pods)	
7.0	NL child	2.8	Spinach	0.7	Apples	0.6	Milk and cream	
6.0	DE child	1.6	Spinach	1.3	Apples	0.4	Oranges	
5.8	WHO Cluster diet B	1.2	Lettuce	1.2	Olives for oil production	0.6	Spinach	
5.4	FR infant	3.4	Spinach	0.5	Milk and cream	0.3	Beans (with pods)	
4.4	IE adult	1.0	Spinach	0.3	Lettuce	0.3	Other leafy brassica	
4.0	ES child	1.4	Lettuce	0.6	Spinach	0.4	Olives for oil production	
3.6	ES adult	1.7	Lettuce	0.6	Spinach	0.3	Olives for oil production	
3.5	IT adult	1.2	Lettuce	0.7	Spinach	0.5	Other lettuce and other salad	
3.3	WHO regional European diet	1.2	Lettuce	0.3	Spinach	0.2	Herbs	
3.0	NL general	1.1	Spinach	0.4	Lettuce	0.1	Oranges	
2.9	IT kids/toddler	0.9	Lettuce	0.4	Spinach	0.4	Other lettuce and other salad	
2.8	WHO cluster diet E	0.3	Spinach	0.3	Lettuce	0.3	Herbs	
2.6	SE general population 90th percentile	0.5	Spinach	0.3	Chinese cabbage	0.3	Head cabbage	
2.5	UK Toddler	0.5	Sugar beet (root)	0.4	Milk and cream	0.2	Spinach	
2.4	FR all population	0.6	Other lettuce and other salad plants	0.5	Wine grapes	0.3	Lettuce	
2.4	WHO Cluster diet F	1.0	Lettuce	0.1	Head cabbage	0.1	Wheat	
2.3	WHO cluster diet D	0.4	Herbs	0.2	Chinese cabbage	0.2	Wheat	
2.2	UK Infant	0.8	Milk and cream	0.2	Sugar beet (root)	0.2	Apples	
2.0	DK child	0.5	Lettuce	0.3	Milk and cream	0.2	Apples	
1.7	UK vegetarian	0.5	Lettuce	0.3	Spinach	0.1	Wine grapes	
1.5	PT General population	0.3	Wine grapes	0.2	Olives for oil production	0.1	Rice	
1.4	UK Adult	0.4	Lettuce	0.1	Wine grapes	0.1	Spinach	
1.1	LT adult	0.2	Lettuce	0.2	Apples	0.2	Head cabbage	
1.0	FI adult	0.3	Lettuce	0.1	Milk and cream	0.1	Oranges	
1.0	PL general population	0.2	Apples	0.2	Head cabbage	0.1	Tomatoes	
0.9	DK adult	0.2	Wine grapes	0.1	Milk and cream	0.1	Apples	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

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)
	45.2	Spinach	10/-	45.2	Spinach	10/-	17.9	Spinach	10/-	17.9	Spinach	10/-
	6.1	Head cabbage	0.58/-	3.7	Head cabbage	0.58/-	3.7	Head cabbage	0.58/-	2.2	Head cabbage	0.58/-
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)			
	14.5	Grape juice	2.2/-				1.7	Wine	2.2/-			
	6.8	Peach juice	1.9/-				0.8	Peach preserved with syrup	1.9/-			
	5.3	Plums juice	1.9/-				0.6	Apple juice	0.44/-			
	4.5	Apple juice	0.44/-				0.5	Orange juice	0.23/-			
	3.5	Passion fruit juice	2.28/-				0.2	Tomato (preserved-	0.49/-			
*) 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 Trifloxystrobin, 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.												

Scenario 2

Difenoconazole			
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):	**0.16**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Fall-back (outoor GAP for escaroles.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
18	199
No of diets exceeding ADI:	3

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)
199.0	DE child	132.7	Apples	8.7	Herbal infusions (dried)	7.4	Citrus fruit	
134.9	NL child	69.7	Apples	7.4	Spinach	6.5	Citrus fruit	
101.9	WHO Cluster diet B	22.2	Tomatoes	11.1	Apples	9.3	Wine grapes	
94.9	FR toddler	28.8	Apples	14.2	Spinach	11.0	Beans (with pods)	
77.0	IE adult	9.0	Apples	7.4	Pears	6.5	Wine grapes	
71.2	FR infant	27.5	Apples	8.9	Spinach	8.4	Beans (with pods)	
61.6	PT General population	12.9	Wine grapes	11.6	Apples	8.6	Rice	
58.8	WHO cluster diet E	9.3	Apples	8.3	Wine grapes	3.8	Potatoes	
55.8	ES child	12.6	Apples	7.1	Tomatoes	5.3	Rice	
54.1	UK Toddler	18.8	Apples	6.3	Rice	4.6	Sugar beet (root)	
50.8	UK Infant	17.2	Apples	7.0	Rice	5.7	Peas (without pods)	
50.6	DK child	25.6	Apples	7.5	Pears	3.8	Tomatoes	
50.5	SE general population 90th percentile	11.6	Apples	5.5	Tomatoes	4.4	Rice	
49.4	WHO regional European diet	7.9	Tomatoes	7.3	Apples	4.0	Potatoes	
49.1	WHO cluster diet D	7.3	Apples	7.3	Tomatoes	6.1	Rice	
46.8	NL general	13.0	Apples	3.3	Wine grapes	3.1	Tomatoes	
44.6	FR all population	20.8	Wine grapes	5.2	Apples	3.1	Tomatoes	
42.4	IT kids/toddler	10.3	Tomatoes	9.8	Apples	3.8	Pears	
42.4	PL general population	22.5	Apples	6.4	Tomatoes	3.4	Potatoes	
42.0	ES adult	8.5	Apples	5.6	Tomatoes	3.6	Pears	
39.4	WHO Cluster diet F	7.2	Apples	4.9	Tomatoes	3.4	Potatoes	
38.6	IT adult	8.7	Apples	8.4	Tomatoes	2.6	Pears	
36.4	LT adult	20.5	Apples	4.5	Tomatoes	3.2	Potatoes	
32.0	UK vegetarian	6.5	Apples	4.5	Tomatoes	4.2	Wine grapes	
29.3	DK adult	8.6	Apples	7.2	Wine grapes	3.0	Tomatoes	
26.9	UK Adult	5.6	Wine grapes	4.5	Apples	4.0	Rice	
17.7	FI adult	4.4	Apples	3.1	Tomatoes	1.8	Citrus fruit	

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 17.7–199 % of the ADI.
For 3 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):		**2**	**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)
159.2	Apples	2.6/1.63	117.4	Apples	2.6/2.21	49.0	Celery	3.4/-	36.2	Celery	3.4/-
148.0	Pears	2.6/1.75	106.4	Pears	2.6/2.44	36.5	Apples	2.6/-	30.3	Apples	2.6/-
97.6	Celery	3.4/-	97.6	Celery	3.4/-	34.9	Pears	2.6/-	26.7	Pears	2.6/-
64.8	Persimmon	2.6/-	46.3	Persimmon	2.6/-	23.1	Persimmon	2.6/-	16.8	Cardoons	3.4/-
42.2	Lettuce	2.51/-	29.0	Scarole (broad-leaf	0.53/-	23.0	Cardoons	3.4/-	16.7	Persimmon	2.6/-
29.0	Scarole (broad-leaf	0.53/-	25.3	Lettuce	2.51/-	17.2	Lettuce	2.51/-	10.3	Lettuce	2.51/-
27.5	Beet leaves (chard)	2.51/-	20.9	Beet leaves	2.51/-	12.9	Quinces	2.6/-	10.3	Quinces	2.6/-
23.8	Quinces	2.6/-	18.5	Quinces	2.6/-	11.6	Beet leaves (chard)	2.51/-	9.8	Beet leaves (chard)	2.51/-
19.7	Medlar	2.6/-	14.9	Medlar	2.6/-	9.7	Medlar	2.6/-	7.3	Medlar	2.6/-
16.1	Peppers	0.41/-	11.7	Strawberries	1.2/-	5.2	Rice	1.1/-	5.2	Rice	1.1/-
14.7	Leek	0.4/-	11.5	Peppers	0.41/-	4.8	Leek	0.4/-	4.4	Blueberries	2.2/-
11.7	Strawberries	1.2/-	10.5	Leek	0.4/-	4.4	Blueberries	2.2/-	4.0	Strawberries	1.2/-
8.7	Rice	1.1/-	8.7	Rice	1.1/-	4.2	Globe artichokes	0.64/-	3.6	Leek	0.4/-
8.0	Globe artichokes	0.64/-	5.7	Globe artichokes	0.64/-	4.2	Peppers	0.41/-	3.0	Globe artichokes	0.64/-
7.2	Apricots	0.37/-	5.7	Apricots	0.37/-	4.0	Strawberries	1.2/-	3.0	Peppers	0.41/-
6.3	Head cabbage	0.19/-	4.3	Rhubarb	0.26/-	3.8	Head cabbage	0.19/-	2.9	Scarole (broad-leaf endive)	0.53/-
6.0	Rhubarb	0.26/-	4.3	Blueberries	2.2/-	2.9	Scarole (broad-leaf	0.53/-	2.3	Head cabbage	0.19/-
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 Difenoconazole, 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.

