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Scientific support for preparing an EU position for the 52nd 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 52nd session of the Codex Committee on Pesticide Residues (CCPR). In 2019, JMPR evaluated 20 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (acetochlor, boscalid, chlorothalonil, cyprodinil, dicamba, mesotrione, metaflumizone, thiabendazole, afidopyropen, buprofezin, clethodim, dimethoate, metconazole, omethoate, pyflubumide, pyridate, pyrifluquinazon, tolclofos-methyl, triflumuron, valifenalate) and 47 active substance regarding the setting of Maximum Residue Limits (MRLs) (acetochlor, azoxystrobin, boscalid, chlorantraniliprole, chlorothalonil, cyantraniliprole, cyprodinil, dicamba, fenazaquin, flonicamid, flupyradifurone, fosetyl-Al, glyphosate, mesotrione, metaflumizone, S-methoprene, pendimethalin, spirotetramat, tebuconazole, thiabendazole, acetamiprid, afidopyropen, benzovindiflupyr, bifenthrin, buprofezin, carbendazim, clethodim, cyclaniliprole, cypermethrins, dimethoate, fluazifop-p-butyl, fluensulfone, kresoxim-methyl, mandestrobin, metconazole, omethoate, penthiopyrad, picoxystrobin, pydiflumetofen, pyflubumide, pyrifluquinazon, pyriofenone, pyriproxyfen, tolclofos-methyl, tolfenpyrad, triflumuron, valifenalate). 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.

Keywords: consumer risk assessment, toxicological evaluation, residue definitions, MRL setting, 52nd CCPR meeting

Requestor: European Commission

Question number: EFSA-Q-2019-00551; EFSA-Q-2019-00552; EFSA-Q-2019-00553; EFSA-Q-2019-00554; EFSA-Q-2019-00555; EFSA-Q-2019-00556; EFSA-Q-2019-00557; EFSA-Q-2019-00558; EFSA-Q-2019-00559; EFSA-Q-2019-00560; EFSA-Q-2019-00561; EFSA-Q-2019-00562; EFSA-Q-2019-00563; EFSA-Q-2019-00564; EFSA-Q-2019-00565; EFSA-Q-2019-00566; EFSA-Q-2019-00567; EFSA-Q-2019-00569; EFSA-Q-2019-00568; EFSA-Q-2019-00706; EFSA-Q-2019-00707; EFSA-Q-2019-00708; EFSA-Q-2019-00709; EFSA-Q-2019-00710; EFSA-Q-2019-00711; EFSA-Q-2019-00712; EFSA-Q-2019-00713; EFSA-Q-2019-00714; EFSA-Q-2019-00715; EFSA-Q-2019-00716; EFSA-Q-2019-00717; EFSA-Q-2019-00718; EFSA-Q-2019-00719; EFSA-Q-2019-00720; EFSA-Q-2019-00721; EFSA-Q-2019-00722; EFSA-Q-2019-00723; EFSA-Q-2019-00724; EFSA-Q-2019-00725; EFSA-Q-2019-00726; EFSA-Q-2019-00727; EFSA-Q-2019-00728; EFSA-Q-2019-00729; EFSA-Q-2019-00730; EFSA-Q-2019-00731; EFSA-Q-2019-00732; EFSA-Q-2019-00733; EFSA-Q-2019-00734; EFSA-Q-2019-00735

Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

For the preparation of the 52nd 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 Joint FAO/WHO Meetings on Pesticide Residues (JMPR) (extraordinary meeting of May and regular meeting of September), in particular on the recommended toxicological reference values and the proposed MRLs at steps 3 and 6 of the Codex procedure.

In the two meetings held in 2019, JMPR evaluated in total 20 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (acetochlor, boscalid, chlorothalonil, cyprodinil, dicamba, mesotrione, metaflumizone, thiabendazole, afidopyropen, buprofezin, clethodim, dimethoate, metconazole, omethoate, pyflubumide, pyridate, pyrifluquinazon, tolclofos-methyl, triflumuron, valifenalate). EFSA compared the acceptable daily intake (ADI) and acute reference dose (ARfD) values derived by JMPR with the values derived at EU level and, in case differences were identified, EFSA provided further explanations for the reasons of the differences.

Regarding the setting of Maximum Residue Limits (MRLs), JMPR assessed 47 substances (acetochlor, azoxystrobin, boscalid, chlorantraniliprole, chlorothalonil, cyantraniliprole, cyprodinil, dicamba, fenazaquin, flonicamid, flupyradifurone, fosetyl-Al, glyphosate, mesotrione, metaflumizone, S-methoprene, pendimethalin, spirotetramat, tebuconazole, thiabendazole, acetamiprid, afidopyropen, benzovindiflupyr, bifenthrin, buprofezin, carbendazim, clethodim, cyclaniliprole, cypermethrins, dimethoate, fluazifop-p-butyl, fluensulfone, kresoxim-methyl, mandestrobin, metconazole, omethoate, penthiopyrad, picoxystrobin, pydiflumetofen, pyflubumide, pyrifluquinazon, pyriofenone, pyriproxyfen, tolclofos-methyl, tolfenpyrad, triflumuron, valifenalate). EFSA provided comments on the proposed Codex MRLs as well as on active substances that were re-assessed by JMPR following specific concerns raised in the previous years and on general issues discussed in the 2019 JMPR meetings.

It is highlighted that the EFSA comments were derived based on the information provided in the JMPR reports. Since the JMPR reports do not contain the full detailed information on the studies submitted to JMPR, the EFSA comments are restricted to the specific questions specified in the Terms of Reference. Hence, the conclusions reached on Codex MRL proposals reported 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.

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1. Introduction

1.1. Background

Manufacturers of pesticides who are interested in the setting of Codex Maximum Residue Limits (CXLs) submit data to the Joint Meeting on Pesticide Residues (JMPR) for assessment. The most recent JMPR evaluations of the toxicological data and the residue studies are summarised in the Extra and Regular JMPR Reports 2019 (FAO, 2019, 2020). It comprises in total 49 active substances: 20 of them were assessed for both toxicological reference values and residues, 47 active substances were assessed in view of setting new CXLs and 8 active substances were assessed for specific concerns raised by the official delegations.

On 13 August 2019, the European Commission requested EFSA to provide support for the preparation of the EU-coordinated position for the 52nd session of the Codex Committee on Pesticide Residues (CCPR). In particular, EFSA was asked to give advice and to provide comments on the recommendations of the 2019 Joint FAO/WHO meeting on pesticide residues (JMPR). Additionally, the European Commission requested EFSA to give its comments on other proposed Codex MRLs that were retained at Step 4 or 7, respectively, in previous years and are likely to be discussed in the 52nd CCPR meeting, in case that such new advice from EFSA is needed and appropriate.

Furthermore, the European Commission asked for comments on the general chapters of the JMPR 2019 report, where relevant for risk assessment as well as other comments on the proposed crop groupings, the JMPR priority list and documents related to the revision of the IESTI equation.

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

Question number	Subject
EFSA-Q-2019-00551	Thiabendazole (65) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00552	Chlorothalonil (81) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00553	S-Methoprene (147) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00554	Glyphosate (158) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00555	Tebuconazole (189) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00556	Cyprodinil (207) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00557	Boscalid (221) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00558	Azoxystrobin (229) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00559	Spirotetramat (234) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00560	Metaflumizone (236) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00561	Dicamba (240) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00562	Chlorantraniliprole (263) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00563	Mesotrione (277) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00564	Acetochlor (280) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00565	Flonicamid (282) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00566	Flupyradifurone (285) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019

Question number	Subject
EFSA-Q-2019-00567	Pendimethalin (292) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00568	Fosetyl-Al (302) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00569	Fenazaquin (297) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00706	Dimethoate (027) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00707	Omethoate (055) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00708	Cypermethrins (118) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00709	Propiconazole (160) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00710	Buprofezin (173) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00711	Bifenthrin (178) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00712	Clethodim (187) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00713	Tolclofos-methyl (191) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00714	Kresoxim-methyl (199) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00715	Pyriproxyfen (200) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00716	Cyclaniliprole (296) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00717	Pyraclostrobin (210) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00718	Penthiopyrad (253) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00719	Fluxapyroxad (027) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00720	Picoxystrobin (256) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00721	Benzovindiflupyr (261) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00722	Fluensulfone (265) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00723	Tolfenpyrad (269) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00724	Fluazifop-p-butyl (283) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00725	Isofetamid (290) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00726	Mandestrobin (307) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00727	Pydiflumetofen (309) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00728	Pyriofenone (310) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00729	Afidopyropen (312) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019

Question number	Subject
EFSA-Q-2019-00730	Metconazole (313) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00731	Pyflubumide (314) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00732	Pyridate (315) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00733	Pyrifluquinazon (316)- EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00734	Triflumuron (317)- EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019
EFSA-Q-2019-00735	Valifenalate (318) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2019

The draft scientific report of EFSA was submitted for commenting to the EU Member State experts and European Commission on 18 February 2020. All the comments received were addressed either directly in the final EFSA scientific report or though discussion during the Council Working Party meetings for the preparation of the 52nd Session of the Codex Committee on Pesticide Residues.

1.2. Terms of Reference

The requested advice and comments on the recommendations of the 20 active substances of the extraordinary Joint FAO/WHO meeting on pesticides residues (JMPR) of 7–17 May 2019 and the 27 active substances of the JMPR Regular meeting of 17–26 September 2019 and, where appropriate, on other proposed Codex MRLs, retained in the step procedure and reviewed by JMPR in previous years, should contain the following information:

- Background information on all active substances under discussion regarding the status of the active substance at EU level (approval status of the active substance, availability of EFSA conclusions and availability of EFSA reasoned opinions on MRL applications or MRL review);
- In case new toxicological reference values were proposed by JMPR, a comparison of the proposed reference values with agreed EU reference values and an evaluation of the possible reasons for differences;
- As regard the proposed draft Codex MRLs for discussion in CCPR 2020, EFSA should provide 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 2019 report relevant for risk assessment as well as comments on the JMPR priority list can be provided as contribution to the EU coordinated positions when these are discussed with the Member States and do not need to be covered by the scientific report.

(Terms of reference as provided by the European Commission in the Mandate of 13 August 2019)

EFSA agreed with the European Commission to respond to this request with a scientific report.

On 30 November 2019, EFSA submitted the compilation of the comments on the substances covered by the extraordinary JMPR meeting to MSs and European Commission.

A draft report containing the comments on the substances assessed by JMPR in the regular meeting of September 2019 was shared with the European Commission and Member States on 18 February 2020, which was the basis for the discussion in the first Council Working Party held on 4 March 2020. A second draft report addressing the Member State comments was completed on 13 March 2020; this document was then further discussed in the second Council Working Party held on 8 March 2021.

The comments provided by Member States during the commenting period were addressed either directly in the final EFSA scientific report or through discussion during the Council Working Party meetings for the preparation of the 52nd Session of the CCPRs.

2. Assessment

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

For deriving the comments on the third bullet point in the Terms of Reference (comments on the Codex MRL proposals), EFSA compared the levels of the Codex MRL proposals and the enforcement residue definition derived by JMPR with the MRLs and the residue definition established in the EU legislation (Regulation (EC) No 396/2005[2]) 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 or, where these documents are not available, the reports prepared by the European Commission in the framework of the peer review of active substances or Member State evaluations in Draft Assessment Reports. The comparison of the existing EU MRLs and the proposed Codex MRLs are presented in tabular form. Codex MRL proposals that are higher than the existing EU MRLs are printed in bold. In line with the presentation of MRLs in the EU legislation, limit of quantification (LOQ) MRLs are indicated by adding an asterisk ('*') after the value. The comparison of MRL proposals with existing EU MRLs is performed for commodities listed in Part A of the EU food classification, but not for products that are listed in Part B. For MRL proposals for animal products, EFSA verified the plausibility of the Codex MRL proposals without a detailed check of the dietary burden calculation, since this would go beyond the scope of the current mandate and would require the availability of dietary burden calculators for other global regions (USA/Canada, Australia, Japan).

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, 2010b, 2017c) as well as relevant OECD guidelines and guidance documents (OECD, 2011, 2013). It is noted that due to the different data requirements and policies in JMPR (FAO, 2016), the assessment of identical residue data sets submitted in support of an 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).

With regard to the question whether the draft Codex MRLs are sufficiently supported by data, EFSA focused on the availability of residue trials and metabolism studies. Details on independence of residue trials, storage stability, analytical method validation and other details, which would be assessed in detail in the framework of EU MRL applications, are not reported in the JMPR Reports. Hence, comments on these aspects of the dossier are not within the scope of the current assessment.

For the assessment of the safety of the draft Codex MRL proposals, EFSA used the EFSA PRIMo rev. 3.1. (EFSA, 2018c, 2019r). For assessing the acute consumer risk, EFSA applied the standard EU methodology, including the agreed EU variability factors and the 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 STMRs and including the STMR values derived by JMPR for commodities where the proposed Codex MRLs are higher than the existing EU MRLs. It is noted that this approach is likely to overestimate the actual exposure, because it is not likely that each food item consumed contains residues at the maximum level allowed in the European legislation, but it is a sufficiently conservative risk assessment screening. For active substances where

[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.

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 is 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 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.

In addition, it is noted that comments were derived on the basis of the JMPR reports summarising the recommendations of the 2019 JMPR Extraordinary and Regular meeting, which were published, respectively, on 6 June 2019 and 10 January 2020. Due to the timelines agreed with the requestor, EFSA could not use the JMPR evaluations which were published at a later stage to prepare the comments. 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.

3. General Consideration items

3.1. Extraordinary 2019 JMPR meeting

3.1.1. Extra JMPR Meetings

The extraordinary efforts of JMPR to prepare assessments for the extra JMPR meeting are highly appreciated. This meeting was a significant contribution to reduce the backlog for new uses.

3.2. Regular 2019 JMPR meeting

3.2.1. Update to Chapter 5 of the Environmental Health Criteria (EHC) 240: Dose–response assessment and derivation of health-based guidance values

EFSA welcomed the initiative from the WHO to update the chapter 5 of the Environmental Health Criteria (EHC) 240: Dose–response assessment and derivation of health-based guidance values. In line with the WHO EFSA recommends the use of the benchmark dose approach as alternative to the no observed adverse effect level (NOAEL) as the point of departure (EFSA Scientific Committee, 2017a).

3.2.2. Combined exposure to multiple chemicals

In line with the WHO, EFSA is actively involved in the development of guidance for harmonised methodologies for combined exposure to multiple chemicals and it is considered a priority for EFSA. A guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals was published in 2019 (EFSA Scientific Committee, 2019b) and general methodology for classifying pesticides into cumulative assessment groups has been also developed.

In April 2020, EFSA published the final reports of cumulative risk assessments for the effects of pesticide residues on the nervous system and the thyroid (EFSA, 2020f,g). These are pilot assessments preceding a wider programme of implementation of cumulative risk assessments of pesticides in EU. Nervous system and thyroid were the selected organs for this pilot because they are frequent targets of pesticides and this choice allowed testing the methodologies for acute and chronic effects. In February 2021, EFSA published the report of cumulative risk assessment of chronic acetylcholinesterase inhibition by residues of pesticides (EFSA, 2021a) while the assessment of cumulative risk assessment of pesticides regarding cranio-facial malformations is currently ongoing.

These assessments do not entirely fit to the approach suggested by the FAO/WHO expert consultation because they were retrospective cumulative risk assessments, based on the actual dietary exposure – and not prospective assessments, the main scenario of interest for JMPR. The main difference with the FAO/WHO approach lies in the fact that no exposure cut-off was considered or applied in the EFSA assessments.

The assessments conducted by EFSA may include elements of interest to be considered by JMPR and JECFA in further discussion on the guidance under development.

The cumulative risk assessments conducted by EFSA addressed precise assessment questions and were performed in consistency with precise thresholds for regulatory consideration defined by the European risk managers.

The cumulative risks were calculated by probabilistic modelling under the assumption of dose-additivity and expressed in terms of total margin of exposure (MOET). The chemical groups used in these assessments are defined as cumulative assessment groups. They were established based on toxicological effects selected for their relevance in combined toxicity and include substances which can act by either similar or dissimilar mode of action.

The assessments include a rigorous uncertainty analysis conducted following a guidance adopted by the EFSA Scientific Committee and using weight of evidence and expert knowledge elicitation techniques. Each step of the process (hazard identification and characterisation (in other words establishment of cumulative assessment groups), cumulative exposure assessments and cumulative risk characterisation) are reported in individual reports accessible on the EFSA website.

3.2.3. Guidance for the evaluation of genotoxicity of chemical substances in food

In line with WHO, EFSA has been actively involved in the development of guidance for the evaluation of genotoxicity of chemical substances in food (EFSA Scientific Committee, 2011, 2017b, 2019a).

EFSA is aware of the update to Chapter 5 of the EHC 240: Guidance for the evaluation of genotoxicity and provided comments to the WHO accordingly.

3.2.4. Results for probabilistic modelling of acute dietary exposure to evaluate the IESTI equations

EFSA regrets that the final report on the probabilistic acute dietary exposure assessment for the 47 pesticides has been published late (March 2021). The study was intended to provide a benchmarking for the IESTI methodology, providing risk managers information on whether the IESTI calculations are sufficiently protective for consumers. Due to the late publication of the report, a detailed discussion of the conclusions on the interpretation of the findings of the study were not possible in the framework of the current report. As a preliminary comment, EFSA would like to highlight that the study design might not be fully appropriate to address the research question. A more in-depth analysis of the study, however, would be necessary to identify the strengths and the possible limitations of the study.

EFSA agreed with the conclusions of JMPR who discussed the draft paper in its meeting of September 2020 that a more realistic assessment of the level of protection (LoP) could be made by assuming residues at the MRL for a single commodity and residues from monitoring data for other commodities. However, the use of monitoring data requires a careful assessment with regard to their quality in order to be fit for this purpose.

3.2.5. Need for a guidance on toxicological interpretation due to the shift from maximum tolerated dose (MTD)-based to kinetically-derived maximum dose (KMD)-based evaluation of pesticide residues

EFSA agreed that guidance KMD-based toxicity interpretation is needed not only in the area of pesticide residues but in general for toxicological interpretation. Further discussions at OECD/WHO level are recommended.

3.2.6. Comments on chlorpyrifos

In July 2019 the European Commission asked EFSA to provide a statement on the available outcomes of the human health assessment in the context of the pesticides peer review for the renewal of approval of the active substance chlorpyrifos, which was then published in August 2019 (EFSA, 2019q). JMPR is aware of the EFSA statement on chlorpyrifos and strongly recommends chlorpyrifos to be prioritised for re-evaluation. The prioritisation action is welcome by EFSA.

3.2.7. Possible need for amendments to the Environmental Health Criteria (EHC) 240 guidance on appropriate use of toxicological historical control data (HCD)

EFSA agrees that further guidance on appropriate use of toxicological historical control data is needed and welcomes the activity of JMPR.

3.2.8. Use of monitoring data for the estimation of maximum residue levels

EFSA supports the clarifications of JMPR on the approach using monitoring data for MRL setting only in limited cases, i.e. for extraneous residue levels for MRLs for spices, but not for dried chilli peppers, for which residue trials in fresh chilli peppers or in fresh bell peppers should be provided.

4. Responses to specific concerns raised by the Codex Committee on Pesticide Residues (CCPR)

4.1. Buprofezin (173)

The risk assessment of aniline was performed by the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (CEF Panel) in 2007 when re-evaluating the food colour Red 2G (EFSA AFC Panel, 2007). The assessment of JMPR took into consideration new data including a new in vivo genotoxicity study on aniline not assessed yet by EFSA and therefore a conclusion on whether EFSA would support JMPR assessment cannot be done at this stage. See also Section 5.9.

4.2. Diflubenzuron (130)

In the EU, the application for renewal of the approval of diflubenzuron was withdrawn in May 2020 and consequently the approval expired end of December 2020. The reassessment of the toxicological profile of diflubenzuron and their metabolites, including 4-chloroaniline was not finalised.

4.3. Fluxapyroxad (256)

See Section 5.25.

4.4. Iprodione (111)

Given the 24-year gap since iprodione was last reviewed by JMPR and the magnitude of potential concerns for acute intakes identified by the EU, JMPR strongly recommends iprodione be prioritised for periodic re-evaluation. The prioritisation action is welcome by EFSA.

4.5. Isofetamid (290) – Reconsideration of the maximum residue levels for bush berries, dry beans and dry peas

See Section 5.35.

4.6. Picoxystrobin (258)

The last assessment of the available genotoxicity data in the EU took place in 2016 (EFSA, 2016m). JMPR and EFSA differ in their interpretations of the genotoxicity data for picoxystrobin and IN-H8612.

4.7. Propiconazole (160) – Reconsideration of the maximum residue level for peach

See Section 5.8.

4.8. Pyraclostrobin (210)

See Section 5.17.

4.9. Request from CCPR concerning okra

Other options for extrapolation could be acceptable to facilitate the setting of Codex MRLs which are of importance for some Codex members. Although okra is botanically classified in the class of solanaceae, extrapolations form other crops which are morphologically comparable with okra might be acceptable, e.g. extrapolation from beans with pods, provided data are available to support the extrapolations.

5. 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, 2019, 2020). 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 (Tables 1–240).

5.1. Dimethoate (027) R/T

5.1.1. Background information

Table 1: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Periodic review	
RMS	IT	
Approval status	Not approved	Commission Implementing Regulation (EU) 2019/1090[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2018x)
MRL review performed	Yes, see comments	(EFSA, 2009a) (MRLs of concern) (EFSA, 2016r) (prioritised review)
MRL applications/ assessments	Yes, see comments	(EFSA, 2012f) (olives) (EFSA, 2011e) (various crops) (EFSA, 2010c) (various crops) (EFSA, 2010b) (cauliflower, broccoli, Brussels sprouts and lettuce)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	

(a): Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, 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 173, 27.6.2019, p. 39–41.

5.1.2. Toxicological reference values

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

<table>
<tr><th rowspan="2"></th><th colspan="2">JMPR evaluation</th><th colspan="2">EU evaluation</th><th rowspan="2">TRV comparable</th></tr>
<tr><th>Value</th><th>Comments</th><th>Value</th><th>Comments</th></tr>
<tr><td>ADI</td><td>0.001 mg/kg bw per day</td><td>JMPR (2019)
Based on the NOAEL for RBC AChE inhibition in female pups on PND 21 in a developmental special study designed to assess the effects of dimethoate on AChE activity in pregnant rats, preweaning rats and young adult rats; applying an UF of 100</td><td>–</td><td>(EFSA, 2018x)
A genotoxicity potential could not be ruled out in vivo and TRVs were not established</td><td>No</td></tr>
<tr><td>ARfD</td><td>0.02 mg/kg bw</td><td>JMPR (2003, 2019)
Based on an overall acute NOAEL for RBC AChE inhibition in an acute neurotoxicity study and a special study in preweaning females and in young adult females, applying an UF of 100</td><td>–</td><td>(EFSA, 2018x)
A genotoxicity potential could not be ruled out in vivo and TRVs were not established</td><td>No</td></tr>
<tr><td>Conclusion/ comment</td><td colspan="5">Parent:
The submitted studies provided some evidence for dimethoate being weakly genotoxic in bacterial and mammalian cells in in vitro assays.
The JMPR considered the rate of phosphorylation of acetylcholinesterase to be the predominant reaction of dimethoate, whereas mutations resulting from reactions with DNA would only be detected at much higher concentrations and concluded that dimethoate is unlikely to be genotoxic in vivo; accordingly to the JMPR established toxicological reference values for the parent dimethoate. In contrast, the EU peer review considered that in the absence of adequate in vivo follow up to contravene the positive genotoxicity results in vitro, a genotoxic potential could not be ruled out and no toxicological reference values were established.

Metabolites:
Omethoate:
Considering that omethoate showed genotoxic potential in vivo the setting of reference values was not considered appropriate by both the JMPR and EU peer review.

Metabolite III (Dimethoate Carboxylic Acid):
The JMPR considered that the metabolite is a major rat metabolite and as such its toxicity is covered by the toxicological reference values established for the parent dimethoate.
The EU assessment derived an ADI of 0.09 mg/kg bw per day, based on a 28-day study in rats, UF of 1,000 applied; ARfD was not established as not needed.