Azoxystrobin

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.02	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.2**	ARfD (mg/kg bw):	**n.n.**
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
	4 – 21
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)
21	NL child	7.4	Oranges	6.8	Potatoes	1.8	Mandarins	0.2
18	DE child	9.0	Oranges	2.9	Potatoes	1.0	Mandarins	0.1
17	FR toddler	5.8	Potatoes	4.8	Oranges	1.4	Spinach	0.2
14	IE adult	2.6	Potatoes	2.5	Oranges	1.7	Grapefruit	0.0
14	WHO Cluster diet B	3.1	Potatoes	2.0	Oranges	0.9	Onions	0.1
11	UK Toddler	4.7	Oranges	4.0	Potatoes	0.7	Mandarins	0.2
11	SE general population 90th percentile	4.8	Potatoes	1.8	Oranges	1.1	Mandarins	0.1
11	FR infant	4.8	Potatoes	2.2	Oranges	0.9	Spinach	0.1
11	PT General population	6.1	Potatoes	1.5	Oranges	0.9	Wine grapes	0.0
10	WHO cluster diet E	4.4	Potatoes	1.1	Oranges	0.6	Wine grapes	0.0
10	NL general	3.5	Oranges	3.1	Potatoes	0.5	Mandarins	0.0
10	ES child	5.1	Oranges	2.1	Potatoes	0.8	Lettuce	0.1
10	WHO regional European diet	4.6	Potatoes	1.2	Oranges	0.7	Lettuce	0.0
9	WHO cluster diet D	4.7	Potatoes	0.8	Herbs	0.6	Oranges	0.0
9	WHO Cluster diet F	3.9	Potatoes	2.1	Oranges	0.6	Lettuce	0.0
9	UK Infant	3.7	Potatoes	3.1	Oranges	0.3	Peas (without pods)	0.3
7	ES adult	3.1	Oranges	1.1	Potatoes	1.0	Lettuce	0.0
6	FR all population	1.4	Wine grapes	1.3	Potatoes	0.7	Oranges	0.0
6	UK vegetarian	2.1	Oranges	1.6	Potatoes	0.3	Wine grapes	0.0
6	PL general population	4.0	Potatoes	0.4	Onions	0.2	Head cabbage	0.0
6	IT kids/toddler	1.1	Oranges	1.0	Potatoes	0.6	Lettuce	0.0
5	DK child	2.8	Potatoes	0.4	Oranges	0.3	Onions	0.1
5	IT adult	0.9	Oranges	0.7	Lettuce	0.7	Potatoes	0.0
5	FI adult	2.3	Oranges	1.4	Potatoes	0.3	Mandarins	0.0
5	UK Adult	1.6	Potatoes	1.3	Oranges	0.4	Wine grapes	0.0
5	LT adult	3.7	Potatoes	0.2	Head cabbage	0.2	Oranges	0.0
4	DK adult	1.7	Potatoes	0.5	Wine grapes	0.3	Oranges	0.0

Conclusion:

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

Prothioconazole-desthio (M04)

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):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 8
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)
8	WHO Cluster diet B	3.4	Wheat	0.9	Maize	0.6	Soya bean	
7	FR toddler	2.0	Milk and cream	1.5	Carrots	1.0	Wheat	
6	NL child	1.9	Wheat	1.5	Milk and cream	1.2	Potatoes	
6	WHO cluster diet E	1.6	Wheat	0.8	Potatoes	0.6	Barley	
6	IE adult	1.0	Barley	0.9	Wheat	0.8	Maize	
6	WHO cluster diet D	2.6	Wheat	0.8	Potatoes	0.4	Soya bean	
6	UK Infant	1.9	Milk and cream	1.0	Wheat	0.8	Carrots	
5	DK child	2.2	Wheat	0.9	Rye	0.8	Carrots	
5	WHO Cluster diet F	1.4	Wheat	0.7	Potatoes	0.7	Soya bean	
5	FR infant	1.6	Carrots	1.3	Milk and cream	0.8	Potatoes	
4	WHO regional European diet	1.2	Wheat	0.8	Potatoes	0.3	Barley	
4	DE child	1.6	Wheat	0.7	Milk and cream	0.6	Carrots	
4	UK Toddler	1.6	Wheat	1.0	Milk and cream	0.7	Potatoes	
4	ES child	1.8	Wheat	0.6	Milk and cream	0.4	Potatoes	
4	SE general population 90th percentile	1.3	Wheat	0.8	Potatoes	0.6	Milk and cream	
4	PT General population	1.6	Wheat	1.1	Potatoes	0.4	Carrots	
3	IT kids/toddler	2.7	Wheat	0.2	Potatoes	0.1	Carrots	
3	NL general	0.8	Wheat	0.5	Potatoes	0.3	Milk and cream	
3	ES adult	0.9	Wheat	0.4	Barley	0.2	Milk and cream	
2	FR all population	1.3	Wheat	0.2	Potatoes	0.2	Carrots	
2	LT adult	0.6	Potatoes	0.4	Wheat	0.2	Rye	
2	DK adult	0.8	Wheat	0.3	Potatoes	0.3	Milk and cream	
2	IT adult	1.7	Wheat	0.1	Potatoes	0.1	Carrots	
2	UK vegetarian	0.8	Wheat	0.3	Potatoes	0.2	Milk and cream	
1	UK Adult	0.7	Wheat	0.3	Potatoes	0.1	Milk and cream	
1	FI adult	0.4	Wheat	0.3	Milk and cream	0.2	Potatoes	
1	PL general population	0.7	Potatoes	0.2	Carrots	0.1	Beetroot	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Prothioconazole-desthio (M04) 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)
1.2	Birds' eggs	0,01/-	1.2	Birds' eggs	0,01/-	3.2	Poultry: Liver	0,071/-	3.2	Poultry: Liver	0,071/-
0.4	Bovine: Fat	0,018/-	0.4	Bovine: Fat	0,018/-	0.4	Birds' eggs	0,01/-	0.4	Birds' eggs	0,01/-
0.2	Swine: Fat free of lean	0,018/-	0.2	Swine: Fat free of	0,018/-	0.3	Swine: Fat free of lean	0,018/-	0.3	Swine: Fat free of lean meat	0,018/-
						0.1	Bovine: Fat	0,018/-	0.1	Bovine: Fat	0,018/-
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 Prothioconazole-desthio (M04). 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.

Spinetoram

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):	**0.025**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	8 47
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)
46.9	DE child	19.3	Apples	6.1	Oranges	5.1	Table grapes	0.3
42.4	WHO Cluster diet B	12.3	Tomatoes	7.2	Wine grapes	3.4	Wheat	0.1
33.4	NL child	10.1	Apples	5.0	Oranges	3.0	Table grapes	0.6
27.7	IE adult	5.0	Wine grapes	1.7	Oranges	1.6	Tomatoes	0.1
25.6	UK Toddler	9.1	Sugar beet (root)	3.2	Oranges	2.7	Apples	0.3
25.3	PT General population	10.0	Wine grapes	3.6	Tomatoes	2.1	Potatoes	
24.6	FR all population	16.0	Wine grapes	1.7	Tomatoes	1.3	Wheat	0.1
22.4	FR toddler	4.2	Apples	3.2	Oranges	3.1	Tomatoes	0.7
21.1	WHO cluster diet E	6.4	Wine grapes	2.1	Tomatoes	1.6	Wheat	0.1
18.8	DK child	3.7	Apples	2.6	Cucumbers	2.2	Wheat	0.2
17.5	UK Infant	4.0	Sugar beet (root)	2.5	Apples	2.1	Oranges	0.6
17.0	WHO cluster diet D	4.0	Tomatoes	2.6	Wheat	1.6	Potatoes	0.1
16.9	ES child	3.9	Tomatoes	3.5	Oranges	1.8	Apples	0.3
16.2	SE general population 90th percentile	3.1	Tomatoes	1.7	Apples	1.7	Potatoes	0.2
16.0	IT kids/toddler	5.7	Tomatoes	2.7	Wheat	1.4	Apples	
15.9	WHO regional European diet	4.4	Tomatoes	1.6	Potatoes	1.2	Wheat	0.2
15.5	WHO Cluster diet F	2.7	Tomatoes	2.4	Wine grapes	1.4	Wheat	0.1
15.3	NL general	2.5	Wine grapes	2.4	Oranges	1.9	Apples	0.2
14.9	FR infant	4.0	Apples	1.7	Potatoes	1.5	Oranges	0.4
14.0	UK vegetarian	3.3	Wine grapes	2.5	Tomatoes	1.5	Sugar beet (root)	0.1
13.6	ES adult	3.1	Tomatoes	2.1	Oranges	1.7	Wine grapes	0.1
13.1	IT adult	4.7	Tomatoes	1.7	Wheat	1.3	Apples	
13.1	DK adult	5.6	Wine grapes	1.7	Tomatoes	1.3	Apples	0.1
12.5	UK Adult	4.3	Wine grapes	1.7	Tomatoes	1.6	Sugar beet (root)	0.0
11.7	PL general population	3.5	Tomatoes	3.3	Apples	1.4	Potatoes	
9.7	LT adult	3.0	Apples	2.5	Tomatoes	1.3	Potatoes	0.1
8.4	FI adult	1.7	Tomatoes	1.6	Oranges	1.2	Wine grapes	0.1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Spinetoram 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)
23.7	Spinach	1.05/-	23.7	Spinach	1.05/-	10.9	Purslane	1.05/-	9.9	Purslane	1.05/-
18.4	Beet leaves (chard)	1.05/-	16.3	Celery leaves	2.85/-	9.4	Spinach	1.05/-	9.4	Spinach	1.05/-
17.8	Peaches	0.3/-	14.6	Cherries	1.19/-	7.8	Beet leaves (chard)	1.05/-	6.6	Beet leaves (chard)	1.05/-
16.3	Celery leaves	2.85/-	14.0	Beet leaves	1.05/-	5.4	Lamb's lettuce	2.85/-	5.4	Lamb's lettuce	2.85/-
15.9	Purslane	1.05/-	13.1	Peaches	0.3/-	5.2	Peaches	0.3/-	5.0	Cherries	1.19/-
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)	
16.4	Grape juice	0.5/-		2.0	Orange juice	0.2/-	
10.2	Apple juice	0.2/-		1.9	Wine	0.5/-	
9.9	Orange juice	0.2/-		1.3	Apple juice	0.2/-	
8.7	Tomato juice	0.5/-		1.0	Tomato (preserved-	0.5/-	
6.0	Raspberries juice	0.5/-		0.6	Peach preserved with	0.3/-	

*) 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 Spinetoram, 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.

Fluopyram

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):	**0.012**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	13 – 205
No of diets exceeding ADI:	7

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)
205	FR toddler	158	Milk and cream, not concentrated	7	Bovine: Meat	5	Apples	0.0
192	NL child	117	Milk and cream, not concentrated	12	Apples	8	Swine: Meat	0.1
180	UK Infant	155	Milk and cream, not concentrated	4	Wheat	3	Apples	0.1
134	DE child	57	Milk and cream, not concentrated	23	Apples	7	Wheat	0.1
129	FR infant	103	Milk and cream, not concentrated	5	Apples	3	Bovine: Meat	0.0
114	UK Toddler	83	Milk and cream, not concentrated	6	Sugar beet (root)	6	Wheat	0.0
106	ES child	50	Milk and cream, not concentrated	9	Lettuce	7	Bovine: Meat	0.2
92	WHO Cluster diet B	14	Wheat	13	Milk and cream, not concentrated nor	8	Lettuce	0.6
89	DK child	51	Milk and cream, not concentrated	9	Wheat	7	Rye	0.0
76	IE adult	11	Milk and cream, not concentrated	7	Sheep: Liver	7	Peaches	0.5
76	SE general population 90th percentile	50	Milk and cream, not concentrated	5	Wheat	3	Eggs: Chicken	0.1
73	WHO regional European diet	19	Milk and cream, not concentrated	8	Lettuce	6	Swine: Meat	0.1
61	ES adult	20	Milk and cream, not concentrated	12	Lettuce	4	Bovine: Meat	0.1
60	WHO Cluster diet F	16	Milk and cream, not concentrated	7	Lettuce	6	Swine: Meat	0.1
60	WHO cluster diet E	12	Milk and cream, not concentrated	6	Wheat	4	Bovine: Meat	0.2
60	WHO cluster diet D	20	Milk and cream, not concentrated	10	Wheat	3	Bovine: Edible offal	0.2
58	NL general	26	Milk and cream, not concentrated	5	Swine: Meat	4	Bovine: Meat	0.1
41	FR all population	11	Milk and cream, not concentrated	5	Wheat	4	Other lettuce and other salad	0.1
38	LT adult	16	Milk and cream, not concentrated	5	Swine: Meat	4	Apples	0.0
38	DK adult	21	Milk and cream, not concentrated	3	Wheat	3	Bovine: Meat	0.0
36	IT kids/toddler	11	Wheat	6	Lettuce	4	Peaches	0.0
34	FI adult	23	Milk and cream, not concentrated	2	Lettuce	2	Wheat	0.0
33	IT adult	8	Lettuce	7	Wheat	5	Peaches	0.0
30	UK vegetarian	13	Milk and cream, not concentrated	3	Wheat	3	Lettuce	0.0
26	UK Adult	12	Milk and cream, not concentrated	3	Wheat	3	Lettuce	0.0
24	PT General population	6	Wheat	4	Peaches	2	Apples	0.1
13	PL general population	4	Apples	2	Table grapes	1	Tomatoes	0.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 12.6 % to 205 % of the ADI.

For 7 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)
18	Peppers	1.4/-	12.6	Peppers	1.4/-	4.6	Peppers	1.4/-	4.4	Bovine: Edible offal	7.4/-
12	Bovine: Liver	7.4/-	11.9	Bovine: Liver	7.4/-	4.4	Bovine: Edible offal	7.4/-	4.0	Bovine: Liver	7.4/-
12	Milk and milk products:	0.48/-	11.9	Milk and milk	0.48/-	4.0	Bovine: Liver	7.4/-	3.3	Peppers	1.4/-
11	Oranges	0.41/-	10.8	Bovine: Edible	7.4/-	2.7	Poultry: Liver	3/-	2.7	Poultry: Liver	3/-
11	Bovine: Edible offal	7.4/-	7.9	Oranges	0.41/-	2.1	Oranges	0.41/-	2.0	Poultry: Meat	0.86/-
4.6	Mandarins	0.41/-	4.5	Grapefruit	0.25/-	2.0	Poultry: Meat	0.86/-	1.7	Oranges	0.41/-
4.5	Grapefruit	0.25/-	4.4	Basil	32/-	1.7	Milk and milk	0.48/-	1.7	Milk and milk products: Cattle	0.48/-
4.4	Basil	32/-	3.4	Mandarins	0.41/-	1.3	Bovine: Meat	1.1/-	1.3	Bovine: Meat	1.1/-
3.9	Lemons	0.56/-	3.2	Cherries	1.32/-	1.1	Wheat	0.72/-	1.1	Wheat	0.72/-
3.2	Cherries	1.32/-	2.9	Lemons	0.56/-	1.1	Cherries	1.32/-	1.1	Cherries	1.32/-
2.8	Bovine: Meat	1.1/-	2.8	Bovine: Meat	1.1/-	1.1	Mandarins	0.41/-	1.1	Swine: Meat	1.1/-
2.6	Potatoes	0.083/-	2.3	Milk and milk	0.48/-	1.1	Swine: Meat	1.1/-	1.0	Sheep: Meat	1.1/-
2.3	Milk and milk products:	0.48/-	2.3	Sheep: Meat	1.1/-	1.0	Sheep: Meat	1.1/-	1.0	Sheep: Edible offal	7.4/-
2.3	Sheep: Meat	1.1/-	2.1	Wheat	0.72/-	1.0	Sheep: Edible offal	7.4/-	1.0	Sheep: Liver	7.4/-
2.3	Limes	0.56/-	1.9	Poultry: Meat	0.86/-	1.0	Sheep: Liver	7.4/-	1.0	Swine: Liver	7.4/-
2.1	Wheat	0.72/-	1.9	Swine: Meat	1.1/-	1.0	Grapefruit	0.25/-	0.9	HOPS (dried), including hop	25/-
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 Fluopyram, 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.

Isopyrazam			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.03**	ARfD (mg/kg bw):	**0.2**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Explain choice of toxicological reference values.

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	13
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)
13	DE child	10	Apples	0.5	Pears	0.5	Milk and cream	1.0
9	NL child	5	Apples	1.0	Milk and cream	0.5	Wheat	1.6
5	FR toddler	2	Apples	1.3	Milk and cream	0.3	Wheat	1.9
5	DK child	2	Apples	0.6	Pears	0.6	Wheat	0.6
5	WHO Cluster diet B	1	Wheat	0.8	Apples	0.5	Tomatoes	0.9
4	FR infant	2	Apples	0.9	Milk and cream	0.3	Pears	1.2
4	UK Infant	1	Apples	1.3	Milk and cream	0.3	Sugar beet (root)	2.0
4	UK Toddler	1	Apples	0.8	Sugar beet (root)	0.7	Milk and cream	1.8
4	IE adult	1	Apples	0.6	Pears	0.4	Peaches	0.8
3	ES child	1	Apples	0.4	Wheat	0.4	Milk and cream	0.8
3	SE general population 90th percentile	1	Apples	0.4	Milk and cream	0.3	Wheat	0.7
3	WHO cluster diet E	1	Apples	0.4	Wheat	0.2	Barley	0.6
3	LT adult	2	Apples	0.1	Pears	0.1	Milk and cream	0.3
3	PT General population	1	Apples	0.4	Wheat	0.3	Pears	0.4
3	WHO regional European diet	1	Apples	0.3	Wheat	0.2	Tomatoes	0.6
2	WHO cluster diet D	1	Wheat	0.6	Apples	0.2	Tomatoes	0.5
2	IT kids/toddler	1	Apples	0.7	Wheat	0.3	Pears	0.1
2	PL general population	2	Apples	0.2	Pears	0.2	Tomatoes	0.2
2	WHO Cluster diet F	1	Apples	0.4	Wheat	0.1	Milk and cream	0.5
2	NL general	1	Apples	0.2	Milk and cream	0.2	Wheat	0.6
2	ES adult	1	Apples	0.3	Pears	0.2	Wheat	0.4
2	IT adult	1	Apples	0.4	Wheat	0.3	Peaches	0.1
2	DK adult	1	Apples	0.2	Wheat	0.2	Milk and cream	0.3
2	FR all population	0	Apples	0.3	Wheat	0.1	Wine grapes	0.4
1	UK vegetarian	0	Apples	0.2	Wheat	0.1	Sugar beet (root)	0.4
1	UK Adult	0	Apples	0.2	Wheat	0.1	Sugar beet (root)	0.4
1	FI adult	0	Apples	0.2	Milk and cream	0.1	Wheat	0.3

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Isopyrazam 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)
12	Apples	0.24/-	9	Apples	0.24/-	3	Aubergines (egg	0.23/-	3	Aubergines (egg plants)	0.23/-
11	Pears	0.24/-	8	Pears	0.24/-	3	Apples	0.24/-	2	Apples	0.24/-
7	Tomatoes	0.23/-	5	Tomatoes	0.23/-	3	Pears	0.24/-	2	Pears	0.24/-
5	Persimmon	0.24/-	3	Persimmon	0.24/-	2	Tomatoes	0.23/-	1	Tomatoes	0.23/-
3	Carrots	0.1/-	3	Aubergines (egg	0.23/-	2	Persimmon	0.24/-	1	Persimmon	0.24/-
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)	
6.4	Apple juice	0.25/-		0.8	Apple juice	0.25/-	
2.2	Pear juice	0.25/-		0.2	Peach preserved with syrup	0.22/-	
2.0	Peach juice	0.22/-		0.1	Quince jelly	0.25/-	
0.6	Carrot, juice	0.03/-		0.1	Bread/pizza	0.03/-	
0.5	Tomato juice	0.054/-		0.1	Tomato (preserved-	0.054/-	

*) 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 Isopyrazam, 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.