While the JMPR could not conclude on the genotoxicity potential of other metabolites due to lack of studies, the EU peer review appears to have had access to additional toxicological studies, including genotoxicity studies on metabolites and concluded the following:

Metabolite X (O-Desmethyl dimethoate):
Read across from metabolite XI.

Metabolite XI (O-Desmethyl omethoate):
The EU assessment derived an ADI of 0.1 mg/kg bw per day, based on a 28-day study in rats, applying an UF of 1,000; ARfD was not established as not needed.

Metabolite XII (Des-O-methyl isodimethoate):
The EU assessment derived an ADI of 0.015 mg/kg bw per day based on the parental NOAEL of the reproductive/developmental toxicity study in rats, UF of 1,000 applied; ARfD was not established as not needed.</td></tr>
</table>

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
	Metabolite XX (O-Desmethyl omethoate carboxylic acid): The EU assessment derived an ADI of 0.1 mg/kg bw per day, based on the parental and offspring's NOAEL of the reproductive/developmental toxicity study in rat, supported by the 28-day study in rats, UF of 1000 applied; ARfD was not established as not needed. **Metabolite XXIII** (O-Desmethyl N-desmethyl Omethoate): The EU assessment derived an ADI of 0.075 mg/kg bw per day from the parental NOAEL of the reproductive/developmental toxicity study in rats, UF of 1,000 applied; ARfD was not established as not needed.				

5.1.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Dimethoate and omethoate (measured and reported separately)	Reg. 396/2005: separate residue definitions were set for dimethoate and omethoate. Peer review (EFSA, 2018x): dimethoate and omethoate, to be considered separately.	Yes
	Animal products	Dimethoate and omethoate (measured and reported separately) The residue is not fat soluble	Reg. 396/2005: separate residue definitions were set for dimethoate and omethoate. Peer review (EFSA, 2018x): dimethoate and omethoate, to be considered separately. The residue is not fat soluble	Yes
RD RA	Plant products	The Meeting was unable to recommend a definition for dietary risk assessment	Peer review (EFSA, 2018x): Provisionally, the residue definition for risk assessment is proposed as dimethoate and omethoate	Not appropriate
	Animal products	The Meeting was unable to recommend a definition for dietary risk assessment	Peer review (EFSA, 2018x): Provisionally, the residue definition for risk assessment is proposed as dimethoate and omethoate	Not appropriate
Conclusion/ comments	–			

5.1.4. Codex MRL proposals

Table 4: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal[(a)]	EU MRL Dimethoate/ omethoate	Comment
Artichoke, globe	**0.05 (W)**	0.01*/0.01*	All existing Codex MRLs established for dimethoate were proposed for withdrawal, following the considerations that • An ADI or an ARfD for omethoate were not recommended by the WHO panel, due to concerns regarding its genotoxicity; • Due to genotoxicity concerns relating to omethoate and other related metabolites, a conclusion on a residue definition for dietary risk assessment could not be derived; • Consequently, a long-term and acute dietary risk assessment could not be conducted.
Asparagus	**0.05*(W)**	0.01*/0.01*	
Barley	**2 (W)**	0.02*/0.01*	
Brussels sprouts	**0.2 (W)**	0.1*/0.01*	
Cabbage, Savoy	**0.05*(W)**	0.01*/0.01*	
Cattle, Edible offal of	0.05*(W)	–/–	
Cauliflower	**0.2 (W)**	0.01*/0.01*	
Celery	**0.5 (W)**	0.01*/0.01*	
Cherries	**2 (W)**	0.01*/0.01*	
Citrus fruits	**5 (W)**	0.01*/0.01*	
Eggs	0.05*(W)	0.01*–/0.01*	
Lettuce, Head	**0.3 (W)**	0.01*/0.01*	
Mammalian fats (except milk fats)	0.05* (W)	0.01*/0.01*	
Mango	**1 (Po) (W)**	0.01*/0.01*	
Meat of cattle, goats, horses, pigs and sheep	0.05*(W)	0.01*/0.01* (muscle)	
Milk of cattle, goats and sheep	0.05* (W)	0.01*/0.01*	
Pear	**1 (W)**	0.01*/0.01*	
Peas (pods and succulent = immature seeds)	**1 (W)**	0.01*/0.01*	
Peppers Chilli, dried	**3 (W)**	–/–	
Peppers, sweet (including pimento or pimiento)	**0.5 (W)**	0.01*/0.01*	
Potato	**0.05 (W)**	0.01*/0.01*	
Poultry fats	0.05* (W)	0.01*0.01*	
Poultry meat	0.05* (W)	0.01*/0.01* (muscle)	
Poultry, edible offal of	0.05* (W)	0.01*/0.01	
Sheep, edible offal of	0.05* (W)	0.01*/0.01	
Spices, fruits and berries	0.5 (W)	0.05*/0.05*	
Spices, roots and rhizomes	0.1* (W)	0.05*/0.05*	
Spices, seeds	5 (W)	0.05*/0.05*	
Sugar beet	**0.05 (W)**	0.01*/0.01*	
Table olives	0.5 (W)	0.01*/0.01*	
Turnip greens	1 (W)	Chinese cabbage: 0.01*/0.01*	
Turnip, Garden	**0.1 (W)**	0.01*/0.01*(turnips from other root and tuber vegetables except sugar beets)	
Wheat	0.05 (W)	0.01*/0.01*	
Wheat straw and fodder, dry	1 (W)	–/–	

Commodity	Codex MRL proposal[(a)]	EU MRL Dimethoate/ omethoate	Comment
General comments	(a): The Codex MRLs that are proposed for withdrawal refer to the previous residue definition which covered only dimethoate.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.1.5. Consumer risk assessment

Not relevant, since no Codex MRL proposals were derived.

5.2. Omethoate (055) R/T

5.2.1. Background information

Table 5: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Periodic review	
RMS	No RMS assigned	
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[(a)]
EFSA conclusion available	No	No conclusion is available for omethoate, but omethoate was assessed in the framework of the peer review of dimethoate (EFSA, 2018x)
MRL review performed	Yes, see comments	(EFSA, 2016r) (prioritised review)
MRL applications/ assessments	No	
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	

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

5.2.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation	
	Value	**Comments**	**Value**	**Comments**
ADI	–	JMPR (1996) The assessment could not be completed with respect to its mutagenic potential *in vivo* and the ADI for omethoate was withdrawn	–	(EFSA, 2018x) (dimethoate) A genotoxic potential *in vivo* could not be excluded for omethoate and TRVs were not established
ARfD	–	JMPR (1996) The assessment could not be completed with respect to its mutagenic potential *in vivo* and the ADI for omethoate was withdrawn	–	(EFSA, 2018x) (dimethoate) A genotoxic potential *in vivo* could not be excluded for omethoate and TRVs were not established
Conclusion/ comment	See also dimethoate (27)			

5.2.3. Residue definitions

See dimethoate (027).

5.2.4. Codex MRL proposals

Table 7: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal[(a)]	EU MRL	Comment
Spices, fruits and berries	0.01 (W)	0.05*	All existing Codex MRLs established for omethoate were proposed for withdrawal, following the considerations that – An ADI or an ARfD for dimethoate were not recommended by the WHO panel, due to concerns regarding its genotoxicity; – Due to genotoxicity concerns relating to omethoate and other related metabolites, a conclusion on a residue definition for dietary risk assessment could not be derived; – Consequently, a long-term and acute dietary risk assessment could not be conducted.
Spices, roots and rhizomes	0.05 (W)	0.05*	
General comments	(a): The Codex MRLs that are proposed for withdrawal refer to the previous residue definition which covered only omethoate.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.2.5. Consumer risk assessment

Not relevant, since no Codex MRL proposals were derived.

5.3. Thiabendazole (65) R/T

5.3.1. Background information

Table 8: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Approved	Commission Implementing Regulation (EU) 2017/157[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2014p)
MRL review performed	Yes, see comments	(EFSA, 2014k) (EFSA, 2016n) (Art. 43)
MRL applications/ assessments	Yes, see comments	(EFSA, 2021h)[(b)] (various crops)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	The confirmatory data requirements established by Commission Implementing Regulation (EU) 2017/157 requesting information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects have not been addressed. Therefore, in line with the ECHA and EFSA guidance (ECHA and EFSA, 2018) on the identification of endocrine disruptors, additional data are still required before a final conclusion on the endocrine disrupting properties of thiabendazole can be derived ECHA and EFSA guidance (ECHA and EFSA, 2018).

(a): Commission Implementing Regulation (EU) 2017/157 of 30 January 2017 renewing the approval of the active substance thiabendazole 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 25, 31.1.2017, p. 5–9.
(b): The assessment performed in the recently published reasoned opinion could not be taken into account for the assessment in this report.

5.3.2. Toxicological reference values

Table 9: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.1 mg/kg bw per day	JMPR (1992), confirmed by JECFA in 1997	0.1 mg/kg bw per day	(EFSA, 2014p) (2-year rat and 100 UF) confirmed in (European Commission, 2016b)	Yes
ARfD	0.3 mg/kg bw for women of child-bearing age. 1 mg/kg bw for the general population.	JMPR (2006)	0.1 mg/kg bw	(EFSA, 2014p) (Rat developmental study and 100 UF) confirmed in (European Commission, 2016b)	No
Conclusion/ comment	The ARfD derived by the JMPR evaluation is higher than the ARfD derived by the EU evaluation. The JMPR assessed additional toxicological information available since the last review and concluded that no revision of the ADI or ARfDs was necessary. The NOAEL for systemic toxicity from the newly submitted acute neurotoxicity study (50 mg/kg bw) is lower than the NOAEL from the study currently used in the JMPR derivation of the ARfD for the general population (100 mg/kg bw). However, the JMPR concluded that there was no reason to revise the ARfD for the general population because the lowest observed adverse effect level (LOAEL) was 200 mg/kg bw for both studies and the findings in both studies were similar. The EU ADI and ARfD have not been demonstrated to cover the non-rat metabolite benzimidazole, which is included in the tentative residue definitions for risk assessment for plant (relevant to preharvest treatment and rotational crops) and animal products (data gap identified). The consumer risk assessment in the EFSA conclusion was not finalised in terms of residues of the metabolite benzimidazole (EFSA, 2014p).				

5.3.3. Residue definitions

Table 10: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Thiabendazole	Reg. 396/2005: Thiabendazole	Yes
	Animal products	Sum of thiabendazole and 5-hydroxythiabendazole The residue is not fat soluble	Reg. 396/2005: Sum of thiabendazole and 5-hydroxythiabendazole MRL review Art. 43 (EFSA, 2016n): Milk: Sum of thiabendazole, 5–hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole Other animal commodities: Sum of thiabendazole and 5–hydroxythiabendazole expressed as thiabendazole Peer review (EFSA, 2014p):	Yes (the RD proposed by EFSA in the MRL review for milk has not been implemented). See comments below.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			Milk: Thiabendazole, 5–hydroxythiabendazole and its sulfate conjugate, sum expressed as thiabendazole All other animal commodities: Thiabendazole and 5–hydroxythiabendazole, sum expressed as thiabendazole The residue is not fat soluble	
RD RA	Plant products	Thiabendazole	MRL review Art. 43 (EFSA, 2016n): Post-harvest treatment: Thiabendazole (relevant to the authorised uses on citrus fruit, apple, pear, avocado, mango, banana, papaya and consumption potato); this RD is provisional for potatoes and witloof, because of lack of metabolism study. Preharvest treatment and rotational crops: RD 1) Thiabendazole; RD 2) Total benzimidazole (tentative, data gap identified) Peer review (EFSA, 2014p): Post-harvest treatment: Thiabendazole (relevant to the representative uses on citrus and on apple and pear); Preharvest treatment and rotational crops: Thiabendazole, and total benzimidazole (i.e. free and conjugated) (provisional, data gap identified) Processed plant commodities: pending (data gap identified)	No, see comments below
	Animal products	Sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate	MRL review Art. 43 (EFSA, 2016n): Milk: Sum of thiabendazole, 5–OH–thiabendazole and its sulfate conjugate, expressed as thiabendazole; Total benzimidazole (tentative, data gap identified) Other animal commodities: Sum of thiabendazole and 5–OH–thiabendazole, expressed as thiabendazole; Total benzimidazole (tentative, data gap identified) Peer review (EFSA, 2014p): Milk: Thiabendazole, 5–hydroxythiabendazole and its	No, see comments below

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			sulfate conjugate, sum expressed as thiabendazole, and benzimidazole (provisional; data gap identified) All other animal commodities: Thiabendazole and 5–hydroxythiabendazole, sum expressed as thiabendazole, and benzimidazole (provisional; data gap identified)	
Conclusion, comments	The enforcement residue definitions for plant products derived by the JMPR and EU evaluations are comparable. It is noted that JMPR did not assess metabolism studies representative for the post-harvest use in root crops (sweet potatoes). Hence, the appropriateness of the current residue definitions for post-harvest uses in root crops should be verified. In an ongoing EU import tolerance application, a metabolism study for post-harvest use in root crops was requested, which should provide information on the formation of metabolites over time (it is not enough to characterise and identify the nature of residues immediately after the treatment, but nature of residues need to be investigated after an appropriate storage period). The enforcement residue definition for animal products derived by the JMPR evaluation is comparable with the residue definition established in the EU Reg. 396/2005. The EU Peer review and the EFSA MRL review under Art. 43 proposed to include the sulfate conjugate of 5–hydroxythiabendazole in the enforcement residue definition for milk. Risk managers decided not to implement this residue definition. The risk assessment residue definition for plant products derived by the JMPR evaluation is comparable with the residue definition derived by the EU evaluation for plant products post-harvest treatment (relevant to the EU authorised uses on fruits) based on metabolism studies in oranges. The residue definitions derived by the EU evaluation for plant products (preharvest treatment and rotational crops) and for animal products are both wider than the respective JMPR residue definitions, covering also the metabolite benzimidazole and its conjugates (provisional, data gap identified). In the MRL legislation, confirmatory data were requested on the magnitude of residues of benzimidazole for citrus fruit, apples, potatoes and animal products (deadline for submission: 1 July 2019).			

5.3.4. Codex MRL proposals

Table 11: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Beans with pods (includes all commodities in this subgroup)	0.01*	0.01* beans (with pods)	cGAP: USA succulent beans, except soyabean: 0.55 kg a.i./tonne seed treatment; soyabean: 0.20 kg a.i./tonne seed treatment Number of trials: 6 trials in succulent beans with pods Sufficiently supported by data: Yes Specific comments/observations: Levels of thiabendazole in beans with pods were < 0.01 mg/kg (six trials). JMPR proposed a Codex MRL for the subgroups of succulent beans with pods. The description of the commodity related to the code VP 2060 should be corrected (to include the suffix '(includes all commodities in this subgroup')). Information on benzimidazole (tentative second EU residue definition for preharvest uses) is not reported in the JMPR report. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the

Commodity	Codex MRL proposal	EU MRL	Comment
			EU policy on setting MRLs. It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the risk assessment for benzimidazole could not be performed. Follow-up action: None.
Dry beans, subgroup of (includes all commodities in this subgroup)	0.01*	0.01* (dry beans, dry lupins)	cGAP: USA dry beans, except soyabean: 0.55 kg a.i./tonne seed treatment; soyabean: 0.20 kg a.i./tonne seed treatment Number of trials: 9 in dry beans Sufficiently supported by data: Yes Specific comments/observations: Levels of thiabendazole in dry beans were < 0.01 mg/kg (nine trials). Information on benzimidazole (tentative second EU residue definition for preharvest uses) is not reported in the JMPR report. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the risk assessment for benzimidazole could not be performed. Follow-up action: None
Dry peas, subgroup of (includes all commodities in this subgroup)	0.01*	0.01* dry peas, dry lentils	cGAP: USA 0.33 kg a.i./tonne seed treatment Number of trials: 10 overdosed trials (≥ 2.4N rate) Sufficiently supported by data: Yes Specific comments/observations: Levels of thiabendazole in dry peas were < 0.01 mg/kg (five trials) and < 0.05 mg/kg (five trials). Information on benzimidazole (tentative second EU residue definition for preharvest uses) is not reported in the JMPR report. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the risk assessment for benzimidazole could not be performed. Follow-up action: None
Mango	**7 (Po)**	0.01*	cGAP: Central American GAP 0.24 kg a.i./hL dip solution; Brazil GAP 0.19 kg a.i./hL dip solution. Number of trials: 4 Sufficiently supported by data: No Specific comments/observations: The residue trials assessed in the JMPR evaluation were previously submitted to EFSA in support of an import tolerance application for mango (EFSA-Q-2018-00334). The JMPR evaluation derived an STMR and a HR for residues in the pulp. According to information available to EFSA from an ongoing IT application, the residue trials determined thiabendazole residues in mango pulp on the day of treatment only (DAT = 0). However, translocation of residues from the peel to the pulp cannot be excluded during shipping/storage/ripening. These studies may underestimate the magnitude of residues in the edible portion (mango pulp) following a suitable waiting period under typical shipping/storage/ripening conditions. An EU import tolerance application for mangos is currently on clock-stop due to the lack of a valid study investigating the possible transfer of residues to the pulp after a time period which is realistic for shipment of treated mangoes to Europe. **Conclusion:** The proposed Codex MRL is not acceptable because of a potential acute intake concern identified in scenario 1 (see below). Follow-up action: None

Commodity	Codex MRL proposal	EU MRL	Comment
Peas with pods, subgroup of (includes all commodities in this subgroup)	0.01*	0.01*	cGAP: USA 0.33 kg a.i./tonne seed treatment Number of trials: 6 trials in beans with pods (overdosed) Sufficiently supported by data: Yes, by extrapolation from beans with pods Specific comments/observations: Levels of thiabendazole in beans with pods were < 0.01 mg/kg (six trials). Information on benzimidazole (tentative second EU residue definition for preharvest uses) is not reported in the JMPR report. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the risk assessment for benzimidazole could not be performed. Follow-up action: None
Succulent beans without pods, subgroup of (includes all commodities in this subgroup)	0.01*	0.01*	cGAP: USA succulent beans, except soyabean: 0.55 kg a.i./ tonne seed treatment; soyabean: 0.20 kg a.i./tonne seed treatment Number of trials: 1 trial in beans, 9 trials in peas (overdosed) Sufficiently supported by data: Yes, based on combined trials in beans and peas. Information on benzimidazole (tentative second EU residue definition for preharvest uses) is not reported in the JMPR report. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the risk assessment for benzimidazole could not be performed. Follow-up action: None
Succulent peas without pods, Subgroup of (includes all commodities in this subgroup)	0.01*	0.01*	cGAP: USA 0.33 kg a.i./tonne seed treatment Number of trials: 9 overdosed trials (3–4N rate) Sufficiently supported by data: Yes Specific comments/observations: Information on benzimidazole (tentative second EU residue definition for preharvest uses) is not reported in the JMPR report. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the risk assessment for benzimidazole could not be performed. Follow-up action: None
Sweet potato	**9 (Po)**	0.01*	cGAP: USA 0.16 kg a.i./hL dip solution or spray (on a conveyor belt) at 0.006 kg a.i./tonne post-harvest treatment Number of trials: Spray application GAP: seven trials; dip application GAP: eight trials. Sufficiently supported by data: Yes Specific comments/observations: JMPR evaluation based on dip trials, which gives the highest residues. The residue trials were previously submitted to EFSA in support of an import tolerance application for sweet potato (EFSA-Q-2018-01013). The residue levels of benzimidazole in sweet potatoes were reported in the residue trials (dip and spray application) at PHI 0 days only. The EU evaluation MRL review Art. 12, revised in 2016 (EFSA, 2016n) proposed the residue definition for risk assessment for post-harvest treatment as thiabendazole (provisional). However, further information on the metabolism of thiabendazole in root and tuber vegetables following post-harvest treatment covering a suitable waiting period relevant to the storage period and storage conditions

Commodity	Codex MRL proposal	EU MRL	Comment
			was requested that would allow to confirm the suitability of the residue definition for risk assessment for post-harvest uses for root and tuber group commodities. For a currently ongoing import tolerance application for the post-harvest use on sweet potatoes, this data gap leads to a clock-stop. **Conclusion:** The proposed Codex MRL is not acceptable because of a potential acute intake concern (see below). In addition, it should be highlighted that a suitable metabolism study in root crops (post-harvest use) would be required to verify the appropriateness of the residue definition for sweet potatoes. Follow-up action: None
General comments	Further background information Data gaps identified in the Art. 43 (EFSA, 2016n): • a detailed and reproducible evaluation of the study investigating the nature of residues after pasteurisation, cooking, brewing and sterilisation in order to judge the validity of the study (data gap relevant for all authorisations reported); • data to address the potential for consumer exposure and toxicological properties for the metabolite benzimidazole (data gap relevant for commodities of animal origin and for the authorisations on citrus fruits, apples, potatoes and witloof); Reg. (EU) 2017/1164[(a)]: • Confirmatory data requirement (citrus, apples, potatoes, witloofs, products of animal origin): information on the magnitude of residues of the metabolite benzimidazole (to be submitted by 1 July 2019).		

*: Indicates that the MRL is proposed at the limit of quantification.
(a): Commission Regulation (EU) 2017/1164 of 22 June 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acrinathrin, metalaxyl and thiabendazole in or on certain products. OJ L 170, 1.7.2017, p. 3–30.

5.3.5. Consumer risk assessment

Table 12: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. sweet potatoes and mangoes). For mango, EFSA calculated two scenarios: scenario 1 is based on the HR for the whole fruit (4.5 mg/kg); scenario 2 is based on HR edible part of the crop measured immediately after the treatment (DAT 0 days) (0.03 mg/kg). The risk assessment was performed with the EU ARfD. The calculations are indicative, because information is required on (1) confirmation of the residue definition for risk assessment, (2) the nature of residues after processing	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2016n) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. For mango, the risk assessment used the STMR whole fruit because information is not available to derive a reliable processing factor for peeling after a suitable waiting period. The risk assessment was performed with the EU ADI. The risk assessment calculations are indicative, because data for the metabolite benzimidazole (toxicological studies and information on magnitude of residues in the crops under assessment) are not available. The calculations are indicative, because	**Specific comments:** The JMPR exposure assessment does not include the potential for consumer exposure to the metabolite benzimidazole, which is included in the EU residue definition for risk assessment for plant products (tentative, relevant to preharvest treatment and rotational crops, data gap identified). Information is required on the nature of residues after processing (standard hydrolysis studies). For mango, the JMPR exposure assessment is based on residues in mango pulp (edible potion) on the day of treatment (DAT = 0).

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
(standard hydrolysis studies) and (3) data to address the potential for consumer exposure and toxicological properties for the metabolite benzimidazole. The risk assessment calculations are indicative, because data for the metabolite benzimidazole (toxicological studies and information on magnitude of residues in the crops under assessment) are not available.	information is required on (1) confirmation of the residue definition for risk assessment, (2) the nature of residues after processing (standard hydrolysis studies) and (3) data to address the potential for consumer exposure and toxicological properties for the metabolite benzimidazole. The risk assessment calculations are indicative, because data for the metabolite benzimidazole (toxicological studies and information on magnitude of residues in the crops under assessment) are not available.	
Results: **The calculated short-term exposure exceeded the ARfD for one/several crops under assessment.** Mangoes: scenario 1: 354% of ARfD (NL toddler) scenario 2: 2.4% of ARfD (NL toddler) Sweet potatoes: 145% of ARfD (IE adult)	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 39% of the ADI (NL toddler). Among the crops under consideration, sweet potato was identified as the main contributor, accounting for up to 17% of the ADI (IE adult).	**Results:** Long-term exposure: Max. 2–10% of the JMPR ADI. Short-term exposure: Highest results for sweet potatoes: 4–20% (child) and 1–7% (adult) of ARfD for general population; 3–9% of ARfD for women of child-bearing age.