Saflufenacil

Status of the active substance:	n.a.	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.046	ARfD (mg/kg bw):	0.05
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2012	Year of evaluation:	2012

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 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)
4.4	WHO Cluster diet B	1.6	Sunflower seed	0.6	Wheat	0.2	Tomatoes	
3.9	UK Toddler	1.5	Sugar beet (root)	0.8	Beans	0.4	Milk and cream	
3.2	WHO cluster diet E	0.8	Rape seed	0.8	Sunflower seed	0.3	Wheat	
3.2	UK Infant	0.8	Milk and cream	0.7	Sugar beet (root)	0.5	Beans	
2.9	NL child	0.6	Milk and cream	0.4	Apples	0.4	Potatoes	
2.9	DE child	0.8	Apples	0.3	Milk and cream	0.3	Wheat	
2.8	FR toddler	0.9	Milk and cream	0.3	Sunflower seed	0.3	Potatoes	
2.7	WHO cluster diet D	1.1	Sunflower seed	0.4	Wheat	0.3	Potatoes	
2.7	IE adult	0.4	Sunflower seed	0.2	Sweet potatoes	0.1	Maize	
2.2	PT General population	0.6	Sunflower seed	0.3	Potatoes	0.3	Wheat	
2.0	WHO Cluster diet F	0.4	Rape seed	0.2	Wheat	0.2	Potatoes	
1.9	ES child	0.3	Wheat	0.3	Milk and cream	0.3	Sunflower seed	
1.8	WHO regional European diet	0.3	Sunflower seed	0.3	Potatoes	0.2	Wheat	
1.8	DK child	0.4	Wheat	0.3	Rye	0.3	Milk and cream	
1.7	FR infant	0.6	Milk and cream	0.3	Potatoes	0.2	Carrots	
1.7	FR all population	0.7	Sunflower seed	0.3	Wine grapes	0.2	Wheat	
1.5	SE general population 90th percentile	0.3	Potatoes	0.3	Milk and cream	0.2	Wheat	
1.4	UK vegetarian	0.4	Beans	0.2	Sugar beet (root)	0.1	Wheat	
1.2	ES adult	0.2	Sunflower seed	0.2	Wheat	0.1	Milk and cream	
1.2	IT kids/toddler	0.4	Wheat	0.1	Other cereal	0.1	Tomatoes	
1.2	NL general	0.2	Potatoes	0.1	Milk and cream	0.1	Wheat	
1.1	UK Adult	0.3	Sugar beet (root)	0.2	Beans	0.1	Wheat	
0.9	IT adult	0.3	Wheat	0.1	Tomatoes	0.1	Beans	
0.9	LT adult	0.2	Potatoes	0.1	Apples	0.1	Sunflower seed	
0.8	DK adult	0.1	Wheat	0.1	Milk and cream	0.1	Potatoes	
0.7	PL general population	0.2	Potatoes	0.1	Apples	0.1	Tomatoes	
0.7	FI adult	0.1	Milk and cream	0.1	Potatoes	0.1	Wheat	

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): ---			**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)
18.3	Beans	0.5/-	18.3	Beans	0.5/-	6.3	Beans	0.5/-	6.3	Beans	0.5/-
9.7	Bovine: Liver	0.6/-	9.7	Bovine: Liver	0.6/-	3.2	Bovine: Liver	0.6/-	3.2	Bovine: Liver	0.6/-
9.2	Potatoes	0.03/-	9.1	Melons	0.03/-	3.2	Pumpkins	0.03/-	3.2	Pumpkins	0.03/-
9.1	Melons	0.03/-	7.3	Watermelons	0.03/-	2.4	Watermelons	0.03/-	2.4	Watermelons	0.03/-
8.0	Oranges	0.03/-	6.6	Potatoes	0.03/-	2.4	Melons	0.03/-	2.4	Melons	0.03/-
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)			
3.1	Apple juice	0.03/-				0.6	Orange juice	0.03/-			
3.0	Orange juice	0.03/-				0.4	Apple juice	0.03/-			
2.6	Carrot, juice	0.03/-				0.3	Bread/pizza	0.03/-			
2.0	Grape juice	0.03/-				0.2	Wine	0.03/-			
1.1	Peach juice	0.03/-				0.2	Pineapples preserved	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 Saflufenacil, 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.

Imazamox

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**3**	ARfD (mg/kg bw):	**3**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2002**	Year of evaluation:	**2002**

Update of PRIMo prepared in the framework of the MRL review. (replacement of TRV with values derived in peer review, inclusion of barley).

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)
0.013	NL child	0.010	Milk and milk products: Cattle	0.001	Beans (with pods)	0.001	Peas (without pods)	
0.011	FR infant	0.009	Milk and milk products: Cattle	0.001	Beans (with pods)	0.000	Peas (without pods)	
0.010	WHO Cluster diet B	0.004	Maize	0.001	Sunflower seed	0.001	Soya bean	
0.009	IE adult	0.004	Maize	0.002	Barley	0.001	Milk and milk products: Cattle	
0.008	ES child	0.004	Milk and milk products: Cattle	0.001	Rice	0.000	Maize	
0.007	WHO cluster diet E	0.001	Barley	0.001	Milk and milk products: Cattle	0.001	Rape seed	
0.006	DE child	0.005	Milk and milk products: Cattle	0.000	Rice	0.000	Maize	
0.006	WHO cluster diet D	0.002	Milk and milk products: Cattle	0.001	Rice	0.001	Maize	
0.005	WHO Cluster diet F	0.001	Milk and milk products: Cattle	0.001	Soya bean	0.001	Barley	
0.005	SE general population 90th percentile	0.004	Milk and milk products: Cattle	0.001	Rice	0.000	Beans (with pods)	
0.005	UK Infant	0.002	Maize	0.001	Rice	0.001	Peas (without pods)	
0.004	WHO regional European diet	0.002	Milk and milk products: Cattle	0.000	Barley	0.000	Bovine: Meat	
0.004	ES adult	0.002	Milk and milk products: Cattle	0.001	Barley	0.000	Rice	
0.004	NL general	0.002	Milk and milk products: Cattle	0.000	Barley	0.000	Beans (with pods)	
0.004	PT General population	0.001	Rice	0.001	Maize	0.001	Soya bean	
0.004	FR toddler	0.002	Beans (with pods)	0.001	Rice	0.001	Peas (without pods)	
0.003	UK Toddler	0.001	Beans	0.001	Rice	0.000	Peas (without pods)	
0.002	FR all population	0.001	Milk and milk products: Cattle	0.001	Sunflower seed	0.000	Beans (with pods)	
0.002	LT adult	0.001	Milk and milk products: Cattle	0.000	Rice	0.000	Bovine: Meat	
0.002	UK vegetarian	0.001	Rice	0.001	Beans	0.000	Peas (without pods)	
0.001	UK Adult	0.001	Rice	0.000	Beans	0.000	Peas (without pods)	
0.001	IT kids/toddler	0.000	Rice	0.000	Peas (without pods)	0.000	Beans (with pods)	
0.001	IT adult	0.000	Rice	0.000	Beans (with pods)	0.000	Peas (without pods)	
0.001	DK adult	0.000	Bovine: Meat	0.000	Peas (without pods)	0.000	Rice	
0.000	FI adult	0.000	Rice	0.000	Beans (with pods)	0.000	Beans	
0.000	DK child	0.000	Rice	0.000	Bovine: Liver	0.000	Beans (with pods)	
0.000	PL general population	0.000	Beans	0.000	Peas	0.000	Sunflower seed	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of imazamox 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)
0.0	Milk and milk products:	0.01/-	0.0	Milk and milk	0.01/-	0.0	Rice	0.05/-	0.0	Rice	0.05/-
0.0	Beans	0.05/-	0.0	Beans	0.05/-	0.0	Beans	0.05/-	0.0	Beans	0.05/-
0.0	Rice	0.05/-	0.0	Rice	0.05/-	0.0	Barley	0.04/-	0.0	Barley	0.04/-
0.0	Beans (with pods)	0.05/-	0.0	Beans (with pods)	0.05/-	0.0	Beans (with pods)	0.05/-	0.0	Beans (with pods)	0.05/-
0.0	Peas (without pods)	0.05/-	0.0	Peas (without	0.05/-	0.0	Peas (without pods)	0.05/-	0.0	Peas (without pods)	0.05/-
0.0	Maize	0.05/-	0.0	Maize	0.05/-	0.0	Milk and milk	0.01/-	0.0	Milk and milk products: Cattle	0.01/-
0.0	Lentils	0.05/-	0.0	Lentils	0.05/-	0.0	Peas	0.05/-	0.0	Peas	0.05/-
0.0	Milk and milk products: Goat	0.01/-	0.0	Milk and milk products: Goat	0.01/-	0.0	Lentils	0.05/-	0.0	Lentils	0.05/-
0.0	Peas	0.05/-	0.0	Peas	0.05/-	0.0	Maize	0.05/-	0.0	Maize	0.05/-
0.0	Sunflower seed	0.05/-	0.0	Sunflower seed	0.05/-	0.0	Milk and milk products: Goat	0.01/-	0.0	Milk and milk products: Goat	0.01/-
0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-
0.0	Soya bean	0.05/-	0.0	Soya bean	0.05/-	0.0	Sunflower seed	0.05/-	0.0	Sunflower seed	0.05/-
0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-
0.0	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-	0.0	Soya bean	0.05/-	0.0	Soya bean	0.05/-
0.002	Barley	0.04/-	0.0	Barley	0.04/-	0.0	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-
0.0	Rape seed	0.05/-	0.0	Rape seed	0.05/-	0.0	Bovine: Kidney	0.01/-	0.0	Bovine: Kidney	0.01/-
0.0	Bovine: Kidney	0.01/-	0.0	Bovine: Kidney	0.01/-	0.0	Milk and milk	0.01/-	0.0	Milk and milk products: Sheep	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)			
0.0	Maize flour	0.05/-				0.0	Maize flour	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 imazamox, 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.

Flonicamid

Status of the active substance:	**Approved**	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:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

MRL according to Regulation (EU) 2016/1902 except the MRL proposed under the current MRL aplication.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
2	18
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)
18.1	WHO Cluster diet B	11.9	Wheat	1.7	Tomatoes	0.5	Beans (with pods)	
18.0	DK child	7.7	Wheat	6.2	Rye	1.0	Cucumbers	
14.8	NL child	6.6	Wheat	2.1	Milk and cream	1.5	Apples	
14.6	DE child	5.8	Wheat	2.9	Apples	1.1	Rye	
13.1	WHO cluster diet D	9.1	Wheat	0.6	Rye	0.6	Tomatoes	
12.3	UK Toddler	5.5	Wheat	2.7	Sugar beet (root)	1.5	Milk and cream	
11.5	FR toddler	3.7	Wheat	2.9	Milk and cream	1.5	Beans (with pods)	
11.4	IT kids/toddler	9.3	Wheat	0.8	Tomatoes	0.2	Apples	
10.3	UK Infant	3.7	Wheat	2.8	Milk and cream	1.2	Sugar beet (root)	
10.3	WHO cluster diet E	5.5	Wheat	0.6	Rye	0.6	Barley	
10.3	ES child	6.2	Wheat	0.9	Milk and cream	0.5	Tomatoes	
9.2	WHO Cluster diet F	5.0	Wheat	1.1	Rye	0.4	Potatoes	
8.9	SE general population 90th percentile	4.5	Wheat	0.9	Milk and cream	0.5	Potatoes	
8.5	WHO regional European diet	4.2	Wheat	0.6	Tomatoes	0.5	Potatoes	
8.3	IE adult	3.2	Wheat	0.8	Barley	0.3	Potatoes	
7.9	PT General population	5.5	Wheat	0.6	Potatoes	0.5	Tomatoes	
7.7	IT adult	5.8	Wheat	0.7	Tomatoes	0.2	Beans (with pods)	
6.6	FR infant	1.9	Milk and cream	1.2	Wheat	1.1	Beans (with pods)	
6.3	FR all population	4.6	Wheat	0.2	Tomatoes	0.2	Milk and cream	
6.3	ES adult	3.3	Wheat	0.4	Tomatoes	0.4	Milk and cream	
6.2	NL general	2.9	Wheat	0.5	Milk and cream	0.3	Beans (with pods)	
5.6	DK adult	2.8	Wheat	1.0	Rye	0.4	Milk and cream	
5.5	LT adult	1.5	Rye	1.5	Wheat	0.4	Apples	
5.1	UK vegetarian	2.9	Wheat	0.5	Sugar beet (root)	0.3	Tomatoes	
4.2	UK Adult	2.3	Wheat	0.5	Sugar beet (root)	0.2	Tomatoes	
3.9	FI adult	1.4	Wheat	1.0	Rye	0.4	Milk and cream	
2.0	PL general population	0.5	Tomatoes	0.5	Apples	0.4	Potatoes	

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)
18.6	Beans (with pods)	0.41/-	18.6	Beans (with pods)	0.41/-	8.7	Beans (with pods)	0.41/-	8.7	Beans (with pods)	0.41/-
8.8	Peas	0.52/-	8.8	Peas	0.52/-	6.9	Peas	0.52/-	6.9	Peas	0.52/-
6.7	Beans	0.091/-	6.7	Beans	0.091/-	4.4	Peas (with pods)	0.35/-	4.4	Peas (with pods)	0.35/-
6.6	Peas (without pods)	0.2/-	6.6	Peas (without	0.2/-	3.0	Peas (without pods)	0.2/-	3.0	Peas (without pods)	0.2/-
4.8	Peas (with pods)	0.35/-	4.8	Peas (with pods)	0.35/-	2.3	Beans	0.091/-	2.3	Beans	0.091/-
2.8	Beans (without pods)	0.1/-	2.8	Beans (without	0.1/-	2.0	Beans (without pods)	0.1/-	2.0	Beans (without pods)	0.1/-
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 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.

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". EFSA-Q-2017-00673 (adapted from EFSA-Q-2015-00422).

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	2 – 13
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)
13	WHO Cluster diet B	4.5	Wheat	1.3	Maize	0.7	Wine grapes	
12	UK Toddler	4.3	Sugar beet (root)	2.1	Wheat	1.9	Beans	
10	IE adult	1.2	Maize	1.2	Maize	0.7	Peas	
10	NL child	2.5	Wheat	1.4	Milk and cream	1.1	Apples	
9	UK Infant	1.9	Sugar beet (root)	1.8	Milk and cream	1.4	Wheat	
9	DE child	2.2	Wheat	2.2	Apples	0.7	Milk and cream	
9	DK child	2.9	Wheat	2.3	Rye	0.6	Milk and cream	
8	FR toddler	1.9	Milk and cream	1.4	Wheat	0.9	Potatoes	
8	WHO cluster diet D	3.5	Wheat	0.8	Potatoes	0.3	Rice	
8	WHO cluster diet E	2.1	Wheat	0.7	Potatoes	0.6	Wine grapes	
8	ES child	2.4	Wheat	0.6	Milk and cream	0.6	Lentils	
7	PT General population	2.1	Wheat	1.0	Potatoes	1.0	Wine grapes	
7	IT kids/toddler	3.5	Wheat	0.8	Other cereal	0.4	Lettuce	
6	WHO regional European diet	1.6	Wheat	0.8	Potatoes	0.5	Lettuce	
6	WHO Cluster diet F	1.9	Wheat	0.6	Potatoes	0.4	Rye	
5	FR infant	1.2	Milk and cream	0.8	Potatoes	0.6	Beans (with pods)	
5	ES adult	1.2	Wheat	0.7	Lettuce	0.3	Barley	
5	FR all population	1.7	Wheat	1.6	Wine grapes	0.2	Potatoes	
5	SE general population 90th percentile	1.7	Wheat	0.8	Potatoes	0.6	Milk and cream	
5	UK vegetarian	1.1	Wheat	0.9	Beans	0.7	Sugar beet (root)	
5	IT adult	2.2	Wheat	0.5	Lettuce	0.4	Other cereal	
5	NL general	1.1	Wheat	0.5	Potatoes	0.3	Milk and cream	
4	UK Adult	0.9	Wheat	0.7	Sugar beet (root)	0.5	Beans	
4	DK adult	1.1	Wheat	0.5	Wine grapes	0.4	Rye	
3	LT adult	0.6	Potatoes	0.6	Rye	0.6	Wheat	
2	FI adult	0.5	Wheat	0.4	Rye	0.3	Milk and cream	
2	PL general population	0.6	Potatoes	0.4	Apples	0.2	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): ---			**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)
44	Peaches	1.1/-	31.9	Peaches	1.1/-	12.8	Peaches	1.1/-	9.9	Peaches	1.1/-
13	Plums	0.59/-	10.5	Plums	0.59/-	3.7	Plums	0.59/-	3.1	Cherries	1.1/-
9	Cherries	1.1/-	9.0	Cherries	1.1/-	3.1	Cherries	1.1/-	3.0	Plums	0.59/-
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 Flupyradifurone, 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.

Quinclorac

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.4**	ARfD (mg/kg bw):	**2**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2015**	Year of evaluation:	**2015**

The risk assessment is considered as indicative only.

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
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)
0.8	UK Infant	0.5	Milk and cream	0.2	Rice	0.0	Sugar beet (root)	
0.7	FR toddler	0.5	Milk and cream	0.1	Rice	0.0	Bovine: Meat	
0.6	NL child	0.4	Milk and cream	0.1	Rice	0.0	Swine: Meat	
0.6	UK Toddler	0.3	Milk and cream	0.2	Rice	0.1	Sugar beet (root)	
0.4	ES child	0.2	Rice	0.2	Milk and cream	0.0	Bovine: Meat	
0.4	FR infant	0.3	Milk and cream	0.0	Rice	0.0	Potatoes	
0.4	DE child	0.2	Milk and cream	0.1	Rice	0.0	Apples	
0.4	WHO Cluster diet B	0.2	Rice	0.0	Milk and cream	0.0	Wheat	
0.4	SE general population 90th percentile	0.2	Milk and cream	0.1	Rice	0.0	Birds' eggs	
0.4	WHO cluster diet D	0.2	Rice	0.1	Milk and cream	0.0	Wheat	
0.3	PT General population	0.3	Rice	0.0	Potatoes	0.0	Wheat	
0.3	WHO cluster diet E	0.1	Rape seed	0.1	Rice	0.0	Milk and cream	
0.3	WHO Cluster diet F	0.1	Rice	0.0	Rape seed	0.0	Milk and cream	
0.3	DK child	0.2	Milk and cream	0.0	Rice	0.0	Wheat	
0.3	WHO regional European diet	0.1	Rice	0.1	Milk and cream	0.0	Rape seed	
0.2	IE adult	0.1	Rice	0.0	Milk and cream	0.0	Rhubarb	
0.2	UK vegetarian	0.1	Rice	0.0	Milk and cream	0.0	Sugar beet (root)	
0.2	ES adult	0.1	Rice	0.1	Milk and cream	0.0	Bovine: Meat	
0.2	NL general	0.1	Milk and cream	0.1	Rice	0.0	Swine: Meat	
0.2	UK Adult	0.1	Rice	0.0	Milk and cream	0.0	Sugar beet (root)	
0.2	LT adult	0.1	Rice	0.0	Milk and cream	0.0	Swine: Meat	
0.1	FR all population	0.0	Rice	0.0	Milk and cream	0.0	Wine grapes	
0.1	DK adult	0.1	Milk and cream	0.0	Rice	0.0	Bovine: Meat	
0.1	FI adult	0.1	Milk and cream	0.0	Rice	0.0	Potatoes	
0.1	IT kids/toddler	0.1	Rice	0.0	Wheat	0.0	Other cereal	
0.1	IT adult	0.1	Rice	0.0	Wheat	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 Quinclorac 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)
0.9	Rice	1.45/-	0.9	Rice	1.45/-	0.5	Rice	1.45/-	0.5	Rice	1.45/-
0.9	Rhubarb	0.46/-	0.6	Rhubarb	0.46/-	0.2	Rhubarb	0.46/-	0.2	Rhubarb	0.46/-
0.3	Milk and milk products:	0.05/-	0.3	Milk and milk	0.05/-	0.0	Milk and milk	0.05/-	0.0	Milk and milk products: Cattle	0.05/-
0.1	Cranberries	1.36/-	0.1	Cranberries	1.36/-	0.0	Poultry: Meat	0.05/-	0.0	Poultry: Meat	0.05/-
0.1	Milk and milk products:	0.05/-	0.1	Milk and milk	0.05/-	0.0	Milk and milk	0.05/-	0.0	Milk and milk products: Goat	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)	
0.0	Apple juice	0.01/-		0.0	Orange juice	0.01/-	
0.0	Orange juice	0.01/-		0.0	Apple juice	0.01/-	
0.0	Carrot, juice	0.01/-		0.0	Bread/pizza	0.01/-	
0.0	Grape juice	0.01/-		0.0	Wine	0.01/-	
0.0	Peach juice	0.01/-		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 Quinclorac, 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.