5.4. Chlorothalonil (81) R/T

5.4.1. Background information

Table 13: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Not approved	Commission Regulation (EU) 2019/677[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2018a)
MRL review performed	Yes, see comments	(EFSA, 2012i)
MRL applications/ assessments	Yes, see comments	(EFSA, 2020p) (Art. 12 confirmatory data) (EFSA, 2015m) (cranberries)
Classification of a.s. – cut-off criteria	No	Regulation (EC) No 1272/2008[(b)]
Endocrine effects of a.s.	Not assessed/not concluded	It is noted that the assessment was not performed following the ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605)[(c)]

(a): Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, 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 Commission Implementing Regulation (EU) No 540/2011. OJ L 114, 30.4.2019, p. 15–17.
(b): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.
(c): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.4.2. Toxicological reference values

Table 14: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	**Parent:** 0.02 mg/kg bw per day	JMPR (2009), 2-year rat and 100 UF	**Parent:** 0.015 mg/kg bw per day	(European Commission, 2006b): 90-day rat, supported by the 2-year rat and 100 UF, confirmed in (EFSA, 2018a)	No
	SDS-3701: 0.008 mg/kg bw per day	JMPR (2009) 1-year, dog and 100 UF	**SDS-3701 (R182281):** not concluded (genotoxic potential inconclusive)	(EFSA, 2018a)	
	SDS-46851 (R611965): Covered by the parent, expressed as chlorothalonil	JMPR (2019)	**SDS-46851** (R611965): 0.5 mg/kg bw per day	(EFSA, 2018a) 90-day, dog and 100 UF	
	R417888: Covered by the parent, expressed as chlorothalonil	JMPR (2019)	**R417888**: not concluded (genotoxic potential inconclusive)	(EFSA, 2018a)	
ARfD	**Parent:** 0.6 mg/kg bw	JMPR (2009) acute toxicity study in rat and 100 UF	**Parent:** 0.05 mg/kg bw	(EFSA, 2018a) Maternal toxicity in developmental toxicity in rabbit and 100 UF	No
	SDS-3701: 0.03 mg/kg bw	JMPR (2009) Developmental toxicity in rabbit and 100 UF	**SDS-3701** (R182281): not concluded (genotoxic potential inconclusive)	(EFSA, 2018a)	
	SDS-46851 (R611965): Covered by the parent, expressed as chlorothalonil	JMPR (2019)	**SDS-46851** (R611965): 0.83 mg/kg bw	(EFSA, 2018a) Developmental toxicity in rabbit LOAEL and 300 UF	
	R417888: Covered by the parent, expressed as chlorothalonil	JMPR (2019)	**R417888:** not concluded (genotoxic potential inconclusive)	(EFSA, 2018a)	
Conclusion/ comment	Regarding the parent, **chlorothalonil**, the JMPR and EU assessments agreed on the NOAEL of 1.8 mg/kg bw per day for kidney toxicity (increased weight, focal tubular epithelial hyperplasia) in the 2-year rat study, but interpreted differently the outcome of the 90-day study in rats for which the EU assessment concluded on a lower NOAEL of 1.5 mg/kg bw per day for kidney effects (histopathological changes, increased weight). Regarding the ARfD, different points of departure were established by the two institutions. The JMPR used an NOAEL of 60 mg/kg bw per day for kidney effects from an acute toxicity study in rats. The EU assessment considered the maternal NOAEL of 5 mg/kg bw per day for body weight loss observed at the beginning of exposure at 10 mg/kg bw per day in the developmental toxicity study in rabbits.				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
	The JMPR concluded that the ADI and ARfD of chlorothalonil cover the toxicity of metabolites **R611965** and **R417888**, expressed as chlorothalonil. With regard to metabolite **SDS-3701**, an ADI was established at 0.008 mg/kg bw per day based on reduction in body weight gain in females, reduction in erythrocytes in males and increased serum concentrations of glucose in males and females in a 1-year study in dogs, applying an UF 100. The ARfD was established at 0.03 mg/kg bw, based on the NOAEL of 2.5 mg/kg bw per day for early implantation loss observed in the developmental toxicity study in rabbit, applying an UF of 100 (JMPR, 2009, 2019). The EU assessment did not conclude on the toxicity profile of metabolites SDS-3701 (R182281) and R417888. **SDS-3701** (R182281): positive and equivocal results for gene mutation observed *in vitro;* lack of appropriate *in vivo* follow-up. Hence, the genotoxicity profile of metabolite could not be concluded, and no toxicological reference values were established by the EU assessment. **R417888:** Not concluded due to a positive and an equivocal *in vitro* gene mutation assay in mammalian cells which were not followed up *in vivo* and due to a potential for aneugenicity *in vivo.* For metabolites **R613636** (SDS-19221) and **SYN548581**, a genotoxic potential could not be excluded due to a lack of data and no toxicological reference values were derived. **SDS-46851** (R611965): An ADI of 0.5 mg/kg bw per day was derived from the NOAEL of 50 mg/kg bw per day observed in a 90-day toxicity study in dogs, applying an UF of 100; the ARfD was established at 0.83 mg/kg bw, based on a maternal and developmental LOAEL of 250 mg/kg bw per day from the developmental toxicity study in rabbits, applying an increased UF of 300 to account for the use of an LOAEL. Metabolites R418503 (SYN548708), R419492 (SYN548765), R471811 (SYN548766), SYN548008 (SYN548738), SYN548580, R611968 (SDS-47525) and SYN507900 (SDS-66882) are unlikely to be genotoxic (EFSA, 2018a). New tox studies have been performed which according to the applicant demonstrated that plant metabolites R182281, R613636 and R417888 are not genotoxic, which would address the concerns. However, these studies have not been evaluated yet in the EU.				

5.4.3. Residue definitions

Table 15: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Chlorothalonil	Reg. 396/2005: Chlorothalonil Peer review (EFSA, 2018a): 1) Chlorothalonil 2) R182281(SDS-3701) 3) R611965 (SDS-46851) for rotational crops (provisional)	Yes (compared with current RD in legislation)
	Animal products	SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile) The residue is not fat soluble	Reg. 396/2005: 2,5,6-trichloro-4-hydroxyphtalonitrile (SDS-3701) Peer review (EFSA, 2018a): R182281(SDS-3701) (provisional) The residue is not fat soluble	Yes (compared with current RD in legislation)
RD RA	Plant products	1) Chlorothalonil 2) SDS 3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile)	Peer review (EFSA, 2018a): 1) Chlorothalonil and its conjugates 2) R182281 (SDS-3701) and its conjugates 3) R613636 (SDS-19221) for processed commodities 4) R611965 (SDS-46851)/ R417888 and conjugates of	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			metabolites R613636, R613800 (C15) and R611968 (for rotational crops) Residue definitions provisional MRL review: 1) Chlorothalonil 2) R182281(SDS-3701)	
	Animal products	SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile)	MRL review: 1) R182281(SDS-3701) (ruminants and poultry) Peer review (EFSA, 2018a): R182281(SDS-3701) (provisional)	Yes
Conclusion, comments	The existing EU enforcement residue definitions in plant and animal commodities are comparable with those recommended by JMPR. For plant commodities, a separate risk assessment RD has been derived in the MRL review and by JMPR to cover SDS-3701 residues; in the EU also the conjugates were included. Also for parent chlorothalonil the proposed EU risk assessment residue definition includes chlorothalonil conjugates. In addition, the EU peer review proposed separate residue definitions in rotational crops and in processed commodities (not yet implemented). The residue definitions will have to be modified, considering the conclusions on the toxicological profile for SDS-3707.			

5.4.4. Codex MRL proposals

Table 16: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cranberry	15	0.01*	cGAP: USA, 3 × 5.5 kg/ha, PHI 50 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: The information on SDS-3701 residues was provided (< 0.01 (4)–0.019 mg/kg). The samples prior to analysis were stored frozen for 22 days (relevant to assess validity of SDS-3701 data). Residue data on SDS-3701 are reported separately (4 < 0.01, 0.019). In 2015/2016 JMPR assessed the use of chlorothalonil in cranberries. Due to low storage stability for chlorothalonil and SDS-3701 after 10 months, no MRL proposal was made, as the validity of the residue trials in cranberries was questionable. The residue trials assessed in 2019 were stored for up to 22 days. The EU MRL for cranberries was recently lowered from 5 to 0.01 mg/kg, following the decision on non-renewal of the approval. Following the assessment of confirmatory data, it was decided that separate MRLs for SDS-3701 should not be established. **Conclusion:** Considering that for SDS-3701 a risk assessment could not be performed (inconclusive results on genotoxicity), the proposed MRL for cranberries is not acceptable. Follow-up action: None
General comments			

*: Indicates that the MRL is proposed at the limit of quantification.

5.4.5. Consumer risk assessment

Table 17: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed for chlorothalonil residues, using PRIMo rev. 3.1 The ARfD was updated to most recent value of 0.05 mg/kg derived by European Commission in 2019 (European Commission, 2019a). The exposure to SDS-3701 was estimated using PRIMo rev. 3.1. with TRV as set by the European Commission in 2006 (European Commission, 2006b). No acute consumer intake concerns were identified. The peer review (EFSA, 2018a), due to a number of data gaps, could not conclude on the TRV for SDS-3701. The risk assessment for parent chlorothalonil was performed with the EU ARfD. For SDS-3701 an indicative risk calculation of the expected exposure was calculated. Lacking an EU ARfD for this metabolite, no risk assessment was possible. For SDS-46851 (provisional residue definition for rotational crops) no exposure/risk assessment could be performed, lacking information on the expected concentration of this metabolite in processed cranberries. However, considering that the ARfD is significantly higher than the ARfD for the parent compound, it is not expected that the exposure to SDS-4651 would exceed the ARfD. It is noted that exposure assessment does not take into consideration conjugates of chlorothalonil and of SDS-3701. Data on conjugates not available for EU uses assessed in the MRL review as RD for risk assessment did not include conjugates. For cranberries data on conjugates not available, as JMPR RD for risk assessment does not include conjugates.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1 The input values of the most recent long-term risk assessment (EFSA, 2020p), were updated, including the STMR values derived by the JMPR for cranberries. The risk assessment was performed with the EU ADI derived for chlorothalonil. The exposure to SDS-3701 from the intake of cranberries (and commodities of animal origin) was estimated using PRIMo rev. 3.1. A full risk assessment is not possible, since no EU ADI could be derived for this metabolite, due to a number of data gaps, identified in the peer review (2018).	**Specific comments:** Exposure assessment was done separately for chlorothalonil and SDS-3701, considering TRVs set individually for each compound. For metabolite R613636 (relevant in processed commodities undergone sterilisation process), the TTC approach was applied to consider exposure from the intake sterilised foods. Concern was unlikely. The same approach and conclusion were taken for metabolites SYN548764 and R611968 (rotational crop metabolite).
Results: **No short-term consumer health risk was identified for the crops under assessment.** Cranberries: 69% of ARfD for chlorothalonil	**Results:** **No long-term consumer health risk was identified.** Chlorothalonil: the overall chronic exposure accounted for 0.8% of the ADI.	**Results:** Long-term exposure: Max 10–50% of the JMPR ADI for chlorothalonil; Max 4–10% of the JMPR ADI for SDS-3701

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
SDS-3701: the acute exposure accounted for 0.09 μg/kg bw.	The contribution of residues in cranberries is low (< 1% of the ADI). SDS-3701: the overall chronic exposure accounted for 0.00020 μg/kg bw per day.	Short-term exposure: Cranberries: 9% of ARfD (children) for chlorothalonil; 0% of ARfD for SDS-3701

5.5. Cypermethrin (including alpha and zeta-cypermethrin) (118) R

5.5.1. Background information

Table 18: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	BE	
Approval status	Approved	Cypermethrin: Commission Directive 2005/53/EC[(a)] (decision on renewal of the approval is pending)
	Not approved	Alpha-cypermethrin: approval expired on 07/06/2021 Beta-cypermethrin: Commission Implementing Regulation (EU) 2017/1526[(b)] Zeta-cypermethrin: approval expired on 01/12/2020
EFSA conclusion available	Yes, see comments	Cypermethrin: (EFSA, 2018s) Alpha-cypermethrin: (EFSA, 2018t) Beta-cypermethrin: (EFSA, 2014h) Zeta-cypermethrin: (EFSA, 2009b)
MRL review performed	Yes, see comments	Ongoing (Cypermethrin, alpha-cypermethrin, beta-cypermethrin, Zeta-cypermethrin)
MRL applications/ assessments	Yes, see comments	(EFSA, 2011i) (various crops)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/ not concluded	Not concluded (for all cypermethrin isomer mixtures): based on the available evidence, no conclusions on ED assessment, according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(c)]), can be drawn. It is noted that the assessment was not performed following the ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605)

(a): Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances. OJ L 241, 17.9.2005, p. 51–56.
(b): Commission Implementing Regulation (EU) 2017/1526 of 6 September 2017 concerning the non-approval of the active substance beta-cypermethrin 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 231, 7.9.2017, p. 1–2.
(c): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.5.2. Toxicological reference values

Table 19: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		**EU evaluation**		**TRV comparable**
	Value	**Comments**	**Value**	**Comments**	
ADI	0.02 mg/kg bw per day	JMPR (2006) (3-mo dog with alpha-cypermethrin, with safety factor 100)	0.005 mg/kg bw per day	(EFSA, 2018s) (2-year rat, with uncertainty factor 100; supported by DNT study, with uncertainty factor 3000)	No
ARfD	0.04 mg/kg bw	JMPR (2006) (acute rat neurotoxicity with alpha-cypermethrin, with safety factor 100)	0.005 mg/kg bw	(EFSA, 2018s) (DNT study, with uncertainty factor 3000)	No
Conclusion/comment	JMPR derived in 2006 a group ADI and ARfD for cypermethrin, alpha-cypermethrin and zeta-cypermethrin. In the EU, toxicological reference values were derived for the individual isomers:				
			ADI (mg/kg bw per day)		ARfD (mg/kg bw)
	Alpha-cypermethrin		0.00125 (pup LOAEL in developmental neurotoxicity study, UF 200)		0.00125 (pup LOAEL in developmental neurotoxicity study, UF 200)
	Zeta-cypermethrin		0.04 (overall dog NOAEL with cypermethrin, UF 200 to account for higher acute toxicity of zeta-cypermethrin)		0.125 (rat developmental study, supported by acute neurotoxicity study)
	Beta-cypermethrin Beta-cypermethrin		0.0016 (pup LOAEL in developmental neurotoxicity study, UF 300)		0.0016 (pup LOAEL in developmental neurotoxicity study, UF 300)
In the EU evaluations (EFSA, 2018s), specific developmental neurotoxicity studies were provided for cypermethrin and alpha-cypermethrin. For cypermethrin, an increased uncertainty factor of 3000 was applied (based on limited investigations and lack of gavage of the pups) to the pup LOAEL in the developmental neurotoxicity study. For alpha-cypermethrin, an increased uncertainty factor of 200 was applied to the pup LOAEL in the developmental neurotoxicity study. In the EFSA conclusion for zeta-cypermethrin (EFSA, 2009b), the ADI was based on an overall cypermethrin NOAEL for dogs with an increased uncertainty factor of 200 to take into account the higher toxicity of zeta-cypermethrin versus cypermethrin (no developmental neurotoxicity study was available).					

DNT: developmental neurotoxicity.

5.5.3. Residue definitions

Table 20: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cypermethrin (sum of isomers)	Reg. 396/2005 and Peer review (EFSA, 2018s): Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes
	Animal products	Cypermethrin (sum of isomers) The residue is fat soluble	Reg. 396/2005 and Peer review (EFSA, 2018s): Cypermethrin including other mixtures of constituent isomers (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Cypermethrin (sum of isomers)	Peer review (EFSA, 2018s): Cypermethrin (sum of isomers) Provisional, pending finalisation of the assessment of the genotoxic potential of 3-phenoxybenzoic acid (3-PBA) and review of the preliminary conclusions in toxicology on the whole group of related metabolites bearing the 3-phenoxybenzoyl moiety (besides 3-PBA also, e.g. PBAldehyde, 4-OH-PBA) once the confirmatory data on lambda-cyhalothrin have been peer reviewed.	Yes, when compared with provisional RD
	Animal products	Cypermethrin (sum of isomers)	Peer review (EFSA, 2018s): Cypermethrin including other mixtures of constituent isomers (sum of isomers) Provisional, pending clarification on the relative toxicity of individual cypermethrin isomers and finalisation of the assessment of the genotoxic potential of 3-phenoxybenzoic acid (3-PBA) and review of the preliminary conclusions in toxicology on the whole group of related metabolites bearing the 3-phenoxybenzoyl moiety once the confirmatory data on lambda-cyhalothrin have been peer reviewed.	Yes, when compared with provisional RD.
Conclusion, comments	The residue definitions for monitoring for products of plant and animal origin are the same whilst the residue definitions for risk assessment are regarded as provisional pending the outcome of the assessment of the outstanding toxicological data.			

5.5.4. Codex MRL proposals

Table 21: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Ginseng	**0.03***	–	cGAP: Republic of Korea, Foliar, 3 × 0.005 kg a.s./hL, PHI 45 days Number of trials: 6 trials compliant with the cGAP Sufficiently supported by data: Yes Specific comments/observations: In the EU, MRLs are not set for fresh ginseng; ginseng is classified in the class of herbal infusions from roots for which the MRLs refer to dried products. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Ginseng, dried including red ginseng	0.15	0.1* (0633020, ginseng)	cGAP: Republic of Korea, Foliar, 3 × 0.005 kg a.s./hL, PHI 45 days Fresh ginseng samples from residue trials reported above were dried or steamed (to produce red ginseng). The results refer to dried ginseng (washed or steamed), which would be

Commodity	Codex MRL proposal	EU MRL	Comment
			the commodity for which EU MRLs are established. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Ginseng, extracts	0.06*	–	For processed products no EU MRLs are established.
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.5.5. Consumer risk assessment

Table 22: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for ginseng only. The calculations are indicative, because in the EU a final residue definition for risk assessment could not be derived. The risk assessment was performed with the EU ARfD for cypermethrin.	**RA assumptions:** For ginseng, no chronic consumption data are available in PRIMo rev. 3.1. Since ginseng is not expected to be consumed in significant amounts, the overall dietary exposure situation will not be impacted by the proposed Codex MRL for ginseng. It is noted that the comprehensive MRL review for cypermethrin and its isomers will be performed in the near future (depending on the agreement on prioritisation). In this framework, a reliable, comprehensive risk assessment will be performed for cypermethrin, including existing Codex MRLs.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. The exposure accounted for 1% of ARfD for the adults	**Results:** –	**Results:** Long-term exposure: previous risk assessment not affected by the new use in ginseng. Short-term exposure: Ginseng: 0% of ARfD

5.6. S-Methoprene (147) R

5.6.1. Background information

Table 23: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	–	No RMS allocated
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[(b)]
EFSA conclusion available	No	
MRL review performed	No	
MRL applications/assessments	No	
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet.

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.
(b): 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.

5.6.2. Toxicological reference values

Table 24: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.09 mg/kg bw per day (for the R,S racemate); 0.05 mg/kg bw (for S-methoprene)	JMPR (2005)	–	No toxicological reference values established in EU	Not applicable
ARfD	Unnecessary	JMPR (2005)	–	No toxicological reference values established in EU	Not applicable

5.6.3. Residue definitions

Table 25: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Methoprene	Reg. 396/2005: Methoprene	Yes
	Animal products	Methoprene The residue is fat soluble	Reg. 396/2005: Methoprene The residue is not fat soluble	Yes
RD RA	Plant products	Methoprene	–	Not applicable
	Animal products	Methoprene	–	Not applicable
Conclusion, comments	**EU:** In the framework of the EU pesticide legislation, methoprene and S-methoprene were never evaluated. The current residue definition was introduced in 2008, when temporary MRLs were established for the first time under Regulation 396/2005; the residue definition was set by default as the parent compound. An EU assessment for the appropriate residue definitions has not been performed. Methoprene and S-methoprene have not been authorised for use as pesticide at EU level under Council Directive 91/414[(a)] or Regulation 1107/2009.[(b)] **JMPR:** The residue definition is set as methoprene for plant and animal commodities, for both enforcement and dietary risk assessment. The definition is not specific to S-methoprene and covers also residues arising from the use of methoprene. The residue definition of JMPR was based on pant metabolism studies conducted with radiolabelled methoprene in wheat (post-harvest treatment), alfalfa and rice (leaf painting application). A metabolism in pulses and oilseeds after post-harvest treatment (or other appropriate foliar metabolism studies) is not available. JMPR concluded that residue is fat-soluble (based on log P_{ow} of 4 for methoprene and approximate 6 for S-methoprene).			

(a): Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
(b): 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.

5.6.4. Codex MRL proposals

Table 26: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

<table>
<tr><th>Commodity</th><th>Codex MRL proposal</th><th>EU MRL</th><th>Comment</th></tr>
<tr><td>Peanut, whole</td><td>5 Po</td><td>0.05*</td><td>Post-harvest: US GAP, 36.4 g S-methoprene/1,000 bushels (corresponding to up to 4.5 g/tonne), no (zero day) withholding period.
Number of trials: 5 underdosed residue trials. See also specific comments.
Sufficiently supported by data: No, trials were underdosed
Specific comments/observations: JMPR derived the MRL proposal on the basis of the application rate of S-methoprene, which was rounded up to the next MRL class.
JMPR considered the impact of setting an MRL for peanuts on the dietary burden for livestock calculated in 2016, where JMPR proposed a modification for oilseeds, except peanuts. JMPR concluded that the new use would not require a modification of the MRLs for animal products.
The JMPR proposal refers to SO 0703 which is probably an obsolete code for Peanuts, whole. It should be verified if this is the correct code and commodity description; a second code is available for Peanuts (SO 0697).
Conclusion: The proposed Codex MRL is not acceptable (see risk assessment and general comments).
Follow-up action: None</td></tr>
<tr><td>General comments</td><td colspan="3">Overall, the following deficiencies were noted which should be taken into account by risk managers to decide whether the proposed Codex MRL is acceptable:
• The metabolic behaviour following post-harvest treatment in oilseeds was not investigated.
• Peanuts are processed to oil and meal. The nature and the possible concentration of residues in the processed products was not investigated.
In 2017 CCPR the EU made a reservation for the proposed MRL for oilseeds, except peanuts (post-harvest use, 4 mg/kg) for the following reasons:
• A chronic risk for European consumers could not be excluded.
• Considering the significant background exposure from the existing EU MRLs, there is no scope to raise the MRLs. Further refinements of the chronic exposure calculation are possible; however, the relevant data have not yet been assessed in the EU.
• Studies investigating the metabolic behaviour after post-harvest treatment and on the nature and magnitude of residues in processed products are lacking.
• It is noted that the dietary burden calculations should be added to the JMPR report to verify the statement that residues in oilseed do not impact on the dietary burden of farm animals.
The first three bullet points are still relevant for the current Codex MRL proposal.
EFSA recommends to reconsider the existing EU MRLs established at levels > LOQ (i.e. cereal grains (5 mg/kg) and animal products. The MRL for cereals probably corresponds to a CXL that was in place in 2008, when the EU temporary MRLs have been established. However, the CXL has been raised in 2006 to 10 mg/kg, which is likely to pose a consumer health risk.</td></tr>
</table>

*: Indicates that the MRL is proposed at the limit of quantification.

5.6.5. Consumer risk assessment

Table 27: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was not performed since no ARfD has been allocated to the a.s. Not relevant since no ARfD was allocated.	**RA assumptions:** The long-term dietary risk assessment was performed using PRIMo rev. 3.1.; EFSA used the MRLs as reported in Reg. (EU) No 899/2012[(a)] and the STMR (5 mg/kg, equal to the CXL) proposed by JMPR for S-methoprene in peanuts. The risk assessment was performed with the JMPR ADI for S-methoprene. The calculations are indicative, because methoprene was never assessed at EU level. The calculations are affected by additional, non-standard uncertainties, related to the lack of information on the existing MRLs above the LOQ (cereals, swine, bovine, sheep fat and edible offal). Further refinements could not be performed as no detailed information is available for these uses.	**Specific comments:** JMPR used the ADI for S-methoprene is 0–0.05 mg/kg bw in the risk assessment.
Results: Not relevant	**Results:** **The calculated long-term exposure exceeded the ADI set by JMPR for methoprene.** The overall chronic exposure accounted for 136% of the ADI set by JMPR for S-methoprene. The main contributors to the overall exposure were the existing MRLs on wheat (up to 72% of the ADI) and maize (up to 70% of the ADI). MRLs at the LOQ covered 8% of the ADI. The maximum contribution to the chronic exposure of the peanuts (expressed as percentage of the ADI) was 3% (NL child)	**Results:** Long-term exposure: Max 60% of the JMPR ADI set for s-methoprene. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

(a): Commission Regulation (EU) No 899/2012 of 21 September 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acephate, alachlor, anilazine, azocyclotin, benfuracarb, butylate, captafol, carbaryl, carbofuran, carbosulfan, chlorfenapyr, chlorthal-dimethyl, chlorthiamid, cyhexatin, diazinon, dichlobenil, dicofol, dimethipin, diniconazole, disulfoton, fenitrothion, flufenzin, furathiocarb, hexaconazole, lactofen, mepronil, methamidophos, methoprene, monocrotophos, monuron, oxycarboxin, oxydemeton-methyl, parathion-methyl, phorate, phosalone, procymidone, profenofos, propachlor, quinclorac, quintozene, tolylfluanid, trichlorfon, tridemorph and trifluralin in or on certain products and amending that Regulation by establishing Annex V listing default values. OJ L 273, 6.10.2012, p. 1–75.