Bicyclopyrone

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.003**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
3 42

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)
42.1	FR toddler	26.4	Milk and cream	5.8	Bovine: Edible offal	1.7	Potatoes	
40.2	NL child	19.5	Milk and cream	3.6	Bovine: Liver	3.4	Swine: Liver	
40.1	UK Infant	25.8	Milk and cream	4.4	Bovine: Liver	3.4	Sugar beet (root)	
33.0	WHO Cluster diet B	7.0	Bovine: Edible offal	3.5	Bovine: Liver	2.8	Wheat	
29.4	IE adult	10.8	Sheep: Liver	5.1	Sheep: Edible offal	1.9	Milk and cream	
28.8	UK Toddler	13.8	Milk and cream	7.6	Sugar beet (root)	1.3	Wheat	
25.2	FR infant	17.2	Milk and cream	1.6	Bovine: Edible offal	1.4	Potatoes	
22.8	DE child	9.5	Milk and cream	4.0	Apples	1.4	Wheat	
22.4	DK child	8.4	Milk and cream	6.1	Bovine: Liver	1.8	Wheat	
21.8	WHO regional European diet	4.8	Bovine: Edible offal	4.0	Swine: Edible offal	3.2	Milk and cream	
21.7	WHO cluster diet D	5.0	Bovine: Edible offal	3.4	Milk and cream	2.9	Swine: Edible offal	
21.6	ES child	8.3	Milk and cream	3.0	Swine: Liver	1.5	Wheat	
21.5	WHO cluster diet E	5.1	Swine: Edible offal	3.7	Bovine: Edible offal	2.0	Milk and cream	
17.4	WHO Cluster diet F	3.2	Bovine: Edible offal	2.6	Milk and cream	2.5	Swine: Edible offal	
15.0	SE general population 90th percentile	8.3	Milk and cream	1.4	Potatoes	1.1	Wheat	
12.6	NL general	4.4	Milk and cream	1.2	Swine: Liver	0.9	Potatoes	
10.9	ES adult	3.3	Milk and cream	0.8	Swine: Liver	0.8	Wheat	
10.1	FR all population	2.8	Bovine: Edible offal	1.8	Milk and cream	1.3	Wine grapes	
9.9	DK adult	3.6	Milk and cream	2.6	Bovine: Liver	0.7	Wheat	
9.0	LT adult	2.6	Milk and cream	1.1	Potatoes	1.0	Swine: Liver	
7.0	UK vegetarian	2.2	Milk and cream	1.3	Sugar beet (root)	0.7	Wheat	
6.9	UK Adult	2.0	Milk and cream	1.3	Sugar beet (root)	0.6	Bovine: Liver	
6.9	PT General population	1.8	Potatoes	1.3	Wheat	0.8	Wine grapes	
6.3	FI adult	3.8	Milk and cream	0.4	Potatoes	0.3	Wheat	
5.5	IT kids/toddler	2.2	Wheat	0.5	Other cereal	0.5	Tomatoes	
4.0	IT adult	1.4	Wheat	0.4	Tomatoes	0.3	Apples	
3.2	PL general population	1.1	Potatoes	0.7	Apples	0.3	Tomatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Bicyclopyrone 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):**		**---**	**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)
221.9	Bovine: Liver	2.75/1.23	221.9	Bovine: Liver	2.75/1.23	81.4	Bovine: Edible offal	2.75/-	81.4	Bovine: Edible offal	2.75/-
200.1	Bovine: Edible offal	2.75/1.37	200.1	Bovine: Edible offal	2.75/1.37	74.1	Bovine: Liver	2.75/-	74.1	Bovine: Liver	2.75/-
30.6	Swine: Liver	2.75/-	30.6	Swine: Liver	2.75/-	18.8	Sheep: Edible offal	2.75/-	18.8	Sheep: Edible offal	2.75/-
24.8	Milk and milk products:	0.02/-	24.8	Milk and milk	0.02/-	18.8	Sheep: Liver	2.75/-	18.8	Sheep: Liver	2.75/-
21.5	Bovine: Kidney	0.57/-	21.5	Bovine: Kidney	0.57/-	18.2	Swine: Liver	2.75/-	18.2	Swine: Liver	2.75/-
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)			
5.1	Apple juice	0.01/-				1.0	Orange juice	0.01/-			
5.0	Orange juice	0.01/-				0.7	Apple juice	0.01/-			
4.3	Carrot, juice	0.01/-				0.4	Bread/pizza	0.01/-			
3.3	Grape juice	0.01/-				0.4	Wine	0.01/-			
1.8	Peach juice	0.01/-				0.3	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 Bicyclopyrone, 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.

Cyclaniliprole

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.0043**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2016**	Year of evaluation:	

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	7 48
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)
47.8	WHO cluster diet D	18.3	Chinese cabbage	9.2	Kale	9.2	Kale	0.0
46.7	NL child	15.7	Kale	10.8	Apples	4.1	Cauliflower	0.0
41.4	IE adult	20.1	Other leafy brassica	4.4	Wine grapes	1.8	Broccoli	0.0
39.1	DE child	20.5	Apples	4.4	Table grapes	1.4	Cherries	0.0
35.6	SE general population 90th percentile	20.0	Chinese cabbage	5.0	Kale	1.8	Apples	0.0
35.6	WHO Cluster diet B	8.7	Chinese cabbage	6.3	Wine grapes	2.9	Tomatoes	0.0
23.5	NL general	9.9	Kale	2.2	Wine grapes	2.1	Cauliflower	0.0
22.7	WHO Cluster diet F	6.3	Chinese cabbage	3.2	Kale	3.2	Kale	0.0
19.9	FR all population	14.0	Wine grapes	0.8	Apples	0.8	Cauliflower	0.0
18.8	FR toddler	4.5	Apples	3.5	Broccoli	3.5	Broccoli	0.0
17.6	PT General population	8.7	Wine grapes	1.8	Apples	1.2	Potatoes	
17.0	WHO cluster diet E	5.6	Wine grapes	1.4	Apples	1.0	Kale	0.0
15.9	UK Toddler	5.3	Sugar beet (root)	2.9	Apples	1.0	Cauliflower	0.0
15.9	WHO regional European diet	3.3	Kale	1.9	Cauliflower	1.1	Apples	0.0
14.3	DK child	3.9	Apples	1.3	Wheat	1.1	Pears	0.0
13.0	UK Infant	2.7	Apples	2.3	Sugar beet (root)	2.2	Cauliflower	0.0
12.7	FR infant	4.2	Apples	2.6	Broccoli	1.0	Cauliflower	0.0
12.3	DK adult	4.9	Wine grapes	1.5	Chinese cabbage	1.3	Apples	0.0
11.5	PL general population	3.5	Apples	2.0	Chinese cabbage	1.1	Table grapes	
10.9	IT kids/toddler	1.9	Other leafy brassica	1.5	Wheat	1.5	Apples	
10.7	IT adult	2.9	Other leafy brassica	1.3	Apples	1.1	Tomatoes	
10.4	UK vegetarian	2.8	Wine grapes	1.0	Cauliflower	1.0	Apples	0.0
9.6	ES child	1.9	Apples	1.0	Wheat	0.9	Tomatoes	0.0
9.5	UK Adult	3.8	Wine grapes	0.9	Sugar beet (root)	0.7	Apples	0.0
8.5	ES adult	1.5	Wine grapes	1.3	Apples	0.7	Tomatoes	0.0
8.1	FI adult	3.5	Chinese cabbage	1.1	Wine grapes	0.7	Apples	0.0
6.9	LT adult	3.2	Apples	0.7	Potatoes	0.6	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 Cyclaniliprole 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 Cyclaniliprole residues is unlikely to present a pulbic health concern.					

Fenazaquin

Status of the active substance:	**Pending**	Code no.	**67**
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.005**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**DAR**	Source of ARfD:	**DAR**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

The risk assessment performed in the framework of the MRL application for tea (EFSA, 2010) was updated. The ARfD was updated according to the outcome of the peer review (EFSA, 2013) and the input values for hops and cherries were included.