5.7. Glyphosate (158) R

5.7.1. Background information

Table 28: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	

		Comments, references
Type of JMPR evaluation	New use	
RMS	DE	According to Reg. (EU) 2019/724,[(a)] FR, HU, NL, SE will act jointly as RMS
Approval status	Approved	Commission Implementing Regulation (EU) 2017/2324[(b)]
EFSA conclusion available	Yes, see comments	(EFSA, 2015x)
MRL review performed	Yes, see comments	(EFSA, 2018i) (EFSA, 2019m) Revised version of MRL review to take into account omitted data
MRL applications/ assessments	No	Ongoing: Import tolerance request for soyabeans Other assessments: Evaluation of the impact of glyphosate and its residues in feed on animal health (EFSA, 2018k)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	No	(EFSA, 2017j)

(a): Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State. OJ L 124, 13.5.2019, p. 32–35.

(b): Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate 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 333, 15.12.2017, p. 10–16.

5.7.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–1 mg/kg bw per day	JMPR (2011, 2016) (rat, 2-year; 100 UF)	0.5 mg/kg bw per day	(EFSA, 2015x) (Developmental toxicity, rabbit and 100 UF) confirmed in (European Commission, 2017d)	No
ARfD	Unnecessary	JMPR (2011, 2016) (unnecessary)	0.5 mg/kg bw	(EFSA, 2015x) (Developmental toxicity, rabbit and 100 UF) confirmed in (European Commission, 2017a–d)	No
Conclusion/ comment	The JMPR and EU assessments agreed on the overall NOAEL for long term toxicity/ carcinogenicity of 100 mg/kg bw per day, but disagreed on the NOAEL for developmental toxicity in rabbits where the EU peer review considered a lower NOAEL for both maternal and developmental toxicity of 50 mg/kg bw per day for post-implantation loss, reduced foetal weight and ossification at maternal toxic doses due to gastrointestinal signs, reduced body weight gain, abortions and increased mortality. These observations were considered potentially relevant to an acute exposure and therefore both the ADI and ARfD were derived from this NOAEL applying an uncertainty factor of 100. Both assessments concluded that the toxicological reference values of glyphosate apply to the metabolites AMPA, N-acetylglyphosate and N-acetyl-AMPA (EFSA, 2015x, 2018k).				

5.7.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Soyabean, maize and rape: Sum of glyphosate and N-acetyl glyphosate, expressed as glyphosate Other crops: glyphosate	Reg. 396/2005: Glyphosate MRL review Art. 12 (EFSA, 2018i) (not yet implemented in EU MRL legislation): Two different options proposed by EFSA for further considerations by risk managers: **Main RD-enforcement**: – For plants with glyphosate tolerant genetically modified varieties currently available on the market (sweet corn, cotton seeds, sugar beets, rapeseeds, maize and soybeans): sum of glyphosate, AMPA and N-acetyl glyphosate, expressed as glyphosate – For all other plant commodities: glyphosate **Optional RD-enforcement**: – For all plant commodities (including plants with glyphosate tolerant genetically modified varieties currently available on the market): sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate Peer review (EFSA, 2015x): Sweet corn, oilseed rape, soyabeans and maize (non-tolerant and tolerant, all modifications): sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate Other plant commodities: glyphosate	Yes, for RD implemented in MRL Regulation, except for soyabeans, maize, rapeseed
	Animal products	Sum of glyphosate and N-acetyl glyphosate, expressed as glyphosate The residue is not fat soluble	Reg. 396/2005: Glyphosate MRL review Art. 12 (EFSA, 2018i): Sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate Peer review (EFSA, 2015x): Sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate The residue is not fat soluble	No
RD RA	Plant products	Glyphosate, N-acetyl glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate	MRL review Art. 12 (EFSA, 2018i): Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate Peer review (EFSA, 2015x): Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate	Yes
	Animal products		MRL review Art. 12 (EFSA, 2018i): Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate Peer review (EFSA, 2015x): Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate	Yes
Conclusion, comments	For the commodities under assessment (conventional crops), the residue definitions are comparable. In case the optional residue definition for enforcement will be legally implemented in the EU legislation, the residue definitions for the crops under consideration will not be comparable.			

5.7.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL/ proposed EU MRL[(a)]	Comment
Dry beans, Subgroup of (includes all commodities in this subgroup) (except soyabeans)	**15**	Beans (dry): 2/15 Lupins (dry): 10/10	cGAP: UK, one application at 1.44 kg a.i./ha preharvest with a PHI of 7 days Number of trials: 13 Sufficiently supported by data: Yes Specific comments/observations: Residue trials on dry beans performed in USA at an application rate of 4.20 kg a.i./ha pre-emergence and an application rate of 1.71 kg a.i./ha preharvest with harvest 7 DALA. The Meeting considered that the pre-emergence applications would not contribute significantly to residue levels at harvest. This conclusion is supported by EFSA. Residues were analysed for both glyphosate and AMPA. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Dry peas, Subgroup of (includes all commodities in this subgroup)	**10**	Peas (dry): 10/15 Lentils (dry): 10/10	cGAP: USA, 2 applications at 4.2 kg a.i./ha pre-emergence and 2.5 kg a.i./ha preharvest with a PHI of 7 days. Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: Combined data set of trials on dry lentils (11) and dry peas (5) approximating the GAP. Residues were analysed for both glyphosate and AMPA. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
General comments	The Codex MRL proposals for dry beans, dry peas and dry lentils are expected to be covered by the MRLs derived during the MRL review. For dry lupins, the Codex MRL proposal is higher than the MRL derived during the Article 12 review. It is underlined that the legal implementation of the MRL review is still pending. (a): MRL proposal derived in the MRL review (EFSA, 2019m) for the residue definition glyphosate.		

5.7.5. Consumer risk assessment

Table 32: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: In the framework of the Article 12 MRL review, EFSA calculated the acute risk assessment with the HR values, which were higher than the HR values derived from the trials assessed by JMPR (22 mg/kg for dry beans and peas, 15.2 mg/kg for dry lentils and lupins). Considering that for pulses the acute exposure calculation should be performed according to IESTI case 3, a second scenario was calculated, using the STMR values derived in the MRL review (see chronic RA).	**RA assumptions:** The most recent risk assessment performed by EFSA in the framework of the Art. 12 MRL review was updated, by including the STMR values for the crops under consideration for which a higher STMR was derived by the JMPR (lentils and lupins). The results reported below are based on the STMR values derived during the MRL review (0.92 for dry beans and peas) and derived by the JMPR (1.7 for dry lentils and 0.32 for dry lupins).	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
The risk assessment was performed with the EU ARfD and the EFSA PRIMo rev. 2.	The risk assessment was performed with the EU ADI and the EFSA PRIMo rev. 2.	
Results: **No short-term consumer health risk was identified for the crops under assessment.** Results considering the HR (as performed during the MRL review): Dry beans: 80.4% of ARfD Dry peas: 18.5% of the ARfD Dry lentils: 18.7% of the ARfD Dry lupins: not reported Results considering the STMR: Dry beans: 3.4% of ARfD Dry peas: 0.8% of the ARfD Dry lentils: 2.1% of the ARfD Dry lupins: not reported	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 18.8% of the ADI. Among the crops under consideration, beans were identified as the main contributor, accounting for up to 0.14% of the ADI.	**Results:** Long-term exposure: Max 4% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.8. Propiconazole (160) R

5.8.1. Background information

Table 33: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Follow-up evaluation due to concern form	In 2018 CCPR, the EU raised a reservation: over the decision of the 2017 JMPR to use the CF*3 Mean to recommend the CXL for post-harvest uses (peach); due to toxicological concerns with certain metabolites; due to an acute intake concern.
RMS	FI	
Approval status	Not approved	Commission Implementing Regulation (EU) 2018/1865[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2017h)
MRL review performed	Yes, see comments	(EFSA, 2015a)
MRL applications/ assessments	Yes, see comments	(EFSA, 2021c) (Art. 12 confirmatory data)
Classification of a.s. – cut-off criteria	Yes, see comments	Toxic for reproduction cat. 1B
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet. The RMS informed EFSA that endocrine effects are currently evaluated under biocide process; the assessment is not yet finalised

(a): Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of approval of the active substance propiconazole, 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 Commission Implementing Regulation (EU) No 540/2011. C/2018/7843. OJ L 304, 29.11.2018, p. 6–9.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.8.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.07 mg/kg bw per day	JMPR (2015)	0.04 mg/kg bw per day	(EFSA, 2017h) (Chronic rat study with uncertainty factor of 100)	No
ARfD	0.3 mg/kg bw	JMPR (2015)	0.1 mg/kg bw	(EFSA, 2017h) (Developmental study in rat with uncertainty factor of 300)	No
Conclusion/ comment	–				

5.8.3. Residue definitions

Table 35: 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	Reg. 396/2005: Propiconazole (sum of isomers)	Yes
	Animal products	Propiconazole The residue is fat soluble	Reg. 396/2005: Propiconazole (sum of isomers) Peer review (EFSA, 2017h): CGA91305 (free and conjugated) ((1RS)-1-(2,4-dichlorophenyl)2-(1H-1,2,4-triazol-1-yl) ethanol) The residue is fat soluble	Yes, compared with the current residue definition in Reg. (EU) No 396/2005
RD RA	Plant products	Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoicacid, expressed as propiconazole.	MRL review (EFSA, 2015a): Parent propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers) Peer review (EFSA, 2017h): Primary crops (For all categories of crops): 1) Propiconazole (sum of isomers) 2) CGA 118244 (3,5-dideoxy-1,2-O-[(1RS)-1-(2,4-dichlorophenyl)-2-(1H-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, 1H-1,2,4-triazol-1-ylacetic acid) and CGA131013 (TA,3-(1H-1,2,4-triazol-1-yl)-D,L-alanine)	Yes, compared with the current residue definition in Reg. (EU) No 396/2005
	Animal products	Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoicacid, expressed as propiconazole.	MRL review (EFSA, 2015a): Parent propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers)	Yes, compared to the RD derived in the MRL review

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			Peer review (EFSA, 2017h): 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)	
Conclusion, comments	–			

5.8.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL/ proposed EU MRL[(a)]	Comment
Peaches	**4**	0.01*	cGAP: USA, one post-harvest in-line dip/drench treatment to peach application of 0.014 kg a.i./hL; Number of trials: 4 Sufficiently supported by data: No Specific comments/observations: Peaches are a category 3 crop for JMPR; therefore, at least 5 trials would be required. The MRL proposal was derived using the Mean + 4SDs. STMR: 1.7 mg/kg; HR: 2.5 mg/kg. **Conclusion:** The proposed Codex MRL is not acceptable because of an acute intake concern (see below) and because of the insufficient number of residue trials. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.8.5. Consumer risk assessment

Table 37: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the proposed Codex MRL proposal in peaches. The risk assessment was performed with the EU ARfD. For the TDMs, no acute risk assessment could be performed. The risk assessment is affected by additional non-standard uncertainties, since information provided for propiconazole was considered insufficient to conclude on the toxicological profile of the metabolites containing the 2,4-dichlorobenzoic acid	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. Considering that at EU level the lowering of the existing MRLs to the LOQ was proposed (EFSA, 2021c), input values were all set at the LOQ of 0.01, except for peaches, where the STMR derived by JMPR was used. The risk assessment was performed with the EU ADI. For the TDMs no acute risk assessment could be performed. The risk assessment is affected by additional non-standard uncertainties, since information provided for	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
(metabolites included in the residue definitions for risk assessment).	propiconazole was considered insufficient to conclude on the toxicological profile of the metabolites containing the 2,4-dichlorobenzoic acid (metabolites included in the residue definitions for risk assessment).	
Results: **The calculated short-term exposure exceeded the ARfD for one/several crops under assessment.** Peaches: 238% of ARfD	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 2% of the ADI. The contribution of peaches was 0.13% of the ADI.	**Results:** Long-term exposure: Max 7% of the JMPR ADI. Short-term exposure: 40% of the JMPR ARfD.

5.9. Buprofezin (173) R/T

5.9.1. Background information

Table 38: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New uses and response to concern	The EU raised a public health concern about the potential for the formation of aniline from residues of buprofezin in commodities which are subject to processing.
RMS	IT	
Approval status	Approved	Commission Directive 2011/6/EU,[(a)] in 2017 the use of buprofezin was restricted to non-edible crops (Commission Implementing Regulation (EU) 2017/360[(b)]).
EFSA conclusion available	Yes, see comments	(EFSA, 2010h) (EFSA, 2015n) confirmatory
MRL review performed	No	Assessment in EFSA statement (EFSA, 2019b); all existing EU MRLs were lowered to the LOQ (Regulation 2019/91[(c)])
MRL applications/ assessments	No	
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	No	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(d)]) has not been performed yet

(a): Commission Directive 2011/6/EU of 20 January 2011 amending Council Directive 91/414/EEC to include buprofezin as active substance. OJ L 18, 21.1.2011, p. 38–40.
(b): Commission Implementing Regulation (EU) 2017/360 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance buprofezin. OJ L 54, 1.3.2017, p. 11–13.
(c): Commission Regulation (EU) 2019/91 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products. OJ L 22, 24.1.2019, p. 74–78.
(d): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.9.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Buprofezin					
ADI	0.009 mg/kg bw per day	JMPR (2008) (2-year rat, safety factor 100)	0.01 mg/kg bw per day	(EFSA, 2010h) (2-year rat, uncertainty factor 100)	Yes
ARfD	0.5 mg/kg bw	JMPR (2008) (13-week dog study, safety factor 100)	0.5 mg/kg bw	(EFSA, 2010h) (rat developmental study, uncertainty factor 100)	Yes
Aniline					
ADI	0.02 mg/kg bw per day	JMPR (2008) (human volunteer study, safety factor 10)	–	–	Not appropriate
ARfD	0.02 mg/kg bw	JMPR (2008) (human volunteer study, safety factor 10)	–	–	Not appropriate
Conclusion/ comment	The EU ADI is 0.01 mg/kg bw per day, based on the 2-year rat study (applying an uncertainty factor of 100). The 2008 JMPR proposed the same ADI also based on the 2-year rat study. The different ADI values are a result of different policies on rounding. The EU ARfD is 0.5 mg/kg bw, based on the rat developmental study (applying an uncertainty factor of 100). The 2008 JMPR proposed the same ARfD, based on the 13-week dog study (applying a safety factor 100). Relevant metabolites assessed during the EU peer review (EFSA, 2015n): On the basis of the available information, no reference values could be established for plant metabolites BF4, BF9, BF12 and aniline. Concerning aniline, 2019 JMPR received a new in vivo genotoxicity study in transgenic rats. JMPR considers that the mode of action (MoA) for spleen tumours is not genotoxic. The new genotoxicity study has not been peer reviewed yet at EU level.				

5.9.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Buprofezin	Reg. 396/2005: Buprofezin Peer review (EFSA, 2015n): Buprofezin	Yes
	Animal products	Buprofezin The residue is not fat soluble	Reg. 396/2005: Buprofezin Peer review (EFSA, 2010h): Not RD proposed, since not considered necessary for the representative uses The residue is fat soluble	Yes
RD RA	Plant products	Buprofezin	Peer review (EFSA, 2015n): Sum of buprofezin and BF4 conjugates analysed as BF9 + BF12 under acidic conditions and expressed as buprofezin	No
	Animal products	Buprofezin	Peer review (EFSA, 2015n): Not necessary	Not appropriate
Conclusion, comments	–			

5.9.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus pulp, dry	5	–	14 processing studies in oranges pulp, dry; PF ranged from 1.1 to 4.8, best estimate for PF: 2.9.
Citrus oil, edible	6	–	10 processing studies in oranges oil; PF ranged from 0.88 to 8.9, best estimate for PF: 5.4.
Olive oil, crude	20	–	8 processing studies in olive oil (crude); PF ranged from 0.9 to 4.1, best estimate for PF: 3.5. It is noted that JMPR derived a Codex MRL proposal for crude olive oil, although no MRL proposal is made for unprocessed olives for oil production (SO 0305).The MRL proposal is probably derived by recalculating the existing CXL for table olives (FT 0305) (5 mg/kg) to olive oil, using the PF. However, it is our understanding that a CXL needs to be established for the RAC olives for oil production.
Group of tree nuts	**0.05***	0.01*	cGAP: USA, 1 × 2.24 kg a.i./ha, PHI 60 days Number of trials: 11 (6 in almonds and 5 in pecan nuts) Sufficiently supported by data: Yes Specific comments/observations: In none of the residue trials quantifiable residues were found. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. To discuss with RM whether the concerns of the EU were sufficiently addressed by JMPR. Follow-up action: None
Almond hulls	3	–	In the EU, no MRLs are set for almond hulls. JMPR derived the MRL proposal from 7 residue trials approximating the US GAP for almonds (see above).
Almond	0.05* (W)	0.01*	Existing CXL is withdrawn; to be replaced with Codex MRL proposal for the group of tree nuts
Mammalian fats except milk fats	0.01*	0.01*	In cattle feeding study conducted at exaggerated dose rates (12N and 35N the estimated dietary burden) no quantifiable residues were found in tissues and milk. Codex MRLs have been established for other animal products except mammalian fat in 2010. Sufficiently supported by data: Yes **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Eggs	0.01*	0.01*	The dietary burden for poultry was very low (0.002 ppm). No feeding study for poultry is available. JMPR derived the MRL proposal for poultry products, considering the findings of the feeding study in cattle. Sufficiently supported by data: No **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable although no feeding study is available, considering the low dietary burden for poultry. Follow-up action: None
Poultry, edible offal of	0.01*	0.01*	See eggs.
Poultry fats	0.01*	0.01*	See eggs.
Poultry meat	0.01*	0.01*	See eggs.
General comments:			

*: Indicates that the MRL is proposed at the limit of quantification.

5.9.5. Consumer risk assessment

Table 42: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed for parent buprofezin using PRIMo rev. 3.1 tree nuts. The risk assessment was performed with the EU/Codex ARfD. The calculations are indicative, because no information is available on the magnitude of residues for metabolites included in the EU residue definition (BF4 conjugates analysed as BF9 + BF12 under acidic conditions) Exposure to aniline residues expected in processed products was not calculated, since no aniline concentrations were reported for the crops under consideration.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (normal mode). The calculations were performed with the STMR values derived by JMPR for tree nuts and the existing EU MRLs for the remaining crops. The risk assessment was performed with the EU ADI. The calculations are indicative, because no information is available on the magnitude of residues for metabolites included in the EU residue definition (BF4 conjugates analysed as BF9 + BF12 under acidic conditions) Exposure to aniline residues expected in processed products was not calculated, since no aniline concentrations were reported for the crops under consideration.	**Specific comments:** JMPR calculated the long-term exposure for buprofezin and the short-term exposure for parent buprofezin and for aniline.
Results: No short-term consumer health risk was identified for the crops under assessment. All ≤ 0.1% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 13% of the ADI. Among the crops under consideration, coconut was identified as the main contributor, accounting for up to 0.25% of the ADI.	**Results:** **Buprofezin:** Long-term exposure: Max 4–40% of the JMPR ADI. Short-term exposure (including all crops for which CXLs were established/proposed in 2019 JMPR: Highest result for apples and grapes: 10% of ARfD, respectively. **Aniline:** Long-term exposure: The long-term dietary risk for buprofezin adequately addresses long-term dietary risk to aniline (from uses of buprofezin). Short-term exposure (including all crops for which CXLs were established/proposed in 2019 JMPR: Highest result for apples and grapes: 0% of ARfD, respectively.

5.10. Bifenthrin (178) R

5.10.1. Background information

Table 43: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Other evaluation, see comment	Follow-up assessment for draft MRL proposals retained at step 4 and 7

		Comments, references
RMS	BE	
Approval status	Not approved	Regulation (EU) No 2019/324,[(a)] approval expired in July 2019
EFSA conclusion available	Yes, see comments	(EFSA, 2008b) (EFSA, 2011f)
MRL review performed	Yes, see comments	(EFSA, 2015j)
MRL applications/assessments	Yes, see comments	(EFSA, 2020u) (Art. 12 confirmatory data assessment and import tolerance for sweet corn)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) have not been performed yet

(a): Commission Implementing Regulation (EU) 2019/324 of 25 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances bifenthrin, carboxin, FEN 560 (also called fenugreek or fenugreek seed powder), pepper dust extraction residue and sodium aluminium silicate. OJ L 57 of 26.2.2019, p. 1–3.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.10.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.01 mg/kg bw per day	JMPR (2009)	0.015 mg/kg bw per day	(EFSA, 2008b, 2011f) (1-year dog, supported by developmental studies with safety factor 100)	No
ARfD	0.01 mg/kg bw	JMPR (2009)	0.03 mg/kg bw	(EFSA, 2008b, 2011f) (90-day rat neurotoxicity with safety factor 100)	No
Conclusion/ comment	–				

5.10.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Bifenthrin (sum of isomers)	Reg. 396/2005 and MRL review Art. 12 (EFSA, 2015j): Bifenthrin (sum of isomers) Peer review (EFSA, 2011f): bifenthrin (sum of isomers)	Yes
	Animal products	Bifenthrin (sum of isomers) The residue is fat soluble	Reg. 396/2005 and MRL review Art. 12 (EFSA, 2015j): Bifenthrin (sum of isomers) Peer review (EFSA, 2011f): bifenthrin (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Bifenthrin (sum of isomers)	MRL review Art. 12 (EFSA, 2015j): Bifenthrin (sum of isomers)	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			Peer review (EFSA, 2011f): bifenthrin (sum of isomers)	
	Animal products	Bifenthrin (sum of isomers)	MRL review Art. 12 (EFSA, 2015j): Bifenthrin (sum of isomers)	Yes
Conclusion, comments	The residue definitions are comparable.			

5.10.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL/ assessment of confirmatory data	Comment
Strawberry	**3**	1 (ft)/further risk management considerations required	cGAP: USA, 0.045–0.22 kg a.i./ha, total seasonal rate: 0.56 kg a.i./ha; PHI: not specified. Number of trials: 19 (4 × 0.22 kg a.i./ha, RTI 14 days) Sufficiently supported by data: Yes Specific comments/observations: In 2019, JMPR also received a new US GAP for strawberries (4 × 0.11 kg a.i./ha, PHI 3 days). Since the previously assessed, more critical GAP is still authorised in the USA, the JMPR confirmed its previous MRL proposal of 3 mg/kg. **Conclusion:** Although the proposed Codex MRL is sufficiently supported by residue trials, it is not acceptable because a short-term consumer risk was identified by JMPR and by EFSA (see below). It is noted that JMPR has not recommended withdrawal of the current CXL of 1 mg/kg. It is proposed to include a recommendation in the EU comments to discuss the withdrawal of the current CXL of 1 mg/kg on strawberries. Follow-up action: None
Straw and fodder (dry) of cereal grains	1 (dw)	–	cGAP (for barley, assessed by JMPR in 2010): Switzerland, 2 × 0.016 kg a.i./ha; PHI 42 days. Number of trials: 13 The JMPR derived an MRL proposal based on trials on cereal straws from barley, oats, triticale and wheat. Trials were carried out with ~ 2 × lower application rates and were scaled to comply with the GAP. The maximum dietary burdens calculated based on 2018 OECD Feed diets was less than 10% of the maximum total dietary burden estimated by JMPR in 2010 and did not change the estimated residues in animal commodities. Follow-up action: Switzerland to verify whether the use in cereals still exists.
General comments	In 2016, CCPR agreed to retain proposed MRLs for strawberries, celery and lettuce at step 4, in light of acute intake risk identified in the 2015 JMPR and await an alternative GAP for review by 2017 JMPR which was then further postponed to 2019 JMPR. In 2010, JMPR recommended withdrawal of the CXL of 0.05 mg/kg* for barley and the CXL of 0.5 mg/kg for barley straw and fodder. Since the manufacturer committed to submit supporting data for barley, barley straw and fodder, CCPR 2011 agreed to retain these CXLs under 4 years periodic review procedure. In 2016, CCPR agreed to retain the existing CXL for barley and barley straw and fodder dry, awaiting the outcome of the 2018 JMPR (CCPR 48–60). Data for barley straw were now submitted (see table).		

Commodity	Codex MRL proposal	EU MRL/ assessment of confirmatory data	Comment
	In 2017 CCPR agreed to hold the draft MRL for okra at step 7 awaiting data from India. Additional data were submitted, but since the number of trials was insufficient to derive an MRL proposal for okra, the previous draft MRL proposal of 0.2 mg/kg should be withdrawn. Since no data were submitted to 2019 JMPR for celery and lettuce, a decision on withdrawal of the MRL proposal needs to be taken in CCPR 52.		

5.10.5. Consumer risk assessment

Table 47: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for strawberries. Two scenarios were calculated, using the EU ARfD (scenario 1) and the JMPR ARfD (scenario 2).	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2015j) were updated, including the STMR value derived by JMPR for strawberries. In addition, for CXLs implemented in the EU MRL legislation in 2018 the corresponding STMR values were included in the calculation model. Two scenarios were calculated, using the EU ADI (scenario 1) and the JMPR ADI (scenario 2)	**Specific comments:** JMPR concluded that the estimated acute dietary exposure to residues of bifenthrin for the consumption of strawberries may present a public health concern.
Results: The calculated short-term exposure exceeded the ARfD in both scenarios. Scenario 1, considering ARfD derived by (EFSA, 2008b, 2011f): Short-term exposure concern was identified (max 125% ARfD for strawberries). Scenario 2: considering ARfD derived by JMPR (2009): Short-term exposure concern was identified (max 376% ARfD for strawberries)	**Results: No long-term consumer health risk was identified.** Scenario 1, considering ADI derived by (EFSA, 2008b, 2011f): The overall chronic exposure (refined mode) accounted for 43% of the ADI. Strawberries contribution accounting for up to 1.5% of the ADI. Scenario 2, considering ADI derived by (JMPR, 2009): The overall chronic exposure (refined mode) accounted for 64% of the ADI.	**Results:** Long-term exposure: Max 10–40% of the JMPR ADI. Short-term exposure: Highest result for children: 380% of ARfD

5.11. Clethodim (187) R/T

5.11.1. Background information

Table 48: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Periodic review	
RMS	SE	
Approval status	Approved	Commission Implementing Regulation (EU) 2018/1266[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2011m)

		Comments, references
MRL review performed	Yes, see comments	(EFSA, 2019e)
MRL applications/ assessments	No	
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2018/1266 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide. OJ L 238, 21.9.2018, p. 81–83.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.11.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.2 mg/kg bw per day	JMPR (2019) (2-year rat, with safety factor 100)	0.16 mg/kg bw per day	(EFSA, 2011m) (2-year rat, with uncertainty factor 100)	Yes
ARfD	Unnecessary	JMPR (2019)	Not necessary, not allocated	(EFSA, 2011m)	Yes
Conclusion/ comment	In both assessments (JMPR and EFSA), the same NOAEL of 16 mg/kg bw per day was derived for the 2-year rat study and rounded to 0.2 by JMPR for the setting of the ADI. JMPR concluded that the ADI for clethodim applies also to clethodim sulfoxide (free and conjugated), 5-hydroxy sulfone, clethodim imine sulfoxide, clethodim imine sulfone, M15R, M17R, M18R and S-methyl sulfoxide, expressed as clethodim. For these metabolites the setting of an ARfD was not considered necessary. JMPR, however, was unable to conclude on the toxicological relevance of metabolites clethodim sulfone, clethodim oxazole sulfoxide, clethodim oxazole sulfone, M19R and M15A. In the EU evaluation (EFSA, 2011m), it was concluded that the metabolites clethodim imine sulfone, clethodim 5-OH sulfone, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone, M17R, M18R and M15R were covered by the TRV of clethodim. In the framework of the MRL review, EFSA concluded that the genotoxic potential of the clethodim metabolite 3-chloroallyl alcohol, the aglycon of 3-chlorolallyl alcohol glucoside (M14A/ M15A) could not be concluded and no toxicological reference values could be derived for this metabolite. Until a conclusion on the toxicological properties of the metabolite is reached, a decision on the residue definition for risk assessment cannot be made which is a prerequisite to perform a reliable dietary risk assessment.				

5.11.3. Residue definitions

Table 50: 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 clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl) propyl]-pentanedioate (DME) and dimethyl 3-[2-(ethylsulfonyl) propyl]-3-hydroxy-pentanedioate (DME-OH), expressed as clethodim	MRL review Art. 12 (EFSA, 2019e): For raw plant commodities: Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim For processed commodities: inconclusive (pending on submission of additional hydrolysis studies) Peer review (EFSA, 2011m): Root/tuber vegetable and Oilseeds/Pulses group: Sum of clethodim, clethodim sulfoxide and clethodim sulfone expressed as clethodim	No
	Animal products	Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl) propyl]-pentanedioate (DME), expressed as clethodim The residue is fat soluble	MRL review Art. 12 (EFSA, 2019e): Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim (tentative) Peer review (EFSA, 2011m): Not proposed and not required for sugar beet use, since residues in food of animal origin were assessed to be insignificant and MRLs were not proposed. The residue is not fat soluble	No
RD RA	Plant products	A conclusion could not be reached	MRL review Art. 12 (EFSA, 2019e): Residue definition for risk assessment one (tentative): Sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/M15R, M16R/M17R and M18R/M19R, expressed as clethodim is tentatively proposed Residue definition for risk assessment two (tentative): M14A/M15A For processed commodities: inconclusive Peer review (EFSA, 2011m): Root/tuber vegetables and Oilseeds/Pulses groups: Sum of clethodim, clethodim sulfone, clethodim sulfoxide and metabolites M15R, M17R and M18R expressed as clethodim	No
	Animal products	A conclusion could not be reached	MRL review Art. 12 (EFSA, 2019e): Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim (tentative) Peer review (EFSA, 2011m): Not proposed and not required for sugar beet use, since residues in food of animal origin were assessed to be insignificant and MRLs were not proposed.	No
Conclusion, comments	Since JMPR was unable to conclude on the toxicological relevance of metabolites clethodim sulfone (relevant for plant and animal commodities), M19R, M15A and clethodim oxazole sulfoxide (relevant for plant products), residue definition for dietary risk assessment could not be derived. JMPR used the TTC approach for genotoxicity for clethodim sulfone, M19R and M15A and the TTC approach for Cramer Class III for clethodim oxazole sulfoxide. However, the estimated chronic exposure exceeded the TTC for clethodim sulfone, M19R and M15A.			

5.11.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Alfalfa fodder	10 (W)	–	EU MRLs are not established for feed items.
Beans fodder	10 (W)	–	EU MRLs are not established for feed items.
Beans (dry)	2 (W)	2	JMPR withdrew the previous recommendation for dry beans of 2 mg/kg (EU GAP) because residue trials did not measure all analytes in the clethodim residue definition.
Beans, except broad bean and soyabean	0.5* (W)	0.5	JMPR withdrew the previous recommendation since no residue data were provided.
Cotton seed	0.5 (W)	0.5	JMPR withdrew the previous recommendation since no residue data were provided.
Cotton seed oil, crude	0.5* (W)	–	EU MRLs are not established for processed products.
Cotton seed oil, edible	0.5* (W)	–	EU MRLs are not established for processed products.
Edible offal (Mammalian)	0.2* (W)	0.2	The dietary burden, considering that the only potential feed item was apple wet pomace, was calculated to be 0 ppm. JMPR did not derive a recommendation to replace the previous CXL. It is noted that the MRL proposal for pome fruit (LOQ of 0.2 mg/kg) was not put in the recommendations, probably because of the open toxicological questions related to the residue definition for risk assessment.
Eggs	0.05* (W)	0.05*	See edible offal (mammalian)
Field pea (dry)	2 (W)	2	EU MRLs are not established for feed items.
Fodder beet	0.1* (W)	–	JMPR withdrew the previous recommendation since no residue data were provided.
Garlic	0.5 (W)	0.5	JMPR withdrew the previous recommendation; the data submitted in support of the cGAP (NL) since the trials did not match the GAP.
Meat (from mammals other than marine mammals)	0.2* (W)	0.2	See edible offal (mammalian)
Milks	0.05* (W)	0.05*	See edible offal (mammalian)
Onion, Bulb	0.5 (W)	0.5	JMPR withdrew the previous recommendation; the data submitted in support of the cGAP (NL) since the trials did not match the GAP.
Peanut	5 (W)	5	JMPR withdrew the previous recommendation since no residue data were provided.
Potato	0.5 (W)	0.5	JMPR withdrew the previous recommendation since no residue data were provided.
Poultry meat	0.2* (W)	0.2	See edible offal (mammalian)
Poultry, Edible offal of	0.2* (W)	0.2	See edible offal (mammalian)
Rape seed	0.5 (W)	1	JMPR withdrew the previous recommendation; the data submitted in support of the GAPs (cGAP SK; fall-back GAP UK) since the trials did not match the cGAP or were insufficient (4 trials for UK GAP).
Rape seed oil, Crude	0.5* (W)	–	EU MRLs are not established for processed products.
Rape seed oil, Edible	0.5* (W)	–	EU MRLs are not established for processed products.
Soyabean (dry)	10 (W)	10	JMPR withdrew the previous recommendation since no residue data were provided.
Soyabean oil, crude	1 (W)	–	EU MRLs are not established for processed products.
Soyabean oil, refined	0.5* (W)	–	EU MRLs are not established for processed products.
Sugar beet	0.1 (W)	0.5	JMPR withdrew the previous recommendation since no residue data were provided.

Commodity	Codex MRL proposal	EU MRL	Comment
Sunflower seed	0.5 (W)	0.5	JMPR withdrew the previous recommendation since no residue data were provided.
Sunflower seed oil, crude	0.1* (W)	–	EU MRLs are not established for processed products.
Tomato	1 (W)	1	JMPR withdrew the previous recommendation since no residue data were provided.
General comments	In the recently performed MRL review (Art. 12 of Regulation (EC) No 396/2005), EFSA did not derive MRL proposals, because no conclusion on the toxicological properties of the metabolite could be reached, and therefore, the residue definition for risk assessment cannot be derived which is a prerequisite to perform a reliable dietary risk assessment.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.11.5. Consumer risk assessment

Table 52: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was allocated.	**RA assumptions:** Not relevant, since no Codex MRLs were proposed. In the framework of the MRL review, EFSA did not perform a risk assessment, considering the outlined uncertainties.	**Specific comments:** Because JMPR was unable to conclude on the toxicological relevance of metabolites clethodim sulfone, clethodim oxazole sulfoxide, M19R and M15A, the meeting could not reach a conclusion on the residue definitions. As a result, the dietary risk assessment could not be concluded.
Until a conclusion on the toxicological properties of the metabolite is reached, a decision on the residue definition for risk assessment cannot be made which is a prerequisite to perform a reliable dietary risk assessment.		

5.12. Tebuconazole (189) R

5.12.1. Background information

Table 53: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	DK	
Approval status	Approved	Commission Directive 2008/125/EC[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2008a) (EFSA, 2014a) (amendment of the approval conditions) (EFSA, 2018p) (conclusion on TDMs) EFSA conclusion (under consideration)
MRL review performed	Yes, see comments	(EFSA, 2011k)
MRL applications/ assessments	Yes, see comments	(EFSA, 2018g) (olives, rice, herbs and herbal infusions (dried)) (EFSA, 2017f) (beans with pods) (EFSA, 2015v) (rye and wheat) (EFSA, 2015c) (cucumbers and courgettes) (EFSA, 2013h) (poppy seed) (EFSA, 2012h) (citrus except oranges, lettuce and other salad plants, parsley and chives)
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded	

(a): Commission Directive 2008/125/EC of 19 December 2008 amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances. OJ L 344, 20.12.2008, p. 78–88.

5.12.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.03 mg/kg bw per day	JMPR (2010) (1-year, dog, UF 100)	0.03 mg/kg bw per day	(EFSA, 2008a) (1-year dog supported by developmental mouse study, LOAEL with UF of 100 (dog) and 300 (mouse), confirmed in (European Commission, 2008b)	Yes
ARfD	0.3 mg/kg bw	JMPR (2010) (Maternal and developmental NOAEL in rat and rabbit's developmental toxicity studies, supported by a 28-day study in rats, UF 100)	0.03 mg/kg bw	(EFSA, 2008a) (Developmental mouse study, LOAEL with UF 300), confirmed in (European Commission, 2008b)	No
Conclusion/ comment	There was a different interpretation of the developmental toxicity study in mice between the JMPR and the EU assessments that resulted in the derivation of different ARfDs between the 2 assessments. The EU peer review considered that malformations and post implantation losses were relevant in mice at the LOAEL of 10 mg/kg bw per day (the lowest dose tested). At EU level, ADI and ARfD were also derived individually for the triazole derivative metabolites (TDMs) 1,2,4-triazole, triazole alanine and triazole acetic acid (EFSA, 2018q). New TRVs were recently derived for these common metabolites in the EFSA conclusion on TDMs (EFSA, 2018p). The approach to perform the consumer risk assessment to all triazole active substances is under discussion.				

5.12.3. Residue definitions

Table 55: 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 Peer review (EFSA, 2014a): Sum of enantiomers contained in tebuconazole (provisional)	Yes
	Animal products	Tebuconazole The residue is not fat soluble	Reg. 396/2005: Sum of tebuconazole, hydroxy-tebuconazole, and their conjugates, expressed as tebuconazole Peer review (EFSA, 2014a): Tebuconazole + hydroxy-tebuconazole and their conjugates (sum of enantiomers) expressed as tebuconazole (provisional) The residue is not fat soluble	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Tebuconazole	MRL review Art. 12 (EFSA, 2011k): Tebuconazole (provisional) Peer review (EFSA, 2014a): 1) Sum of enantiomers contained in tebuconazole 2) Specific TDM residue definitions applicable to all active substances of the triazole chemical class (TA, TLA, TAA, 1,2,4-T) (EFSA, 2018p)	Yes
	Animal products	Tebuconazole	MRL review Art. 12 (EFSA, 2011k): Sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole Peer review (EFSA, 2014a): 1) Tebuconazole + hydroxy-tebuconazole and their conjugates (sum of enantiomers) expressed as tebuconazole (provisional) 2) Specific TDM residue definitions applicable to all active substances of the triazole chemical class (TA, TLA, TAA, 1,2,4-T) (EFSA, 2018p)	No
Conclusion, comments	For plant commodities, the JMPR residue definition for enforcement is identical with the EU residue definition. For risk assessment, in addition to the parent compound, residue definitions for the triazole derivative metabolites (TDMs) were established in the EU (EFSA, 2018p). It is noted that for post-harvest uses in fruits, no metabolism studies are available (neither in the EU nor at Codex level). In the EU MRL review a study on grapes with foliar application was considered sufficiently representative for post-harvest uses in citrus because it was carried out with short PHIs and parent tebuconazole was the only compound identified. For animal commodities, the residue definitions derived by JMPR and at EU level differ, but since Codex MRLs are proposed only for plant products, the discrepancy is not relevant for the current assessment. Since the TDMs are relevant for risk assessment (and not for enforcement purposes) this should not have any impact on the MRLs derived for tebuconazole. In addition, TDMs are not expected to occur in citrus fruits following post-harvest treatment.			

5.12.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Oranges, Sweet, Sour, subgroup of (includes all commodities in this subgroup)	0.4 (Po)	0.9	cGAP: Spain, post-harvest, 100 g a.i./100 L (drench spray) Number of trials: 4 Sufficiently supported by data: Yes Orange is a major crop and 8 trials would be required. However, JMPR assumed that for post-harvest treatments, the variability of residue levels is expected to be less than in field trials and therefore 4 trials were considered sufficient. According to the EU guidance document on extrapolation (rev. 10.3) a reduced number

Commodity	Codex MRL proposal	EU MRL	Comment
			of trials for post-harvest treatment is acceptable. According to the report the trials were 'approximating' the cGAP; it should be verified that the trials were within the 25% deviation rule. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Mandarins (including Mandarin-like hybrids) Subgroup of (including all commodities in this subgroup)	0.7 (Po)	5 mandarins 5 tangelos (classified under grapefruits, see comments)	cGAP: Spain, post-harvest, 100 g a.i./100 L (drench spray) Number of trials: 4 Sufficiently supported by data: Yes. Mandarin is a major crop and 8 trials would be required. However, JMPR assumed that for post-harvest treatments, the variability of residue levels is expected to be less than in field trials and therefore 4 trials were considered sufficient. According to the EU guidance document on extrapolation (rev. 10.3) a reduced number of trials for post-harvest treatment is acceptable. According to the report the trials were 'approximating' the cGAP; it should be verified that the trials were within the 25% deviation rule. Specific comments/observations: this subgroup includes tangelo, which is classified in the EU under 'Grapefruits'. In the Codex food classification tangelos are mentioned twice: • in the subgroup of mandarins, 'Tangelo, small and medium sized cultivars, see Mandarins, FC 0003, Hybrids of Mandarins × Grapefruit or Mandarin × Shaddock'; • in the subgroup of grapefruits, 'Tangelo, large-sized cultivars, see Pummelo and Grapefruits, FC 0005, Citrus × tangelo J.W.Ingram&H.E.Moore'. The assignment to two groups may cause problems in implementing MRLs established for Subgroup Pummelo and Grapefruit, and Subgroup of mandarins. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Citrus pulp, Dry	3 (dw)	–	Specific comments/observations: A processing factor of 7.2 was derived based on 1 trial for dry pomace.
Orange oil, edible	10	–	Specific comments/observations: A processing factor of 24.5 was derived based on 1 trial for orange oil. In addition, two PF were derived for marmalade: < 0.22; 0.63.
General comments	–		

5.12.5. Consumer risk assessment

Table 57: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The Codex MRL proposals are lower than the existing EU MRLs. Therefore, an update of the previous EU exposure assessment is not necessary.	**RA assumptions:** The Codex MRL proposals are lower than the existing EU MRLs. Therefore, the previously performed EU risk assessments are still valid (EFSA, 2018g).	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
The previous risk assessment which is still valid was performed with the EU ARfD using EFSA PRIMo rev. 2.	The previous risk assessment which is still valid was performed with the EU ADI using EFSA PRIMo rev. 2.	
Results: No short-term consumer health risk was identified for the crops under assessment. Acute exposure for EU MRL: Oranges: 31% of the ARfD Mandarins: 59% of the ARfD	**Results:** No long-term consumer health risk was identified. Maximum exposure: 16.5% of the ADI	**Results:** Long-term exposure: Max 5% of the JMPR ADI. Short-term exposure: as the ARfD derived by JMPR is higher than the one derived by the EU, its covered by the European assessment.

5.13. Tolclofos-methyl (191) R/T

5.13.1. Background information

Table 58: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Periodic review	
RMS	SE	
Approval status	Approved	Commission Implementing Regulation (EU) 2019/1101[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2018b)
MRL review performed	Yes, see comments	(EFSA, 2014r)
MRL applications/ assessments	Yes, see comments	(EFSA, 2017c) (potatoes)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet.

(a): Commission Implementing Regulation (EU) 2019/1101 of 27 June 2019 renewing the approval of the active substance tolclofos-methyl 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 175, 28.6.2019, p. 20–24.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.13.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.07 mg/kg bw per day	JMPR (2019)	0.064 mg/kg bw per day	(EFSA, 2018b) (2-year mice study and 100 UF) confirmed in (European Commission, 2019b)	Yes
ARfD	Unnecessary	JMPR (2019)	0.14 mg/kg bw	(EFSA, 2018b) (9-month mice study and 100 UF) confirmed in (European Commission, 2019b)	No
Conclusion/ comment	The ADI set by JMPR and EU are comparable. The slightly different value can be attributed to rounding. The ADI derived by JMPR applies also to ph-CH_3, TMO-COOH, ph-COOH, TMO, TM-CH_2OH, DM-TM, DM-TM-CH_2OH and TMO-CH_2OH, expressed as tolclofos-methyl. JMPR considered the setting of an ARfD not necessary. At the EU level, the ARfD of 0.14 mg/kg bw based was set based on the NOAEL of 13.8 mg/kg bw per day for cholinesterase inhibition observed at 564 mg/kg bw per day on day 14 in the 9-month toxicity study in mice. An UF of 100 was applied. The experts acknowledged that dose spacing (ratio NOAEL/LOAEL of 40) in the study and the use of a 14-day data time point lead to a conservative approach. The ARfD provides a margin of exposure of 4,000 relative to the LOAEL for cholinesterase inhibition in mice and therefore the experts considered not necessary to increase the UF because of lack of developmental neurotoxicity in mice. JMPR additionally considered that the acute rat LD_{50} for mice is > 3,500 mg/kg bw suggesting that acute exposure would not elicit a decrease in cholinesterase activity. During the EU peer review, metabolites DM-TM, DM-TM-COOH, DM-TMO, DM-TM-CH2OH, TMO-COOH, TMO-CH2OH and ph-COOH were considered covered by the toxicological profile of the parent. In the EU peer review genotoxicity studies were available to EFSA. Regarding metabolite TM-CH2OH, the available information indicated that it is unlikely to be genotoxic; however, further data would be needed to conclude on general toxicity (data gap). The majority of experts considered that a similar conclusion as drawn on TM-CH2OH can also be drawn for metabolite ph-CH3 and its structurally similar compound ph-CH2OH (i.e. data gap for general toxicity). However, some experts considered that there was some uncertainty regarding evidence of bone marrow exposure in the in vivo micronucleus (MN) test on ph-CH3 and considered the lack of an in vitro MN test a data gap, in particular for aneugenicity since the available in vivo comet assay could cover clastogenicity too. Overall, the experts supported a data gap for an in vitro MN test to reduce uncertainties regarding aneugenicity of ph-CH3 (EFSA, 2018b).				