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	17 – 90
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)
90.2	DE child	24.1	Apples	12.9	Oranges	9.8	Strawberries	
73.8	WHO Cluster diet B	30.8	Tomatoes	5.0	Peppers	4.2	Peaches	
66.0	NL child	12.7	Apples	10.6	Oranges	6.8	Bananas	
57.9	IE adult	10.5	Tea (dried leaves and stalks)	5.7	Peaches	5.0	Strawberries	
55.5	FR toddler	12.5	Strawberries	7.9	Milk and cream	7.7	Tomatoes	
41.7	UK Toddler	6.7	Oranges	5.9	Tomatoes	4.6	Sugar beet (root)	
41.4	UK Infant	7.7	Milk and cream	5.8	Bananas	4.6	Tea (dried leaves and stalks)	
38.3	ES child	9.8	Tomatoes	7.4	Oranges	4.0	Bananas	
37.8	SE general population 90th percentile	7.7	Tomatoes	7.2	Bananas	3.3	Strawberries	
37.0	DK child	6.5	Cucumbers	5.3	Tomatoes	4.6	Apples	
36.2	FR infant	9.8	Strawberries	5.1	Milk and cream	5.0	Apples	
34.6	IT kids/toddler	14.3	Tomatoes	3.5	Peaches	2.4	Strawberries	
34.0	WHO regional European diet	11.0	Tomatoes	3.0	Tea (dried leaves and stalks)	2.1	Peaches	
30.1	WHO cluster diet D	10.1	Tomatoes	2.8	Tea (dried leaves and stalks)	1.3	Apples	
29.9	WHO cluster diet E	5.3	Tomatoes	2.6	Tea (dried leaves and stalks)	1.9	Wine grapes	
29.0	PT General population	9.0	Tomatoes	3.6	Peaches	3.0	Wine grapes	
28.5	IT adult	11.6	Tomatoes	3.8	Peaches	1.6	Apples	
27.6	ES adult	7.8	Tomatoes	4.4	Oranges	2.1	Peaches	
25.2	UK vegetarian	6.2	Tomatoes	3.9	Tea (dried leaves and stalks)	2.9	Oranges	
25.0	WHO Cluster diet F	6.8	Tomatoes	3.0	Oranges	2.3	Bananas	
24.1	NL general	5.1	Oranges	4.3	Tomatoes	2.4	Apples	
22.7	FR all population	4.8	Wine grapes	4.3	Tomatoes	1.8	Strawberries	
20.9	UK Adult	4.4	Tomatoes	4.3	Tea (dried leaves and stalks)	1.9	Oranges	
20.5	PL general population	8.8	Tomatoes	4.1	Apples	1.0	Plums	
18.2	DK adult	4.1	Tomatoes	1.7	Wine grapes	1.6	Apples	
17.1	FI adult	4.3	Tomatoes	3.3	Oranges	1.5	Strawberries	
16.7	LT adult	6.2	Tomatoes	3.7	Apples	1.6	Cucumbers	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fenazaquin 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)
11.8	Cherries	0.965/-	11.8	Cherries	0.965/-	4.1	Cherries	0.965/-	4.1	Cherries	0.965/-
4.6	Tea	4.97/-	4.6	Tea	4.97/-	1.6	HOPS (dried),	9/-	1.6	HOPS (dried),	9/-
0.2	HOPS (dried),	9/-	0.2	HOPS (dried),	9/-	1.5	Tea	4.97/-	1.5	Tea	4.97/-
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 Fenazaquin, 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.

Fenpyrazamine

Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.13	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2012	Year of evaluation:	2012

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 6
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)
5.6	WHO Cluster diet B	1.9	Tomatoes	1.7	Wine grapes	0.4	Peaches	0.0
4.7	FR all population	3.8	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.0
3.9	DE child	1.2	Table grapes	0.6	Tomatoes	0.5	Strawberries	0.1
3.8	PT General population	2.4	Wine grapes	0.6	Tomatoes	0.3	Peaches	0.0
3.6	IE adult	1.2	Wine grapes	0.5	Peaches	0.2	Table grapes	0.0
2.6	WHO cluster diet E	1.5	Wine grapes	0.3	Tomatoes	0.1	Table grapes	0.0
2.4	NL child	0.7	Table grapes	0.4	Tomatoes	0.2	Milk and milk products: Cattle	0.2
2.0	DK adult	1.3	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.0
1.8	IT kids/toddler	0.9	Tomatoes	0.3	Peaches	0.1	Strawberries	0.0
1.8	WHO regional European diet	0.7	Tomatoes	0.2	Wine grapes	0.2	Peaches	0.1
1.7	WHO cluster diet D	0.6	Tomatoes	0.3	Wine grapes	0.2	Table grapes	0.0
1.7	IT adult	0.7	Tomatoes	0.4	Peaches	0.1	Table grapes	0.0
1.6	ES adult	0.5	Tomatoes	0.4	Wine grapes	0.2	Peaches	0.1
1.6	UK Adult	1.0	Wine grapes	0.3	Tomatoes	0.0	Table grapes	0.0
1.5	UK vegetarian	0.8	Wine grapes	0.4	Tomatoes	0.1	Strawberries	0.0
1.5	NL general	0.6	Wine grapes	0.3	Tomatoes	0.2	Table grapes	0.1
1.5	WHO Cluster diet F	0.6	Wine grapes	0.4	Tomatoes	0.1	Table grapes	0.0
1.5	FR toddler	0.6	Strawberries	0.5	Tomatoes	0.2	Table grapes	0.0
1.3	SE general population 90th percentile	0.5	Tomatoes	0.2	Strawberries	0.1	Peaches	0.1
1.3	ES child	0.6	Tomatoes	0.2	Peaches	0.1	Milk and milk products: Cattle	0.1
1.3	UK Toddler	0.4	Tomatoes	0.2	Table grapes	0.2	Strawberries	0.0
1.2	DK child	0.3	Tomatoes	0.3	Cucumbers	0.2	Table grapes	0.0
1.2	PL general population	0.5	Tomatoes	0.3	Table grapes	0.1	Cherries	0.0
1.0	FR infant	0.5	Strawberries	0.2	Milk and milk products: Cattle	0.1	Courgettes	0.2
0.8	FI adult	0.3	Wine grapes	0.3	Tomatoes	0.1	Strawberries	0.0
0.8	UK Infant	0.2	Tomatoes	0.2	Strawberries	0.1	Apricots	
0.6	LT adult	0.4	Tomatoes	0.1	Cucumbers	0.0	Strawberries	0.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of fenpyrazamine 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)
78.2	Peaches	3.95594812164	74.2	Table grapes	3.4/-	36.0	Table grapes	3.4/-	36.0	Table grapes	3.4/-
74.2	Table grapes	3.4/-	57.4	Peaches	3.95594812164	26.9	Wine grapes	3.4/-	26.9	Wine grapes	3.4/-
40.8	Apricots	3.95594812164	32.7	Apricots	3.95594812164	23.0	Peaches	3.95594812164	17.9	Peaches	3.95594812164
36.0	Tomatoes	1.85945701357	26.1	Tomatoes	1.85945701357	15.4	Aubergines (egg	1.85945701357	15.4	Aubergines (egg plants)	1.85945701357
33.1	Peppers	1.57551554828	23.6	Peppers	1.57551554828	10.1	Apricots	3.95594812164	8.4	Apricots	3.95594812164
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)	
28.4	Grape juice	2.59349150009		3.3	Wine	2.59349150009	
23.6	Peach juice	3.95594812164 58/-		2.7	Peach preserved with syrup	3.95594812164 58/-	
21.4	Elderberry juice	4/-		1.2	Tomato (preserved-	1.85945701357	
13.5	Cuurant juice	4/-		0.4	Raisins	2.59349150009	
13.1	Raspberries juice	3.27782174776					

*) 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 fenpyrazamine, 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.

Isoprothiolane

Status of the active substance:	**Non-approved**	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.1**	ARfD (mg/kg bw):	**0.12**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

EFSA-Q-2017-00673 (adapted from EFSA-Q-2011-00327).

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)
1.7	UK Infant	1.0	Rice	0.4	Milk and cream	0.1	Sugar beet (root)	0.7
1.5	UK Toddler	0.9	Rice	0.2	Sugar beet (root)	0.2	Milk and cream	0.6
1.5	PT General population	1.3	Rice	0.1	Potatoes	0.0	Wheat	0.2
1.3	WHO Cluster diet B	0.8	Rice	0.1	Wheat	0.0	Milk and cream	0.5
1.2	FR toddler	0.6	Rice	0.4	Milk and cream	0.1	Potatoes	0.7
1.2	NL child	0.6	Rice	0.3	Milk and cream	0.1	Apples	0.7
1.2	WHO cluster diet D	0.9	Rice	0.1	Wheat	0.1	Milk and cream	0.3
1.1	ES child	0.8	Rice	0.1	Milk and cream	0.0	Wheat	0.3
1.0	SE general population 90th percentile	0.6	Rice	0.1	Milk and cream	0.0	Potatoes	0.3
1.0	DE child	0.4	Rice	0.1	Milk and cream	0.1	Apples	0.5
0.8	UK vegetarian	0.6	Rice	0.0	Sugar beet (root)	0.0	Milk and cream	0.2
0.7	UK Adult	0.6	Rice	0.0	Sugar beet (root)	0.0	Milk and cream	0.2
0.6	IE adult	0.3	Rice	0.0	Sweet potatoes	0.0	Milk and cream	0.4
0.6	WHO cluster diet E	0.3	Rice	0.0	Wheat	0.0	Potatoes	0.3
0.6	FR infant	0.3	Milk and cream	0.1	Rice	0.0	Potatoes	0.4
0.6	WHO Cluster diet F	0.3	Rice	0.0	Milk and cream	0.0	Wheat	0.3
0.6	ES adult	0.4	Rice	0.0	Milk and cream	0.0	Wheat	0.2
0.6	WHO regional European diet	0.3	Rice	0.0	Milk and cream	0.0	Potatoes	0.3
0.6	DK child	0.2	Rice	0.1	Milk and cream	0.1	Wheat	0.4
0.5	LT adult	0.3	Rice	0.0	Milk and cream	0.0	Potatoes	0.2
0.5	NL general	0.3	Rice	0.1	Milk and cream	0.0	Potatoes	0.2
0.5	IT kids/toddler	0.3	Rice	0.1	Wheat	0.0	Other cereal	0.2
0.4	IT adult	0.3	Rice	0.0	Wheat	0.0	Tomatoes	0.1
0.4	FR all population	0.2	Rice	0.0	Wine grapes	0.0	Wheat	0.2
0.3	FI adult	0.2	Rice	0.1	Milk and cream	0.0	Potatoes	0.1
0.3	DK adult	0.1	Rice	0.1	Milk and cream	0.0	Wheat	0.2
0.1	PL general population	0.0	Potatoes	0.0	Apples	0.0	Tomatoes	0.1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Isoprothiolane 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)
16.8	Rice	1.6/-	16.8	Rice	1.6/-	10.0	Rice	1.6/-	10.0	Rice	1.6/-
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 Isoprothiolane, 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.