5.13.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Tolclofos-methyl	Reg. 396/2005: Tolclofos-methyl Peer review (EFSA, 2018b): Tolclofos-methyl (potato (tuber vegetables) and lettuce (leafy crops) MRL review Art. 12 (EFSA, 2014r): Tolclofos-methyl	Yes
	Animal products	Tolclofos-methyl The residue is fat soluble	Reg. 396/2005: Tolclofos-methyl Peer review (EFSA, 2018b): Tolclofos-methyl (provisional)	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			MRL review Art. 12 (EFSA, 2014r): Tolclofos-methyl. Due to limited identification of metabolites in the edible animal matrices, the MRL review Art. 12 was not able to derive a robust residue definition for enforcement in animal commodities. The residue is fat soluble	
RD RA	Plant products	Sum of tolclofos-methyl, 2,6-dichloro-4-methylphenol (ph-CH_3), incl. conjugates), O,O-dimethyl O-2,6-dichloro-4-(hydroxymethyl) phenylphosphorothioate (TM-CH_2OH, incl. conjugates), O-methyl O-hydrogen O-2,6-dichloro-4-(hydroxymethyl) phenylphosphorothioate (DM-TM-CH_2OH) and O-methyl O-hydrogen O-(2,6-dichloro-4-methylphenyl) phosphorothioate (DM-TM), expressed as tolclofos-methyl	Peer review (EFSA, 2018b): Root and tuber crops (potato) for tuber treatment: Tolclofos-methyl and DM-TM-CH_2OH expressed as tolclofos-methyl; Leafy crops (lettuce) for soil treatment (preliminary): • Tolclofos-methyl • TM-CH_2OH-conjugate • ph-CH3-conjugate The EU RDs are preliminary, pending on further information on the relative toxicity of TM-CH_2OH-conjugate and ph-CH_3-conjugate and/or occurrence in field trials. MRL review Art. 12 (EFSA, 2014r): Tentatively derived as sum of tolclofos-methyl, sugar conjugate of ph-CH_3 and sugar conjugate of TM-CH_2-OH, expressed as tolclofos-methyl, limited to the seed treatment on root vegetables and foliar and soil treatments on leafy vegetables.	No
	Animal products	Sum of tolclofos-methyl and 3,5-dichloro-4-hydroxybenzoic acid (ph-COOH), expressed as tolclofos-methyl	Peer review (EFSA, 2018b): Tolclofos-methyl and ph-COOH, expressed as tolclofos-methyl (provisional). MRL review Art. 12 (EFSA, 2014r): sum of tolclofos-methyl, sugar conjugate of ph-CH_3 and sugar conjugate of TM-CH_2-OH, expressed as tolclofos-methyl. Due to limited identification of metabolites in the edible animal matrices, the MRL review Art. 12 was not able to derive a robust residue definition for risk assessment in animal commodities.	Yes
Conclusion, comments	For plant products, the residue definition for monitoring according to the JMPR and EU evaluation for potato (tuber vegetables) and lettuce (leafy crops) are comparable. The residue definitions for risk assessment differ. The EU peer review concluded that metabolism in the crop groups was different. For root and tuber (potato), the residue definition includes tolclofos-methyl and metabolite DM-TM-CH_2OH expressed as tolclofos-methyl; the ratio between the parent and DM-TM-CH2OH was 1:4. For leafy crops (lettuce) and soil treatment, it includes tolclofos-methyl and the metabolites TM-CH_2OH-conjugate and metabolite ph-CH_3-conjugate, and is preliminary pending on toxicological information on the metabolites and/or field trials (data gap) (EFSA, 2018b).			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	The JMPR evaluation RD RA includes also the metabolite DM-TM, a processing degradate of tolclofos-methyl which occurred in a high temperature hydrolytic study (24–87% AR), and detected in heated potatoes and lettuce. For animal products, the JMPR and EU evaluation residue definition for monitoring and for risk assessment are comparable. However, the EU residue definitions for monitoring and for risk assessment are provisional. Finalisation of the EU residue definitions in animals is pending on the recalculation of the dietary burden once the decision on the residue definition for risk assessment for feed items is taken (full information was not available on the magnitude of metabolite residue DM-TM-CH_2OH in the feed item potato). An indicative dietary burden was calculated, based on tolclofos-methyl residues measured in residue trial, using an adjustment factor to take into account the metabolites not analysed. The trigger value for feeding studies for ruminant, swine and poultry was exceeded. The provisional residue definition for animal products (risk assessment) contains the parent compound and one metabolite which was found in milk, kidney, liver of goats and in liver kidney, muscle fat and skin of poultry.			

5.13.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Leafy greens except spinach, purslane and chard	0.7	2 (ft) Lettuces; 0.9 (ft) Lamb's lettuces/corn salads, Escaroles/ broad-leaved endives; 0.02* Chervil	cGAP: Italy, spray application on protected crop when transplanting, 1 × 2,000 g/ha, PHI 28 days Number of trials: Five trials in head lettuce. Sufficiently supported by data: Yes Specific comments/observations: According to the Codex principles, residue trials on head lettuce are suitable for extrapolation to the subgroup 013A of Leafy greens (VL 2050). According to the EU guidelines, lettuce and other salad plants are a major crop and at least eight trials would be required. The samples were analysed only for parent tolclofos-methyl. An adjustment factor of 2 derived from a metabolism study was used to derive the risk assessment values. In Regulation (EU) 2017/1016[(a)] confirmatory data were requested for crops classified in the EU lettuce group (i.e. toxicological data on the sugar conjugates of metabolites ph-CH_3 and TM-CH_2OH and on residue trials including analysis of the sugar conjugates of metabolites ph-CH_3 and TM-CH_2OH). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the missing toxicological data for pH-CH3 and TM-CH_2OH, the lack of information on the actual occurrence of the metabolites included in the RD for RA, taking into account that for most crops concerned the existing EU MRL is higher than the proposed Codex MRL and that the Codex MRL proposal was derived for an European GAP. Follow-up action: None
Potato	**0.3**	0.2	cGAP: Italy, potato seed tuber dressing before planting, 1 × 250 g/t Number of trials: 31 trials Sufficiently supported by data: Yes Specific comments/observations: The samples were analysed only for parent tolclofos-methyl. An adjustment factor of 6 derived from a metabolism study was used to derive the risk assessment values.

Commodity	Codex MRL proposal	EU MRL	Comment
			The estimated acute dietary exposure to residues of tolclofos-methyl exceeds the toxicological reference value (ARfD) (see below). **Conclusion:** The MRL proposal is not acceptable, due to acute intake concerns. It is recommended to review the EU MRL which may also lead to an exceedance taking into account the new acute toxicological reference value and new residue definition derived in the EU peer review. Follow-up action: None
Edible offal (Mammalian)	0.01*	0.01*	JMPR calculated the dietary burden for livestock on the basis of residues in feed crops under assessment and their by-products (potato cull and potato process waste (wet peel)), using an adjustment factor of 6.0 for total residues. The max estimated burden for cattle was calculated for EU beef cattle. Since no feeding study was available, the MRL proposal was derived from the metabolism study. **Conclusion:** The proposed Codex MRL may be considered acceptable despite some data gaps, since the proposed MRL is at the LOQ. Follow-up action: None
Eggs	0.01*	0.01*	JMPR calculated the dietary burden for livestock on the basis of residues in feed crops under assessment and their by-products (potato cull and potato process waste (wet peel)), using an adjustment factor of 6. The max estimated burden for poultry was calculated for EU layer. The JMPR used the hen metabolism study to estimate residue levels in animal commodities **Conclusion:** The proposed Codex MRL may be considered acceptable despite some data gaps, since the proposed MRL is at the LOQ. Follow-up action: None
Mammalian fats (except milk fats)	0.01*	0.01*	See edible offal (mammalian)
Meat (from mammals other than marine mammals)	0.01*	0.01*	See edible offal (mammalian)
Milks	0.01*	0.01*	See edible offal (mammalian)
Poultry fats	0.01*	0.01*	See eggs
Poultry meat	0.01*	0.01*	See eggs
Poultry, Edible offal of	0.01*	0.01*	See eggs
General comments	(ft): EFSA identified some information on residues trials, toxicological data on the sugar conjugates of metabolites ph-CH3 and TM-CH2OH and on residue trials including analysis of the sugar conjugates of metabolites ph-CH3 and TM-CH2OH as unavailable. The missing data should be submitted by 6 February 2018. In 2018 applicant requested extension of the deadline and gave argumentation to reconsider the residue definition for RA.		

*: Indicates that the MRL is proposed at the limit of quantification.

(a): Commission Regulation (EU) 2017/1016 of 14 June 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac in or on certain products. OJ L 159, 21.6.2017, p. 1–47.

5.13.5. Consumer risk assessment

Table 62: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The EU residue definitions for risk assessment for plant and animal origin commodities are tentative. The calculations are affected by additional, non-standard uncertainties, related to the data gap for the toxicological assessment of the metabolites TM-CH_2OH conjugate and ph-CH_3 conjugate (relevant to the consumer risk assessment of the CXL proposal for leafy greens), and the tentative consumer risk assessment considering only exposure to residues in potato using an estimation of the magnitude of the major metabolite DM-TM-CH_2OH (relevant to the consumer risk assessment of the CXL proposal for potatoes). The risk assessment was performed with the JMPR adjustment factors to derive the risk assessment values. The risk assessment was performed with the EU ARfD. The calculations are indicative, because toxicological data for ph-CH_3 and TM-CH_2OH and their conjugates is not available, and there is a lack of information on the actual occurrence of the metabolites included in the residue definition for risk assessment.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2017c) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The EU residue definitions for risk assessment for plant and animal origin commodities are tentative. The calculations are affected by additional, non-standard uncertainties, related to the data gap for the toxicological assessment of the metabolites TM-CH2OH conjugate and ph-CH3 conjugate (relevant to leafy greens) and the tentative consumer risk assessment considering only exposure to residues in potato using an estimation of the magnitude of the major metabolite DM-TM-CH2OH (relevant to potatoes. The risk assessment was performed with the JMPR adjustment factors to derive the risk assessment values. The risk assessment was performed with the EU ADI. The calculations are indicative, because toxicological data for ph-CH3 and TM-CH2OH and their conjugates is not available, and there is a lack of information on the actual occurrence of the metabolites included in the residue definition for risk assessment.	**Specific comments:** None.
Results: **The calculated short-term exposure exceeded the ARfD for one crop under assessment.** Potatoes: 138% of ARfD (UK infant) Escaroles/broad-leaved endives: 22.38% of ARfD Lettuces: 21.21% of ARfD Lamb's lettuce/corn salads: 1.57% of ARfD	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 3% of the ADI. Among the commodities under consideration, milk and potatoes were identified as the main contributors, accounting for up to 0.9% and 0.8% of the ADI, respectively.	**Results:** Long-term exposure: Max 1% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.14. Kresoxim-methyl (199) R

5.14.1. Background information

Table 63: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Periodic review	
RMS	SE	
Approval status	Approved	Commission Implementing Regulation (EU) No 810/2011[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2010k)
MRL review performed	Yes, see comments	(EFSA, 2014b)
MRL applications/ assessments	Yes, see comments	(EFSA, 2018z) (confirmatory data) (EFSA, 2015o) (leeks) (EFSA, 2010n) (blueberries and cranberries)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	

(a): Commission Implementing Regulation (EU) No 810/2011 of 11 August 2011 approving the active substance kresoxim-methyl, 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 207, 12.8.2011, p. 7–11.

5.14.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.3 mg/kg bw per day	JMPR (2018)	0.4 mg/kg bw per day	(EFSA, 2010k) (2-year oral rat with an uncertainty factor of 100)	No
ARfD	Unnecessary	JMPR (2018)	Not allocated	Not necessary	Yes
Conclusion/ comment	2018 JMPR concluded that the ADI derived for parent kresoxim-methyl was applicable also for the metabolites BF-490-1 (490M1) and BF-490-9 (490M9) and their conjugates). As regards BF-490-2 (490M2) JMPR could not conclude that the ADI of parent compound is applicable. Hence the TTC concept was used for this metabolite. In the EU peer review, it was considered unlikely that metabolites BF 490-1 (490M1), BF 490-2 (490M2) and BF 490-9 (490M9) are more toxic than kresoxim-methyl, and therefore, the reference values of the parent were considered applicable.				

5.14.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Kresoxim-methyl	EU Reg. 2019/1015[(a)]: Kresoxim-methyl	Yes
	Animal products	Sum of metabolites (2*E*) (methoxyimino){2-[(2methylphenoxy)methyl]	EU Reg. 2020/856[(b)]: Kresoxim-methyl (BF-490-9 (490M9), expressed as	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		phenyl} acetic acid (490M1), and (2*E*)-{2[(4-hydroxy-2-methylphenoxy) methyl] phenyl}(methoxyimino) acetic acid (490M9) expressed as kresoxim-methyl. The residue is not fat soluble	parent) (applies to all animal products except honey) The residue is not fat soluble	
RD RA	Plant products	Sum of kresoxim-methyl and metabolites (2*E*)-(methoxyimino){2[(2-methylphenoxy)methyl] phenyl} acetic acid (490M1) and (2*E*)-{2[(4-hydroxy-2-methylphenoxy) methyl] phenyl}(methoxyimino) acetic acid (490M9) including their conjugates expressed as kresoxim-methyl.	Art.12 (EFSA, 2014b) and peer-review (EFSA, 2010k): Sum of kresoxim-methyl and the metabolites BF 490-2 (490M2) and BF 490-9 (490M9), free and conjugated, expressed as parent.	No
	Animal products	Sum of metabolites (2*E*) (methoxyimino){2-[(2methylphenoxy)methyl] phenyl} acetic acid 490M1), and (2*E*)-{2[(4-hydroxy-2-methylphenoxy) methyl] phenyl}(methoxyimino) acetic acid (490M9) expressed as kresoxim-methyl.	Art.12 (EFSA, 2014b) and peer-review (EFSA, 2010k): Ruminant matrices and milk: Sum of metabolites BF 490-1 (490M1), BF 490-2 (490M2) and BF 490-9 (490M9), expressed as parent. No residue definition is proposed for poultry matrices.	No
Conclusion, comments	The EU and JMPR residue definitions are comparable only for the enforcement of plant products. For risk assessment in plants, JMPR included 490M1, but not metabolite 490M2. The inclusion of 490M2 and 490M9 in the EU RD was supported by the residue trials on grapes where they were observed at similar levels to the parent. While 490M1 is considered as an intermediate in the metabolic pathway, that is hydroxylated to form metabolites 490M2 and 490M9. The 2018 JMPR also noted that if future uses of kresoxim-methyl result in an increase of the dietary exposure to metabolite 490M2 (BF 490-2), to more than the threshold of toxicological concern (TTC) for a Cramer Class III compound, a reconsideration of the residue definition for dietary exposure may be necessary. For animal products, the current EU RD both for enforcement and risk assessment differ from the ones proposed by JMPR. The EU residue definition for enforcement is restricted to the most relevant metabolite for the respective matrices, while JMPR established a comprehensive residue definition that covers all metabolites observed in animal products. For risk assessment, as in plants, 490M2 (BF 490-2) is included in the EU RD since it is a major compound in metabolism studies.			

(a): Commission Regulation (EU) 2019/1015 of 20 June 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole in or on certain products. OJ L 165, 21.6.2019, p. 23–64.

(b): Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products. OJ L 195, 19.6.2020, p. 9–51.

5.14.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Pome fruit	0.2 (W)	0.2	JMPR proposes to withdraw the MRL for pome fruit and replace it with an MRL of 0.15 mg/kg for the whole pome fruit group, except Japanese persimmon. See below.
Pome fruit (except Persimmon, Japanese)	0.15	0.2 (pome fruits: apples, pears, quinces and medlars) 0.9 (azaroles)	cGAP: 4 foliar treatments × 0.22 kg a.s./ha, 7 days minimum interval, PHI 30 days. Number of trials: 17 trials compliant with GAP on apples and 8 trials compliant with GAP on pears. Sufficiently supported by data: Yes Specific comments/observations: According to Codex food classification, pome fruit include also medlars, azaroles. The existing EU MRL of 0.2 mg/kg was derived from the CXL, which is now proposed to be withdrawn and replaced by a lower CXL of 0.15 mg/kg, which corresponds to the MRL needed to cover the EU uses for pome fruits (apples, pears, quinces, medlar, loquat). **Conclusion:** The proposed Codex MRL is acceptable.It should be discussed with MS whether the existing EU MRL for pome fruit should be lowered. Follow-up action: None
General comments	–		

5.14.5. Consumer risk assessment

Table 67: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was allocated.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2018z) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The risk assessment was performed with the EU ADI. The calculations are indicative, because for the Codex MRLs, the STMRs do not cover metabolite 490M2 (instead, 490M1 is covered, but not included in the EU RD).	**Specific comments:** In 2018, JMPR noted that the recommendation for the residue definition for dietary exposure may be necessary, if for future uses the exposure to metabolite BF 490-2 (490M2) would exceed the TTC for Cramer Class III compounds.
Results: **Not relevant**	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 1% of the ADI. Among the crops under consideration, apple was identified as the main contributor, accounting for up to 0.3% of the ADI.	Results: Long-term exposure: Max 0.4% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). JMPR also updated the exposure calculation for BF-490—2 (490M2) (0.30 μg/kg bw per day) which was found to be below the TTC of 1.5 μg/kg bw per day.

5.15. Pyriproxyfen (200) R

5.15.1. Background information

Table 68: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	The use on mango and banana have been assessed previously by 2018 JMPR, but the trials were insufficient to derive an MRL proposal
RMS	NL	
Approval status	Approved	Commission Directive 2008/69/EC[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2019g)
MRL review performed	No	
MRL applications/ assessments	Yes, see comments	(EFSA, 2016b) (bananas) (EFSA, 2013q) (stone fruits and tea)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	No	Negative: following ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]).

(a): Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances, OJ L 172, 2.7.2008, p. 9–14.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.15.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.1 mg/kg bw per day	JMPR (1999) (1-year dog study, safety factor 100)	0.1 mg/kg bw per day	Commission Directive 2008/69/EC[(a)]	No
			0.05 mg/kg bw per day	(EFSA, 2019g) (78-week mouse study and 300 UF for using an LOAEL instead of an NOAEL) confirmed in (European Commission, 2020)	
ARfD	Unnecessary	JMPR (1999)	Not necessary	Commission Directive 2008/69/EC[(a)]	No
			1 mg/kg bw	(EFSA, 2019g) (rabbit study and 100 UF) confirmed in (European Commission, 2020)	
Conclusion/ comment	During the EU assessment for renewal (EFSA, 2019g), the revised assessment of the 78-week mouse study led to an LOAEL of 16.4 mg/kg bw per day and an agreed ADI of 0.05 mg/kg bw per day by using a total uncertainty factor of 300. Additionally, a revised assessment of the rabbit developmental toxicity study identified the occurrence of malformations leading to an ARfD of 1 mg/kg bw.				

(a): Commission Regulation (EU) 2017/1016 of 14 June 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac in or on certain products. OJ L 159, 21.6.2017, p. 1–47.

5.15.3. Residue definitions

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Pyriproxyfen	Reg. 396/2005: Pyriproxyfen Peer review (EFSA, 2019g): Pyriproxyfen (only for fruit and pulses/ oilseeds)	Yes
	Animal products	Pyriproxyfen The residue is fat soluble	Reg. 396/2005: Pyriproxyfen Peer review (EFSA, 2019g): Pyriproxyfen The residue is fat soluble	Yes
RD RA	Plant products	Pyriproxyfen	Peer review (EFSA, 2019g): Pyriproxyfen (only for fruit and pulses/oilseeds)	Yes
	Animal products	Pyriproxyfen	Peer review (EFSA, 2019g): Pyriproxyfen	Yes
Conclusion, comments	The residue definition proposed by JMPR for enforcement and risk assessment are identical with the EU residue definitions.			

5.15.4. Codex MRL proposals

Table 70: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Mango	0.02*	0.05*	cGAP: Malaysia, 2 $\times$ 5g a.i/hL, 14 days interval, PHI 14 days Number of trials: 6 (< 0.02*) Sufficiently supported by data: Yes Specific comments/observations: In 2018 JMPR assessed a different GAP (2 $\times$ 5 g a.i./ha, 14 days interval, PHI 1 day), which was not sufficiently supported by trials (6 trials were submitted with a PHI of 14 days instead of 1 day). This year JMPR assessed a different GAP. However, it seems that the GAP was wrongly reported (it is expected that the application rate is expressed as g a.i./ha, instead of hL). **Conclusion:** The proposed Codex MRL is acceptable; however, the existing EU MRLs is higher Follow-up action: To check in JMPR evaluation the GAP reported to JMPR (application rate expressed as ha or hL) and whether the residue trials actually match the GAP.
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.15.5. Consumer risk assessment

Table 71: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Although the Codex MRL proposal is lower than the existing EU MRL, an acute exposure was estimated using the HR of the residue trials submitted in support of the Codex MRL request. The previous risk assessment was performed with the recently derived ARfD (EFSA, 2019g).	**RA assumptions:** Since the Codex MRL proposal is lower than the existing EU MRLs, the previously performed EU risk assessments input values derived in 2016 (EFSA, 2016b) and updated for melons and papaya (CXLs have been taken over in the EU legislation) are still valid. The risk assessment was performed with the recently derived ADI (EFSA, 2019g).	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for the crops under assessment. Acute exposure for EU MRL for mango is 0.2% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 22% of the ADI.	**Results:** Long-term exposure: Max 1% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.16. Cyprodinil (207) R/T

5.16.1. Background information

Table 72: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approved	Commission Directive No 2006/64/CE[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2006a) EFSA conclusions (Additional data request)
MRL review performed	Yes, see comments	(EFSA, 2013n)
MRL applications/ assessments	Yes, see comments	(EFSA, 2021e) (blueberries, gooseberries, currants and cranberries) (EFSA, 2019j) (rhubarb) (EFSA, 2019c) (Florence fennel) (EFSA, 2015g) (celery)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not finalised: following ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]), additional data were requested.

(a): Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, p. 107–111.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.16.2. Toxicological reference values

Table 73: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0–0.03 mg/kg bw per day	JMPR (2003)	0.03 mg/kg bw per day	(EFSA, 2006a) (2-year rat study and UF 100) confirmed in (European Commission, 2006c)	Yes
ARfD	Not necessary	JMPR (2003)	Not necessary	(EFSA, 2006a) confirmed in (European Commission, 2006c)	Yes
Conclusion/ comment	The TRV values derived by JMPR and at EU level are identical. In the framework of the renewal of the approval for cyprodinil, the setting of an ARfD is under discussion.				

5.16.3. Residue definitions

Table 74: 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	Reg. 396/2005: Cyprodinil	Yes
	Animal products	Cyprodinil The residue is fat soluble	Reg. 396/2005: Animal products (except milk and honey): Cyprodinil (sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil) Milk: Cyprodinil (sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil). Honey: Cyprodinil The residue is fat soluble	No
RD RA	Plant products	Cyprodinil	MRL review Art. 12 (EFSA, 2013n): Cyprodinil	Yes
	Animal products	Cyprodinil The residue is fat soluble	MRL review Art. 12 (EFSA, 2013n): Animal products (except milk and honey): Cyprodinil (sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil) Milk: Cyprodinil (sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil). Honey: Cyprodinil The residue is fat soluble	No
Conclusion, comments	The different residue definitions for animal products is of no relevance for the current assessment, as the only Codex MRL proposal under assessment refers to soybeans.			

5.16.4. Codex MRL proposals

Table 75: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Soyabean (dry)	**0.3**	0.02*	cGAP: Brazil, 2 × 1.05 kg a.i./ha, appl. interval 7 days and a PHI 30 days Number of trials: 4 GAP compliant trials and 8 trials which were performed at a lower dose rate. 6 of these trials with residues > LOQ were scaled up. Sufficiently supported by data: Yes Specific comments/observations: Soyabean is a major crop and therefore 8 residue trials are required. JMPR scaled residue trials which differed not only in the application rate but also with regard to the interval between the application (14 days instead of 7 days), since the interval did not appear to have a significant impact on the final residues. Details to check the possible impact of the longer RTI of the residue trials on the final residues are not reported in JMPR Evaluation report. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.16.5. Consumer risk assessment

Table 76: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since currently no ARfD was allocated.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2021e) were updated, including the STMR value derived by JMPR for soybeans. The risk assessment was performed with the EU ADI. The calculations are indicative, because there is no sufficient number of residue trials to support the critical GAP for cyprodinil in soyabean.	**Specific comments:** Only long-term dietary exposure assessment was performed.
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 56% of the ADI. The contribution of soybeans to the total intake accounted for up to 1% of the ADI.	**Results:** Long-term exposure: Max 70% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.17. Pyraclostrobin (210) R/T

5.17.1. Background information

Table 77: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Follow-up evaluation due to concern form	Section 3.8 of JMPR report, the EU noted an error in a residue trial in spinaches and commented on the approach taken to set a group MRL for root and tuber vegetables.
RMS	DE	
Approval status	Approved	Commission Implementing Regulation (EU) 2018/1796[(a)]
EFSA conclusion available	No	Peer-review ongoing
MRL review performed	Yes, see comments	(EFSA, 2011l)
MRL applications/ assessments	Yes, see comments	(EFSA, 2019l) (sweet corn) (EFSA, 2018aa) (confirmatory data following Art.12) (EFSA, 2018y) (soyabean) (EFSA, 2018ac) (various crops and import tolerances) (EFSA, 2018ab) (rice) (EFSA, 2017b) (various crops) (EFSA, 2016o) (beet leaves) (EFSA, 2014o) (swedes and turnips) (EFSA, 2014e) (chicory roots) (EFSA, 2013a) (Jerusalem artichokes) (EFSA, 2012b) (leafy brassica and various cereals) (EFSA, 2011c) (various crops)
Classification of a.s. – cut-off criteria	Not assessed/not concluded	
Endocrine effects of a.s.	Not assessed/not concluded	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) is ongoing; further data were requested to conclude on ED properties on non-target organisms (clock-stop).