Fosetyl (sum of fosetyl and phosphonic acid, expressed as fosetyl)

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**2.8**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2015**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
7	43
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)
43	DE child	13	Apples	10	Oranges	5	Table grapes	
39	WHO Cluster diet B	11	Tomatoes	6	Wine grapes	2	Peppers	
32	NL child	8	Oranges	7	Apples	3	Table grapes	
26	IE adult	4	Wine grapes	3	Oranges	2	Melons	
22	FR all population	14	Wine grapes	2	Tomatoes	1	Oranges	
21	PT General population	9	Wine grapes	3	Tomatoes	2	Oranges	
20	FR toddler	5	Oranges	3	Apples	3	Tomatoes	
18	WHO cluster diet E	6	Wine grapes	2	Tomatoes	1	Oranges	
16	UK Toddler	5	Oranges	2	Tomatoes	2	Apples	
16	ES child	6	Oranges	4	Tomatoes	1	Apples	
16	NL general	4	Oranges	2	Wine grapes	2	Tomatoes	
16	WHO regional European diet	4	Tomatoes	1	Oranges	1	Potatoes	
15	WHO cluster diet D	4	Tomatoes	1	Wine grapes	1	Potatoes	
14	SE general population 90th percentile	3	Tomatoes	2	Oranges	1	Potatoes	
14	ES adult	3	Oranges	3	Tomatoes	1	Wine grapes	
13	WHO Cluster diet F	2	Tomatoes	2	Oranges	2	Wine grapes	
13	IT kids/toddler	5	Tomatoes	1	Oranges	1	Apples	
12	DK child	3	Apples	2	Tomatoes	1	Cucumbers	
12	FR infant	3	Apples	2	Oranges	1	Potatoes	
12	UK vegetarian	3	Wine grapes	2	Oranges	2	Tomatoes	
12	IT adult	4	Tomatoes	1	Oranges	1	Apples	
11	DK adult	5	Wine grapes	1	Tomatoes	1	Apples	
11	UK Infant	3	Oranges	2	Apples	1	Tomatoes	
10	UK Adult	4	Wine grapes	2	Tomatoes	2	Oranges	
10	PL general population	3	Tomatoes	2	Apples	1	Table grapes	
8	FI adult	3	Oranges	2	Tomatoes	1	Wine grapes	
7	LT adult	2	Tomatoes	2	Apples	1	Potatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Fosetyl (sum of fosetyl and phosphonic acid, expressed as fosetyl) 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 Fosetyl (sum of fosetyl and phosphonic acid, expressed as fosetyl) residues is unlikely to present a pulbic health concern.							

Phosphonic acid

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**2.25**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2015**

All MRLs.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
6	40
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)
40	DE child	12	Apples	10	Oranges	4	Table grapes	
37	WHO Cluster diet B	10	Tomatoes	6	Wine grapes	2	Peppers	
30	NL child	8	Oranges	7	Apples	3	Table grapes	
25	IE adult	4	Wine grapes	3	Oranges	2	Melons	
21	FR all population	13	Wine grapes	1	Tomatoes	1	Oranges	
20	PT General population	8	Wine grapes	3	Tomatoes	2	Oranges	
19	FR toddler	5	Oranges	3	Apples	3	Tomatoes	
17	WHO cluster diet E	5	Wine grapes	2	Tomatoes	1	Oranges	
16	UK Toddler	5	Oranges	2	Sugar beet (root)	2	Tomatoes	
15	ES child	5	Oranges	3	Tomatoes	1	Apples	
15	WHO regional European diet	4	Tomatoes	1	Oranges	1	Potatoes	
15	NL general	4	Oranges	2	Wine grapes	1	Tomatoes	
15	WHO cluster diet D	3	Tomatoes	1	Wine grapes	1	Potatoes	
14	SE general population 90th percentile	3	Tomatoes	2	Oranges	1	Mandarins	
13	ES adult	3	Oranges	3	Tomatoes	1	Wine grapes	
13	WHO Cluster diet F	2	Tomatoes	2	Oranges	2	Wine grapes	
12	IT kids/toddler	5	Tomatoes	1	Oranges	1	Apples	
12	DK child	2	Apples	2	Tomatoes	1	Cucumbers	
12	FR infant	3	Apples	2	Oranges	1	Spinach	
11	UK vegetarian	3	Wine grapes	2	Oranges	2	Tomatoes	
11	IT adult	4	Tomatoes	1	Oranges	1	Apples	
10	UK Infant	3	Oranges	2	Apples	1	Tomatoes	
10	DK adult	5	Wine grapes	1	Tomatoes	1	Apples	
10	UK Adult	4	Wine grapes	1	Tomatoes	1	Oranges	
9	PL general population	3	Tomatoes	2	Apples	1	Table grapes	
7	FI adult	2	Oranges	1	Tomatoes	1	Wine grapes	
6	LT adult	2	Tomatoes	2	Apples	1	Potatoes	

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

Triflumezopyrim

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.2**	ARfD (mg/kg bw):	**1**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

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)
0.4	UK Infant	0.2	Milk and cream	0.1	Sugar beet (root)	0.0	Rice	0.3
0.4	FR toddler	0.2	Milk and cream	0.0	Potatoes	0.0	Rice	0.3
0.3	NL child	0.1	Milk and cream	0.0	Apples	0.0	Potatoes	0.3
0.3	UK Toddler	0.1	Sugar beet (root)	0.1	Milk and cream	0.0	Rice	0.3
0.3	DE child	0.1	Milk and cream	0.1	Apples	0.0	Wheat	0.3
0.3	WHO Cluster diet B	0.0	Wheat	0.0	Rice	0.0	Milk and cream	0.2
0.2	FR infant	0.1	Milk and cream	0.0	Potatoes	0.0	Carrots	0.2
0.2	DK child	0.1	Milk and cream	0.0	Wheat	0.0	Rye	0.2
0.2	IE adult	0.0	Sweet potatoes	0.0	Milk and cream	0.0	Maize	0.2
0.2	ES child	0.1	Milk and cream	0.0	Wheat	0.0	Rice	0.2
0.2	SE general population 90th percentile	0.1	Milk and cream	0.0	Potatoes	0.0	Rice	0.2
0.2	WHO cluster diet D	0.0	Wheat	0.0	Milk and cream	0.0	Rice	0.1
0.2	WHO cluster diet E	0.0	Wheat	0.0	Potatoes	0.0	Milk and cream	0.1
0.1	WHO regional European diet	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	0.1
0.1	WHO Cluster diet F	0.0	Milk and cream	0.0	Wheat	0.0	Potatoes	0.1
0.1	PT General population	0.0	Rice	0.0	Potatoes	0.0	Wheat	0.1
0.1	NL general	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	0.1
0.1	ES adult	0.0	Milk and cream	0.0	Wheat	0.0	Rice	0.1
0.1	UK vegetarian	0.0	Sugar beet (root)	0.0	Rice	0.0	Milk and cream	0.1
0.1	FR all population	0.0	Wine grapes	0.0	Wheat	0.0	Milk and cream	0.1
0.1	UK Adult	0.0	Sugar beet (root)	0.0	Rice	0.0	Milk and cream	0.1
0.1	IT kids/toddler	0.0	Wheat	0.0	Rice	0.0	Other cereal	0.1
0.1	DK adult	0.0	Milk and cream	0.0	Wheat	0.0	Potatoes	0.1
0.1	LT adult	0.0	Milk and cream	0.0	Potatoes	0.0	Apples	0.1
0.1	FI adult	0.0	Milk and cream	0.0	Potatoes	0.0	Wheat	0.1
0.1	IT adult	0.0	Wheat	0.0	Rice	0.0	Tomatoes	0.1
0.0	PL general population	0.0	Potatoes	0.0	Apples	0.0	Tomatoes	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Triflumezopyrim 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)
0.2	Potatoes	0.01/-	0.2	Melons	0.01/-	0.1	Rice	0.086/-	0.1	Rice	0.086/-
0.2	Melons	0.01/-	0.1	Milk and milk	0.01/-	0.1	Pumpkins	0.01/-	0.1	Pumpkins	0.01/-
0.1	Oranges	0.01/-	0.1	Watermelons	0.01/-	0.0	Watermelons	0.01/-	0.0	Watermelons	0.01/-
0.1	Milk and milk products:	0.01/-	0.1	Potatoes	0.01/-	0.0	Melons	0.01/-	0.0	Melons	0.01/-
0.1	Watermelons	0.01/-	0.1	Rice	0.086/-	0.0	Chinese cabbage	0.01/-	0.0	Chinese cabbage	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)			
0.1	Apple juice	0.01/-				0.0	Orange juice	0.01/-			
0.0	Orange juice	0.01/-				0.0	Apple juice	0.01/-			
0.0	Carrot, juice	0.01/-				0.0	Bread/pizza	0.01/-			
0.0	Grape juice	0.01/-				0.0	Wine	0.01/-			
0.0	Peach juice	0.01/-				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 Triflumezopyrim, 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.