(a): Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron. C/2018/7577. OJ L 294, 21.11.2018, p. 15–17.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.17.2. Toxicological reference values

Table 78: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.03 mg/kg bw per day	JMPR (2003)	0.03 mg/kg bw per day	(European Commission, 2004) (2-year rat study, uncertainty factor of 100)	Yes
ARfD	0.7 mg/kg bw	JMPR (2018)	0.03 mg/kg bw	(European Commission, 2004) (Rabbit developmental study, with an uncertainty factor of 100)	No
Conclusion/ comment	The EU ARfD of 0.03 mg/kg was recently confirmed at the EFSA Pesticide peer review meeting (28 January 2020). The RMS provided detailed comments outlining the reason for the divergent ARfD derived by JMPR and at EU level and noted that the approach taken by JMPR to derive the ARfD using a reduced uncertainty factor was not consistent with JMPR assessments for other substances. It is noted that he previous JMPR ARfD of 0.05 mg/kg bw (JMPR, 2003), that was based on embryo and fetal toxicity in a developmental toxicity study in rabbits (SF 100), has been withdrawn in 2018. Based on additional studies, the meeting concluded that the effects secondary to local irritation following gavage dosing in rabbits were not relevant to human dietary risk assessment. Therefore, the meeting established a new ARfD of 0.7 mg/kg bw based on vomiting and diarrhoea seen during the first week of dosing of dogs (90-day and 1-year studies), and applying a safety factor of 8 since the critical effects are considered to be secondary to a direct local effect on the gastrointestinal tract, which is independent of absorption and metabolism.				

5.17.3. Residue definitions

Table 79: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation**	**EU evaluation**	**RDs comparable**
RD enf	Plant products	Pyraclostrobin	Reg. 396/2005: Pyraclostrobin	Yes
	Animal products	Pyraclostrobin The residue is fat soluble	Reg. 396/2005: Pyraclostrobin The residue is fat soluble	Yes
RD RA	Plant products	Pyraclostrobin	MRL review Art. 12 (EFSA, 2011l): Pyraclostrobin	Yes
	Animal products	Pyraclostrobin	MRL review Art. 12 (EFSA, 2011l): Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole	No
Conclusion, comments	For plants, JMPR and EU residue definitions are similar (both enforcement and risk assessment). For animal only the residue definition for enforcement is identical, while the RA residue definition in EU is wider compared with JMPR. However, since no MRL proposals are under discussion for animal products, this difference is of no relevance. The process of renewal of the EU approval is ongoing; therefore, the EU residue definitions may be revised in the near future.			

5.17.4. Codex MRL proposals

Table 80: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Root vegetables, Subgroup of	**0.5 (W)**		The existing CXL is proposed to be withdrawn and replaced by the group MRL for root vegetables group. See below.
Root vegetables, Subgroup of (includes all commodities in the subgroup except sugar beet)	**0.5**	0.5 (Carrots, celeriacs/turnip-rooted celeries and radishes); 0.09 (Swedes and turnips); 0.1 (salsifies and parsley roots, beet roots); 0.3 (Horseradishes, ginger and parsnips); 0.08 Chicory roots	cGAP: USA, 3 $\times$ 0.234 kg/ha, RTI 8 days, PHI 0 days Number of trials: 6 carrots (major crops), 5 radishes (minor crops). Sufficiently supported by data: Yes Specific comments/observations: The number of the trials is sufficient. Although, according to the extrapolation rules of Codex, trials on carrots, radishes and sugar beet or beetroot are required to derive a group MRL for root vegetables, the database is deemed sufficient to derive a group MRL for root vegetables, except sugar beet. Risk managers to discuss whether the interpretation of the extrapolation rules is acceptable. According to EU extrapolation guidance, 8 residue trials in carrots would be required to set an MRL for root and tuber vegetables (except sugar beets). However, extrapolation to chicory roots is not explicitly mentioned in the EU extrapolation guidance. **Conclusion:** It is recommended to discuss with MS whether the interpretation of the Codex extrapolation is acceptable. If so, the proposed Codex MRL would be acceptable. Follow-up action: None
Spinach	0.6	0.6	cGAP: EU (Italy and Germany), 2 $\times$ 0.1 kg/ha, PHI 14 days, RTI 7 days (IT) and 8 days (DE) Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: The trials were conducted in France, Germany and Italy. JMPR combined NEU and SEU trials to support the MRL proposal. Last year the EU commented that the results for one residue trial was probably incorrect. JMPR reviewed the data, since the wrong result was expected to impact the MRL calculation and the HR. JMPR identified a typo and corrected the HR (0.31 mg/kg) and revised the MRL proposal. The existing EU MRL is derived from NEU residue data set. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
General comments	–		

5.17.5. Consumer risk assessment

Table 81: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal/HR is higher than the existing EU MRL. The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2019l) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The risk assessment was performed with the EU ADI.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Beetroots: 57% of ARfD Swedes: 52% of ARfD Carrots: 51% of ARfD Spinaches: 45% of ARfD Parsnips: 36% of ARfD Turnips: 36% of ARfD Salsifies: 31% of ARfD Parsley roots: 4.5% of ARfD Horseradishes: 0.4% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 18% of the ADI. Among the crops under consideration, swedes and turnips were identified as the main contributors, accounting for up to 0.4% of the ADI.	**Results:** Long-term exposure: Max 7% of the JMPR ADI (JMPR, 2018). Short-term exposure: Highest result for turnip, swedes: 1% of ARfD

5.18. Boscalid (221) R/T

5.18.1. Background information

Table 82: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	SK	
Approval status	Approved	Commission Implementing Regulation (EU) 2018/917[(a)]
EFSA conclusion available	No	In progress
MRL review performed	Yes, see comments	(EFSA, 2014l)
MRL applications/ assessments	Yes, see comments	(EFSA, 2020o) (pomegranates) (EFSA, 2019o) (honey and other agriculture products) (EFSA, 2015f) (beans and peas with pods) (EFSA, 2010j) (various crops) (EFSA, 2009d) (gherkins and courgettes)
Classification of a.s. – cut-off criteria	Not assessed/not concluded	No harmonised classification
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2018/917 of 27 June 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, Gliocladium catenulatum strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine and s-metolachlor. OJ L 163, 28.6.2018, p. 13–16.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.18.2. Toxicological reference values

Table 83: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.4 mg/kg bw per day	JMPR (2006, 2019)	0.04 mg/kg bw per day	EFSA, in progress, (European Commission, 2008a) (rat, 2-year oral feed, 100 UF)	Yes
ARfD	Unnecessary	JMPR (2006, 2019)	Not applicable	EFSA, in progress, (European Commission, 2008a) (dog, 1-year feed, 100 UF)	Yes
Conclusion/ comment	The Reference Values set by JMPR and EC are the same. It is noted that the EFSA Peer Review is ongoing and setting of References Values might change. No information on the toxicological profile of the metabolites is available in (European Commission, 2008a). In JMPR, 2019 M510F47 metabolite was assessed by TTC and categorised in Cramer class III, therefore a TTC of 1.5 μg/kg bw per day applies. For M510F49, the meeting was unable to conclude that this metabolite was of no concern but concluded that M510F49 would be covered by the ADI of the parent compound. Under the currently ongoing peer review, the toxicological profile of the metabolites is under discussion.				

5.18.3. Residue definitions

Table 84: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Boscalid	Reg. 396/2005: Boscalid	Yes
	Animal products	Boscalid The residue is fat soluble	Reg. 396/2005: Sum of boscalid and M 510F01, including its conjugates expressed as boscalid The residue is fat soluble	No
RD RA	Plant products	Boscalid	MRL review (EFSA, 2014l): Boscalid	Yes
	Animal products	Sum of boscalid, 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide (M 510F01) including its conjugate, expressed as boscalid.	MRL review (EFSA, 2014l): Muscle, fat: boscalid Kidney: Sum of boscalid and M 510F01 (2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl)nicotinamide) (free and conjugated), expressed as boscalid Liver: Sum of boscalid and M 510F01 (2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl)nicotinamide) (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid.	No for muscle, fat and liver
Conclusion, comments	The different residue definitions for animal products are not of relevance for the current assessment, since no MRL proposals for animal products were derived by JMPR.			

5.18.4. Codex MRL proposals

Table 85: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Apple	Withdrawn	2	See below (pome fruits (subgroup))
Cherries (subgroup)	**5**	4	cGAP: USA, Canada, 5 × 260 g a.s./ha, 7 days spray interval, PHI 0 days Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Mango	**2**	0.01*	cGAP: Brazil, 2 × 240 g a.i./hL, 14 days interval, PHI 7 days (foliar spray). Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: In some trials the stone was removed already in the field and the 'whole fruit' residue values were calculated/estimated at the time of the analysis. JMPR considered that this procedure would not have an impact since boscalid is stable under freezing storage (metabolism study) and hydrolysis conditions. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Peaches (subgroup)	4	Peaches: 5 Apricots: 5	cGAP: USA, Canada, 5 × 260 g a.s./ha, 7 days spray interval, PHI 0 days Number of trials: 19 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Plums (subgroup)	1.5	3	cGAP: USA, Canada, 5 × 260 g a.s./ha, 7 days spray interval, PHI 0 days Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Pome fruits (subgroup)	**2**	Apples: 2; pears and quinces: 1.5; medlars, loquats: 0.01* Azaraoles: 15 Kaki/Japanese. persimmon: 0.01*	cGAP: CZ: 3 × 200 g a.s./ha, 8 days spray interval, PHI 7 days Number of trials: 22 trials on apples, 8 trials on pears Sufficiently supported by data: Yes Specific comments/observations: EU pome fruit subgroup does not contain azaraoles and kaki/Japanese persimmon. It is noted that using the OECD MRL calculator a lower MRL of 1.5 mg/kg is derived. **Conclusion:** The proposed Codex MRL is not acceptable because a lower MRL of 1.5 mg/kg would be sufficient. Follow-up action: None
Prunes (dry)	5	–	Specific comments: processed commodity, no EU MRL.
Tea	**40**	0.01*	cGAP: Japan, 2 × 270 g a.i./ha, PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The trials were on dried green tea. JMPR proposed the MRL for tea (green, black fermented and dried) which is in line with current JMPR practice.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is acceptable. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.18.5. Consumer risk assessment

Table 86: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was allocated.	**RA assumptions:** The input values of the most recent long-term risk assessment (EFSA, 2020o) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL/STMR is higher than the corresponding EU value (i.e. mango, cherries, medlar, loquat, other pome fruits, kaki/Jap. persimmon and tea). The risk assessment was performed with the EU ADI.	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 75% of the ADI (NL toddler). Among the crops under consideration, tea was identified as the main contributor, accounting for up to 2.2% of the ADI.	**Results:** Long-term exposure: Max 62.3% G09 diet of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.19. Azoxystrobin (229) R

5.19.1. Background information

Table 87: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) 2019/291[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2010e)
MRL review performed	Yes, see comments	(EFSA, 2013r)
MRL applications/ assessments	Yes, see comments	(EFSA, 2021b) (sugar beet roots) (EFSA, 2020m) (confirmatory data and modification of the existing MRLs) (EFSA, 2016d) (grapes) (EFSA, 2016j) (various crops) Ongoing: Import tolerance request for mango and oil palm fruits Ongoing (additional data requested): modification of the existing MRLs in oilseed rape and linseed
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet.

(a): Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine. OJ L 48, 20.2.2019, p. 17–1.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.19.2. Toxicological reference values

Table 88: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
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, 2010e) (2-year rat, safety factor 100) confirmed in (European Commission, 2011b)	Yes
ARfD	Unnecessary	JMPR (2008)	Not necessary	(EFSA, 2010e) confirmed in (European Commission, 2011b)	Yes
Conclusion/ comment	–				

5.19.3. Residue definitions

Table 89: 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	Reg. 396/2005: Azoxystrobin	Yes
	Animal products	Azoxystrobin The residue is fat soluble	Reg. 396/2005: Azoxystrobin The residue is not fat soluble	Yes
RD RA	Plant products	Azoxystrobin	(EFSA, 2013r): Azoxystrobin	Yes
	Animal products	Azoxystrobin	(EFSA, 2013r): Azoxystrobin	Yes
Conclusion, comments	The data gap on general toxicity of the livestock metabolites L1, L4 an L9 identified in the framework of the MRL review has not yet been addressed adequately (EFSA, 2020m). Further risk management discussion and conclusion on the impact of the data gap are still pending. Since the metabolites were found only in liver and kidney of ruminants, the exposure related to the occurrence of metabolites L1, L4 and L9 was low.			

5.19.4. Codex MRL proposals

Table 90: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Guava	**0.2**	0.01*	cGAP: Egypt, 3 × 0.01 kg a.i./hL, with a 7–14 days application interval and a PHI of 7 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: According to JMPR classification, 4 trials would be required (minor crop). In the EU, it is considered a minor crop.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is acceptable. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.19.5. Consumer risk assessment

Table 91: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was allocated.	**RA assumptions:** A long-term dietary risk assessment was performed in the framework of the most recent long-term assessment of (EFSA, 2021b) was updated, including the STMR values derived by JMPR for the guava. The risk assessment was performed with the EU ADI (same as JMPR ADI).	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 22% of the ADI (NL toddler). The contribution of guava is negligible.	**Results:** The JMPR ADI is the same as the EU ADI. The chronic exposure calculated by JMPR for existing CXLs and the proposed Codex MRL ranged from 2% to 20%. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.20. Chlorantraniliprole (230) R

5.20.1. Background information

Table 92: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	IE	
Approval status	Approved	Commission Implementing Regulation (EU) No 1199/2013[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013c)
MRL review performed	Yes, see comments	(EFSA, 2020n)
MRL applications/ assessments	Yes, see comments	(EFSA, 2020t) (strawberries, pulses) (EFSA, 2019n) (oil palms fruits and oil palms kernels) (EFSA, 2018n) (hops and dried cones) (EFSA, 2015p) (various crops)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet.

(a): Commission Implementing Regulation (EU) No 1199/2013 of 25 November 2013 approving the active substance chlorantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 315, 26.11.2013, p. 69–73.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.20.2. Toxicological reference values

Table 93: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–2 mg/kg bw per day	JMPR (2008) (mouse, 18-month study; UF 100)	1.56 mg/kg bw per day	(EFSA, 2013c) (Rat, 2-year study, supported by the mouse, 18-month study and 100 UF) confirmed in (European Commission, 2018a)	No
ARfD	Not applicable	JMPR (2008) (unnecessary)	Not applicable	(EFSA, 2013c) (study not required) confirmed in (European Commission, 2018a)	Yes
Conclusion/ comment	The interpretation of the 2-year study in rats differed between the JMPR and the EU risk assessments, in particular regarding the interpretation of the liver and thyroid findings in this study. According to the EU assessment, the NOAEL for the 2-year study in rats is 156 mg/kg bw per day for increased liver weight and thyroid adenomas in females. The same conclusion is, however, reached between the two assessments for the 18-month study in mice (with an NOAEL of 158 mg/kg bw per day for liver eosinophilic foci, hepatocellular hypertrophy and increased liver weight in mice) leading to a similar point of departure between the two assessments to derive the ADI. The JMPR rounded the resulting ADI from 1.58 mg/kg bw per day to 2 mg/kg bw per day. The risk assessment will be performed according to the EU scenario. It was agreed during the peer review (EFSA, 2013c) that the toxicological reference values of chlorantraniliprole apply to the metabolites IN-HXH44 and IN-K9T00.				

5.20.3. Residue definitions

Table 94: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Chlorantraniliprole	Reg. 396/2005: Chlorantraniliprole (DPX E-2Y45) Peer review (EFSA, 2013c): Chlorantraniliprole	Yes
	Animal products	Chlorantraniliprole The residue is fat soluble	Reg. 396/2005: Chlorantraniliprole (DPX E-2Y45) Peer review (EFSA, 2013c): Chlorantraniliprole The residue is fat soluble	Yes
RD RA	Plant products	Chlorantraniliprole	Peer review (EFSA, 2013c): Chlorantraniliprole	Yes
	Animal products	Chlorantraniliprole	MRL review (EFSA, 2020n): Poultry tissues and eggs: chlorantraniliprole Other animal products: Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole Peer review (EFSA, 2013c): Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole	No
Conclusion, comments	The RA RDs for animals are not compatible. The metabolites IN-HXH44 and IN-K9T00 are included (highlighted in green) in the RA RD derived by EFSA, but not in the one derived by JMPR. Since no Codex MRLs are proposed for animal commodities this year, this difference has no impact on the assessment.			

5.20.4. Codex MRL proposals

Table 95: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Dry beans, Subgroup of (includes all commodities in this subgroup except soyabeans)	0.3	Pulses: 0.3	cGAP: USA, 2 × 0.11 kg a.i./ha, PHI 1 day (3 days Interval, max. seasonal rate 0.23 kg a.i./ha) Number of trials: 10, combined data set of dry beans (5) and dry peas (5) Sufficiently supported by data: Yes Specific comments/observations: Dry beans are major crop; since it is possible to combine dry beans and dry peas, 10 trials are available to support both uses. EU MRL for pulses was recently raised from 0.01* to 0.3 mg/kg, following an MRL application. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Dry peas, Subgroup of (includes all commodities in this subgroup)	0.3	Pulses: 0.3	cGAP: USA, 2 × 0.11 kg a.i./ha, PHI 1 day (3 days Interval, max. seasonal rate 0.23 kg a.i./ha) Number of trials: 10, combined data set of dry beans (5) and dry peas (5). Sufficiently supported by data: Yes Specific comments/observations: Dry peas are major crop; since it is possible to combine dry beans and dry peas, 10 trials are available to support both uses. EU MRL for pulses was recently raised from 0.01* to 0.3 mg/kg, following an MRL application. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Palm fruit (African oil palm)	0.8	0.8	cGAP: Malaysia, 2 × 0.03 kg a.i./ha, PHI 1 day (14-d interval) Number of trials: 4 Sufficiently supported by data: No Specific comments/observations: In our view, the use of chlorantraniliprole in palm trees (Elaeis guineensis Jacq.) would trigger the setting of an MRL for palm fruit (SO 3160) and palm nut (SO 0696). It is our understanding that palm nuts are a major crop at Codex level. Thus, the number of trials would not be sufficient to derive an MRL proposal. At EU level palm nuts are also considered as a major crop. The EU MRL for palm fruit was recently raised from 0.01* to 0.8 mg/kg, following an MRL application supported by 4 residue trials. For oil palm kernels a modification of the existing MRL of 0.01 mg/kg was not necessary (4 GAP compliant and 4 overdosed trials), since the data provided confirmed that no residues are expected in the kernel. See also comments on palm oil, crude. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Palm oil, crude	2		JMPR assessed 6 processing studies on oil palm fruit (mesocarp oil of SO 3160) which demonstrated that the residues are likely to accumulate in the oil (mean PF = 2.6). JMPR also assessed processing studies to estimate the transfer from oil palm fruits to the oil of kernels (SO 0696) and kernel cake. Since no residues were found in the kernel oil, no specific Codex MRL is required. It should be discussed if the setting of an MRL for palm nuts (SO 0696) is necessary. There might be also a need to re-consider the Codex and also the EU classification of palm

Commodity	Codex MRL proposal	EU MRL	Comment
			nuts and palm fruit; the portion of the commodity to which the MRL applies is specified as – Oilseeds (covering palm nuts): unless otherwise specified, seed or kernels, with shell or husk. – Oil fruits (covering palm fruits): whole commodity.
General comments			

*: Indicates that the MRL is proposed at the limit of quantification.

5.20.5. Consumer risk assessment

Table 96: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant	**RA assumptions:** The input values of the long-term risk assessment performed under the MRL review (EFSA, 2020n) were updated, including the STMR values derived in the most recent reasoned opinion of (EFSA, 2020t). Since the proposed Codex MRL proposals were at the same level as the existing EU MRLs, the EU risk assessment values are still valid. The risk assessment was performed with the EU ADI.	**Specific comments:** –
Results: Not relevant Unnecessary (no ARfD value)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.08% of the ADI (NL toddler). Among the crops under consideration, dry beans were identified as the main contributor, accounting for less than 0.01% of the ADI.	**Results:** Long-term exposure: ax 1% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.21. Spirotetramat (234) R

5.21.1. Background information

Table 97: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	AT	
Approval status	Approved	Commission Decision 2007/560/EC[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013i) (EFSA, 2017k) (confirmatory data – potential for endocrine disruptor effects in birds and fish)
MRL review performed	Yes, see comments	(EFSA, 2020c)
MRL applications/ assessments	Yes, see comments	(EFSA, 2021f)[(c)] (leeks, spring onions and honey) (EFSA, 2019a) (various crops) (EFSA, 2019p) (small fruits and berries, kiwi fruits, garlic and fennel and rhubarb) (EFSA, 2017a) (various crops)
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments.	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Decision of 2 August 2007 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chlorantraniliprole, heptamaloxyglucan, spirotetramat and Helicoverpa armigera nucleopolyhedrovirus in Annex I to Council Directive 91/414/EEC (notified under document number C(2007) 3669). OJ L 213, 15.8.2007, p. 29–31.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.
(c): The assessment performed in the recently published reasoned opinion could not be taken into account for the assessment in this report.

5.21.2. Toxicological reference values

Table 98: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.05 mg/kg bw per day	JMPR (2008)	0.05 mg/kg bw per day	(EFSA, 2013i) (1-year dog study and 100 UF) confirmed in (European commission, 2013a)	Yes
ARfD	1 mg/kg bw	JMPR (2008)	1 mg/kg bw	(EFSA, 2013) (acute neurotoxicity rat study and 100 UF) confirmed in (European Commission, 2013a)	Yes
Conclusion/ comment	–				

5.21.3. Residue definitions

Table 99: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Spirotetramat and its enol metabolite, expressed as spirotetramat.	Reg. 396/2005: Sum of spirotetramat, spirotetramat-enol expressed as spirotetramat (implemented in 2020) Previous RD: Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy and BYI08330 enol-glucoside, expressed as spirotetramat. Peer review (EFSA, 2013i): Sum of spirotetramat, spirotetramat-enol expressed as spirotetramat	Yes, for RD recently implemented
	Animal products	Spirotetramat enol metabolite, expressed as spirotetramat. The residue is not fat soluble	Reg. 396/2005: Spirotetramat-enol, expressed as spirotetramat (EFSA, 2020c) Peer review (EFSA, 2013i): Spirotetramat-enol expressed as spirotetramat. The residue is not fat soluble	Yes
RD RA	Plant products	Spirotetramat and its metabolites enol, ketohydroxy, enol glucoside	MRL review (EFSA, 2020c) and Peer review (EFSA, 2013i): Sum of spirotetramat, its -enol, -ketohydroxy,	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		and monohydroxy, expressed as spirotetramat expressed as spirotetramat.	-monohydroxy and -enol-glucoside metabolites expressed as spirotetramat	
	Animal products	Spirotetramat enol metabolite, expressed as spirotetramat	MRL review (EFSA, 2020c) and Peer review (EFSA, 2013i): Sum of spirotetramat-enol and spirotetramat-enol-GA expressed as spirotetramat	No
Conclusion, comments	The EU RD enforcement for plant commodities and for animal products has been recently modified and is now comparable with the JMPR residue definition. The RDs RA for plant commodities are similar. The EU RD RA for animal commodities comprises an additional compound (BYI08330-enolglucuronide).			

5.21.4. Codex MRL proposals

Table 100: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Carrot	0.04	0.07	cGAP: USA, 2 × 0.09 kg/ha, 7 days interval, PHI 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The EU GAP assessed in the MRL review is less critical GAP is registered (4 × 0.075 kg/ha, PHI 21 days). **Conclusion:** The proposed Codex MRL is acceptable.
Strawberry	**0.3**	0.3	cGAP: Spain, 2 × 0.1 kg/ha, PHI 14 days. Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: It is noted that for the Spanish GAP reported in the framework of the MRL review the PHI was not specified. The same residue data set conducted in Spain indoor, was submitted under the art 12 MRL review resulting in the same MRL. **Conclusion:** The proposed Codex MRL is acceptable.
Sugar beet	**0.06**	0.02*	cGAP: USA, Canada, 2 × 0.16 kg/ha, PHI 28 days. Number of trials: A total number of 17 trials were submitted, 6 were conducted in Canada and 11 in USA. Only 15 trials were considered independent. Sufficiently supported by data: Yes Specific comments/observations: **Conclusion:** The proposed Codex MRL is acceptable.
Sugar beet leaves or tops (dry)	8 (dw)		**Conclusion:** For feed crops, no MRLs are established in the EU.
Sugar beet molasses			The PF of 3.85 is proposed based on two studies. The proposal is acceptable
General comments	According to JMPR, the crops used as feed (sugar beet leaves or tops), do not contribute significantly to the dietary burden compared to the previous assessment on livestock assessment (JMPR, 2011). Therefore, there is no need to change the Codex MRL for animal commodities.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.21.5. Consumer risk assessment

Table 101: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3 for strawberries and sugar beets only since the Codex MRL proposals are higher than or equal to the existing EU MRL. The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3. The input values of the most recent long-term risk assessment (EFSA, 2020c) were updated, including the STMR value derived by JMPR for strawberries (proposed Codex MRL is higher than the EU MRL). The risk assessment was performed with the EU ADI.	**Specific comments:** –
Results: No short-term consumer health risk was identified. Strawberry: 0.3% of ARfD. Sugar beets: 0.6% (sugar)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 27% of the ADI. Strawberries has a minor contribution to the overall chronic exposure, accounting for up to 0.08% of the ADI (DE child).	**Results:** Long-term exposure: Max 20% of the JMPR ADI. Short-term exposure: It shown to be less than 0.1% ARfD

5.22. Metaflumizone (236) R/T

5.22.1. Background information

Table 102: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	SE	UK was RMS for the first approval
Approval status	Approved	Commission Implementing Regulation (EU) No 922/2014[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013m)
MRL review performed	Yes, see comments	(EFSA, 2020j)
MRL applications/ assessments	Yes, see comments	(EFSA, 2013k) (various commodities)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 922/2014 of 25 August 2014 approving the active substance metaflumizone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 252, 26.8.2014, p. 6–10.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.22.2. Toxicological reference values

Table 103: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.01 mg/kg bw per day	JMPR (2009)	0.01 mg/kg bw per day	(EFSA, 2013m) (3-and 12-month dog study and 100 × 6* UF)	Yes
ARfD	Unnecessary	JMPR (2009)	0.13 mg/kg bw	(EFSA, 2013m) (rat developmental study and 100 × 3** UF)	No
Conclusion/ comment	*: Additional factor of 2 (for the uncertainties related to oral absorption) and 3 (for the uncertainties related to bioaccumulation in dogs) **: Additional factor of 3 (to cover the likely greater oral absorption of metaflumizone at the levels likely to be encountered by consumers) In the **EU evaluation**, the ARfD was derived from the rat developmental study where an adverse effect was already observed in the dams after 2 or 3 doses (reduced body weight gain). On the basis of the available data, it was also concluded that the E/Z-isomer ratio (9/1) has the same toxicological profile as the Z-isomer of metaflumizone. Metabolite M320I04 (4-{2-oxo-2-[3-(trifluoromethyl) phenyl]ethyl}benzonitrile): in the EU peer review no conclusion could be drawn regarding toxicological profile of the plant metabolite M320I04 (including its genotoxic potential). M320I23 and M320I29: The available data for the metabolites M320I23 and M320I29 did not allow to conclude on the toxicological profile. In the **JMPR evaluations**, M320I23 (4-{5-hydroxy-3-oxo-4-[4-(trifluoromethoxy)phenyl]-6-[3-(trifluoromethyl)phenyl]-2,3,4,5-tetrahydro-1,2,4-triazin-5-yl}benzonitrile) was concluded to be of similar or lower toxicity than metaflumizone, and therefore would be covered by its ADI. The metabolites M320I04 (4-{2-oxo-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile) and M320I29 (m-trifluoromethyl benzoic acid) were considered unlikely to be genotoxic and could be assessed using the TTC value of 1.5 µg/kg bw per day for chronic toxicity.				

5.22.3. Residue definitions

Table 104: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer.	Reg. 396/2005: Sum of metaflumizone E-isomer and metaflumizone Z-isomer Peer review (EFSA, 2013m): Sum of metaflumizone E-isomer and metaflumizone Z-isomer	Yes
	Animal products	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer The residue is fat soluble	Reg. 396/2005: Sum of metaflumizone E-isomer and metaflumizone Z-isomer Peer review (EFSA, 2013m): Sum of metaflumizone E-isomer and metaflumizone Z-isomer The residue is fat soluble	Yes
RD RA	Plant products	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer.	Peer review (EFSA, 2013m): Sum of metaflumizone E-isomer and metaflumizone Z-isomer	Yes
	Animal products	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer.	Peer review (EFSA, 2013m): Sum of metaflumizone E-isomer and metaflumizone Z-isomer	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	Identical RD were proposed for RAC. It is noted that standard hydrolyses studies were not assessed by JMPR (2009); in MRL review (EFSA, 2020j), it was proposed to include a metabolite (M320I04) in the residue definition for processed products on a tentative basis, pending toxicological information on this metabolite.			

5.22.4. Codex MRL proposals

Table 105: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL/ proposal MRL review	Comment
Apple	**0.9**	0.05*/no use	cGAP: Brazil, 4 foliar applications with 0.24 kg a.i./ha; interval 7 days; PHI 3 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: HR: 0.54; STMR: 0.275 **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Coffee bean	**0.15**	0.1*/no use	cGAP: Brazil, 2 foliar applications with 0.48 kg a.i./ha; interval 30 days; PHI 45 days Number of trials: 13 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Grape	**5**	0.05*/no use	cGAP: Brazil, 3 foliar applications with 0.24 kg a.i./ha; interval 7 days; PHI 3 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: Trials on grapes conducted in Brazil; HR: 2.71; STMR = 0.98 mg/kg. **Conclusion:** The proposed Codex MRL is not acceptable because of an acute intake concern (see below). Follow-up action: None
Lemons and Limes, subgroup of (includes all commodities in this subgroup)	**2**	0.05*/no use	cGAP: Brazil, 3 foliar applications with 0.48 kg a.i./ha; interval 7 days; PHI 7 days Number of trials: 5 Sufficiently supported by data: Yes, since lemons and lime are not a major crop according to Codex classification. Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Maize	0.04	0.05*/no use	cGAP: Brazil, 5 foliar applications with 0.24 kg a.i./ha; interval 7 days; PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Melons, except Watermelon	**1**	0.05*/no use	cGAP: Brazil, 5 foliar applications with 0.192 kg a.i./ha; interval 7 days; PHI 3 days Number of trials: 8 on melons Sufficiently supported by data: Yes Specific comments/observations: Three residue trials were reported in which residues in the pulp was below the LOQ of 0.02. JMPR derived a STMR of 0.02 mg/kg for melon

Commodity	Codex MRL proposal	EU MRL/ proposal MRL review	Comment
			pulp. Meanwhile for the chronic and acute RA the results from the unpeeled melons (HR: 0.61; STMR 0.12) were used. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Oranges, Sweet, Sour, subgroup of (includes all commodities in this subgroup)	**3**	0.05*/o use	cGAP: Brazil, 3 foliar applications with 0.48 kg a.i./ha; interval 7 days; PHI 7 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: STMR 0.66 mg/kg, HR 1.35 was derived. A peeling factor of 0.1 was considered appropriate, which was calculated from the lemon and orange trials in which data on pulp and whole fruit were reported. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Raisins	13		PF (derived from 3 processing studies: 2.6).
Soyabean (dry)	**0.2**	0.05*/no use	cGAP: Brazil, 3 foliar applications with 0.24 kg a.i./ha; interval 7 days; PHI 3 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Sugar cane	0.02*	0.05*/no use	cGAP: Brazil, 1 in-furrow application with 0.48 kg a.i./ha at the time of planting. Number of trials: 6 Sufficiently supported by data: Yes, noting that sugar cane is a major crop for Codex. Specific comments/observations: Six trials were made available which were conducted at an exaggerated rate of 1.2 kg a.i./ha. Sugar cane is not listed as major crop in Europe. Residues were all below LOQ of 0.02 mg/kg and a STMR of 0 mg/kg was derived. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Orange oil, edible	100		cGAP: Processed commodity – not applicable for MRL setting in EU.
Edible offal (mammalian)	0.02*	0.02/0.02*	Sufficiently supported by data: Yes Specific comments/observations: MRL proposal derived for Australian dietary burden for dairy cattle. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Eggs	0.02	0.02/-	Sufficiently supported by data: Yes Specific comments/observations: MRL proposal derived for US dietary burden for layers. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Mammalian fats (except milk fats)	**0.15**	0.02/0.02*	Sufficiently supported by data: Yes Specific comments/observations: see edible offal (mammalian) **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

Commodity	Codex MRL proposal	EU MRL/ proposal MRL review	Comment
Meat (from mammals other than marine mammals)	0.02* (fat)	0.02/0.02*	Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal by JMPR refers to fat whereby the value should be aligned with the MRL proposal for mammalian fat. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Milks	**0.02**	0.02/0.02*	Sufficiently supported by data: Yes Specific comments/observations: see edible offal (mammalian) **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Milk fats	0.6		Specific comments/observations: In the EU, specific MRLs are not set for milk fat; normally, a concentration factor of 25 is applied to recalculate the MRL from milk to milk fat (leading to a legal limit of 0.5 mg/kg).
Poultry, edible offal of	0.02*	0.02/–	Sufficiently supported by data: Yes Specific comments/observations: See comments on eggs **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry fats	0.08	0.1/–	Sufficiently supported by data: Yes Specific comments/observations: See comments on eggs **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry meat	0.02* (fat)	0.02/–	Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal by JMPR refers to fat whereby the value should be aligned with the MRL proposal for mammalian fat. The Codex proposal should be revised to 0.08 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
General comments	The MRL proposals derived in the MRL review are not yet implemented.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.22.5. Consumer risk assessment

Table 106: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. EFSA used the HR for pulp of melons and peeled citrus fruit (PF 0.1). The risk assessment was performed with the EU ARfD.	**RA assumptions:** The most recent risk assessment for metaflumizone performed was updated (EFSA, 2013k, 2020j), including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. For melons and citrus fruit input values refer to the peeled product. The previously derived input values and the new input values for the Codex MRL proposals were inserted in EFSA PRIMo rev. 3.1 The risk assessment was performed with the EU ADI which is similar to the Codex ADI.	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: The calculated short-term exposure exceeded the ARfD for table grapes. Table grapes: 152% of ARfD Melons: 71%	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 65% of the ADI (NL toddler). Among the crops under consideration, wine grapes were identified as the main contributor, accounting for up to 36% of the ADI.	**Results:** Long-term exposure: Max 4% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.23. Dicamba (240) R/T

5.23.1. Background information

Table 107: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	DK	
Approval status	Approved	Commission Directive 2008/69/EC[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2011b) (EFSA, 2016t) (confirmatory data on fate and behaviour)
MRL review performed	No	
MRL applications/assessments	Yes, see comments	(EFSA, 2013o) (soyabean) (EFSA, 2013p) (herbs)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed, see comments	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet.

(a): Commission Regulation (EU) 2017/1016 of 14 June 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac in or on certain products. OJ L 159, 21.6.2017, p. 1–47.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.23.2. Toxicological reference values

Table 108: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	Dicamba: 0.3 mg/kg bw per day	JMPR (2010)	Dicamba, 5-OH-dicamba: 0.3 mg/kg bw per day	(EFSA, 2011b) (2 generation rat and 100 UF) (European Commission, 2008b)	Yes
	DCSA; DCGA; 5-OH-dicamba: 0.3 mg/kg bw per day	JMPR (2019)	DCSA; DCGA: 0.04 mg/kg	(EFSA, 2013o)	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ARfD	Dicamba: 0.5 mg/kg bw	JMPR (2010)	Dicamba, 5-OH-dicamba: 0.3 mg/kg bw	(EFSA, 2011b) (rabbit, teratology study and 100 UF) (European Commission, 2016a)	No
	DCSA; DCGA; 5-OH-dicamba: Same ARfD as for parent dicamba	JMPR (2019)	DCSA, DCGA: 0.3 mg/kg	(EFSA, 2013o)	No
Conclusion/ comment	2019 JMPR performed a toxicological assessment of DCSA, DCGA and 5-OH-dicamba. The EU ADI and ARfD for DCSA and DCGA are lower than the TRV derived by JMPR.				

5.23.3. Residue definitions

Table 109: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	For soyabean, maize and cotton: Sum of dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated), expressed as dicamba; (see comments) For other plant commodities: Dicamba	Reg. 396/2005: Dicamba Art. 10 (soybeans) (EFSA, 2013o): Sum of DCSA and its conjugates, expressed as DCSA (not implemented in EU MRL legislation) Peer review (under Council Directive 91/414/EEC): Dicamba, its salts and conjugated dicamba expressed as dicamba	Yes, for conventional crops; no for GM crops
	Animal products	Sum of dicamba and DCSA, expressed as dicamba The residue is not fat soluble	Reg. 396/2005: Dicamba Peer review (EFSA, 2011b): Dicamba and its salts and conjugated dicamba expressed as dicamba The residue is not fat soluble	No
RD RA	Plant products	For soyabean, maize and cotton: Sum of dicamba, 2,5-dichloro-3-hydroxy-6-methoxybenzoic acid (5-OH dicamba), 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated) and 2,5-dichloro-3,6-dihydroxybenzoic acid (DCGA; free and conjugated), expressed as dicamba; (see comments) For other plant commodities: Sum of dicamba and 5-OH dicamba, expressed as dicamba	Peer review (EFSA, 2011b): Dicamba + 5-OH-dicamba, free and conjugated Art. 10 (soybeans) (EFSA, 2013o): Sum of DCSA, DGSA and their conjugates, expressed as DCSA	Yes, for conventional crops, no for GM crops
	Animal products	Sum of dicamba and DCSA, expressed as dicamba	Peer review (EFSA, 2011b): Dicamba (free and conjugated)	No
Conclusion, comments	JMPR derived a new residue definition for soyabean, maize and cotton on the basis of metabolism studies in GM crops. However, the residue definition is not restricted to GM crops, but applies also to conventional soyabeans, maize and cotton.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	In the framework of a previous MRL application (EFSA, 2013o), EFSA proposed a separate residue definition for GM soybeans, as the metabolism pattern of the active substance in genetically modified plants was shown to be different. In addition, as the available data do not allow to conclude whether dicamba and DCSA act through the same toxicological mode of action, EFSA proposes to set the following additional residue definition for soybean, in order to cover the use of dicamba on dicamba-tolerant soybean: Enforcement: Sum of DCSA and its conjugates, expressed as DCSA (risk management decision was taken to not implement the RD in MRL legislation). Risk assessment: Sum of DCSA, DGSA and their conjugates, expressed as DCSA. A risk management decision was taken to maintain the previous residue definition (covering only parent dicamba). Since in GM crops dicamba is almost completely metabolised to DCSA, the current residue definition does not allow to identify whether GM crops have been treated in compliance with the GAP. The possible modification of the EU RD for enforcement (plant commodities) should be discussed at EU level. Import of GM cotton and maize is not approved in the EU.			

5.23.4. Codex MRL proposals

Table 110: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposals[(a)]	EU MRL[(b)]	Comment
Cotton seed	**3**	0.05*	cGAP: US, GAP for genetically modified cotton tolerant to dicamba (MON 88701); 1 × 1.12 kg a.i./ha (pre-emergence) + 2 × 0.56 kg a.i./ha (post-emergence), 7 days apart, PHI 7 days. Number of trials: 13 Sufficiently supported by data: Yes Specific comments/observations: Only 2 trials were exactly matching the GAP, 11 trials with different retreatment interval (5–63 days), which according to JMPR did not have an influence on the final residues in cotton seed. It would be desirable if in the JMPR reports more details on the GM crop varieties are reported. **Conclusion:** The proposed Codex MRL is not compatible with the current EU residue definition. Furthermore, it is noted that import of GM-cotton tolerant to dicamba is approved in the EU. RM should be aware that the current EU RD is not appropriate for herbicide tolerant GM crops, because parent dicamba is not a suitable marker substance for this type of crops. Follow-up action: To verify that GM cotton tolerant to dicamba is approved.
Maize	0.01*	0.5	cGAP: Canada, GAP for genetically modified maize tolerant to dicamba (MON 87419); 1 × 0.58 kg/ha (pre-emergent) + 1 × 0.6 kg a.i./ha (post-emergent). Number of trials: no trials available. Sufficiently supported by data: No Specific comments/observations: JMPR withdrew the old CXL and replaced it with a new MRL proposal at the same level, for the new residue definition. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Maize fodder (dry)	0.6		In the EU, no MRLs are established for feed.
Soyabean (dry)	**10**	10/0.4[(c)]	cGAP: US, GAP for genetically modified soyabean tolerant to dicamba (MON 87708); 1 × 1.12 kg a.i./ha (pre-emergence) + 2 × 0.56 kg a.i./ha (post-emergence), 7 days apart, last application not later than BBCH 60 (first flowers opened).

Commodity	Codex MRL proposals[(a)]	EU MRL[(b)]	Comment
			Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: Dicamba-tolerant soyabean is approved in the EU (MON 87708). Only 5 trials were exactly matching the GAP, 17 trials with different retreatment interval (6–29 days), which according to JMPR did not have an influence on the final residues in the harvested soyabeans. The residue trials in the dicamba tolerant soyabeans would suggest an MRL of 0.5 mg/kg. Since this is lower than the existing CXL which was also taken over in the EU MRL legislation, JMPR proposed to withdraw the old CXL (derived for a desiccant use on conventional crops) and replace it with a new Codex MRL proposal for the new residue definition derived for GM crops at the same level as the old CXL. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Soyabean fodder (dry)	150		In the EU, no MRLs are established for feed.
Soyabean hulls	15		The Codex MRL proposal was derived using two processing studies on dicamba -tolerant soyabeans (median PF: 1.39). For dicamba-tolerant soyabean hulls the required MRL would correspond **0.7 mg/kg** (0.5 (MRL proposal derived for GM soyabeans) × 1.39 (PF). In 2013, a desiccant use in conventional soyabeans was assessed by JMPR (1 × 0.56 kg a.i./ha, 14 d. prior to planting, 1.12 kg a.i./ha foliar use, when soyabean pods have reached mature brown colour and at least 75% leaf drop occurred, PHI 7 days). For this GAP data for soyabean hulls were available, that indicated that the expected residues in soyabean hulls were low (0.117 mg/kg). Thus, the setting of a specific MRL for soyabean hulls was not considered necessary. It is not appropriate to apply the PF derived for the GAP in dicamba-tolerant soyabeans to the current Codex MRL which reflects a different use in conventional crops.
Soyabean meal	15		The Codex MRL proposal was derived using two processing studies on dicamba -tolerant soyabeans (median PF: 1.34). For dicamba-tolerant soyabean meal the required MRL would correspond **0.7 mg/kg** (0.5 (MRL proposal derived for GM soyabeans) × 1.34 (PF). It is not appropriate to apply the PF derived for the GAP in dicamba-tolerant soyabeans to the current Codex MRL which reflects a different use in conventional crops.
General comments	(a): The Codex MRL proposals refer to the residue definition derived for GM crops, i.e. Sum of dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated), expressed as dicamba. (b): The EU MRLs reported in this column refer to the EU enforcement RD for conventional crops (i.e. Dicamba). (c): In the framework of an IT application (EFSA, 2013o) an MRL proposal for GM soybeans was derived which was legally implemented by Regulation (EU) 2015/401[(1)] in the form of a footnote. There are two values set in Regulation (EC) No 396/2005 for soybeans treated with dicamba: 10 mg/kg applies to conventional soybean and 0.4 mg/kg to GM soybean to address the occurrence of 3,6-dichloro-salicylic acid (DCSA). Currently, a GM soybean variety tolerant to dicamba is approved in Europe (MON 87708).		

*: Indicates that the MRL is proposed at the limit of quantification.
(1): Commission Regulation (EU) 2015/401 of 25 February 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, chromafenozide, cyazofamid, dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products. OJ L 71, 14.3.2015, p. 114–156.

5.23.5. Consumer risk assessment

Table 111: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal were derived (cotton, soyabeans and maize). The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The calculations were performed with the existing EU MRLs, including the STMR values derived by JMPR for the crops for which the proposed Codex were derived (cotton, soyabeans and maize). The calculations are affected by additional, non-standard uncertainties, related to the fact that the MRLs were used (which may lead to an overestimation) and because information on the magnitude of residues of metabolite(s) included in the risk assessment residue definition are not available (which may lead to an underestimation of the exposure). The risk assessment was performed with the EU ADI assigned to dicamba.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. For all crops assessed: < 0.1% of ARfD.	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 14% of the ADI. The crops under consideration were minor contributors to the total exposure (max. 0.07% of the ADI.	**Results:** Long-term exposure: Max 1% of the JMPR ADI. Short-term exposure: 0% of ARfD.

5.24. Penthiopyrad (253) R

5.24.1. Background information

Table 112: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	SE	
Approval status	Approved	Commission Implementing Regulation (EU) No 1187/2013[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013b)
MRL review performed	No	Ongoing
MRL applications/assessments	Yes, see comments	(EFSA, 2020r) (fennels and celeries) (EFSA, 2016s) (stone fruits and cereals) (EFSA, 2012j) (various crops)
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 1187/2013 of 21 November 2013 approving the active substance penthiopyrad, 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 313, 22.11.2013, p. 42–46.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.24.2. Toxicological reference values

Table 113: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI for parent	0.1 mg/kg bw per day	JMPR (2011)	0.1 mg/kg bw per day	(EFSA, 2013b) (Two generation rat with safety factor 100)	Yes
ARfD for parent	1 mg/kg bw	JMPR (2011)	0.75 mg/kg bw	(EFSA, 2013b) (Rabbit developmental with safety factor 100)	No
Conclusion/ comment	**Metabolite 753-A-OH** is of a similar toxicity as the parent. During the peer review, the information was not sufficient to conclude on the toxicity of another metabolite, **PAM**. Based on the confirmatory data requested and assessed by EFSA, an ADI of 0.0024 mg/kg bw per day and an ARfD of 0.024 mg/kg bw were derived (EFSA, 2016s). This confirms that a separate assessment is needed for PAM. Further discussions on toxicity of PAM are ongoing in peer review expert meetings.				

5.24.3. Residue definitions

Table 114: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Penthiopyrad	Reg. 396/2005 and peer review (EFSA, 2013b): Penthiopyrad	Yes
	Animal products	Sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad The residue is not fat soluble	Reg. 396/2005: Penthiopyrad Peer review (EFSA, 2013b): Penthiopyrad and PAM The residue is not fat soluble	No, compared to the current RD in Reg. 396/2005
RD RA	Plant products	Sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad	Peer review (EFSA, 2013b): Residue definition 1: Sum of penthiopyrad and metabolite 753-AOH, expressed as penthiopyrad; Residue definition 2: Metabolite PAM	No
	Animal products	Sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad	Peer review (EFSA, 2013b): Residue definition 1: Penthiopyrad Residue definition 2: PAM	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	The residue definition for enforcement is the same, but the residue definition for risk assessment is not comparable for plants between the EU and JMPR. In the European evaluation a separate residue definition was established for PAM, as it has much lower reference values and an additional metabolite, 753-AOH is also included in the residue definition. For animal products both enforcement and residue definitions for risk assessment are not comparable. However, since there are no Codex MRL proposals for animal products under discussion, this discrepancy is of no relevance.			

5.24.4. Codex MRL proposals

Table 115: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cane berries, Subgroup of 004A	**10**	0.01* Blackberries, dewberries, raspberries	cGAP: Canada, foliar, 3 × 0.35 kg/ha, min. 7-day interval between applications, PHI 0 days Number of trials: 1 blackberry + 4 trials on raspberry Sufficiently supported by data: Yes Specific comments/observations: Individual levels of penthiopyrad and PAM were reported separately in the JMPR evaluation. Since metabolite 753-AOH is not included in the JMPR residue definition, information on the occurrence of this metabolite is not available. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable; the enforcement residue definitions are compatible. However, the risk assessment residue definitions are not fully compatible with the EU policy on setting MRLs. Follow-up action: None
Bush berries, Subgroup of	**7**	0.01* (blueberries, currants, gooseberries, rose hips)	cGAP: Canada, foliar, 3 × 0.35 kg/ha, min. 7-day interval between applications, PHI 0 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL for whole group of bush berries covers blueberries, currants, gooseberries and rose hips. According to Codex extrapolation rules, blueberry trials are acceptable to derive the group MRL. In the EU additional trials on currants and/or on grapes would be needed. Individual levels of penthiopyrad and PAM were reported separately in the JMPR evaluation. Since metabolite 753-AOH is not included in the JMPR residue definition, information on the occurrence of this metabolite is not available. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable; the enforcement residue definitions are compatible. Follow-up action: None
Elderberries	**7**	0.01*	cGAP: Canada, foliar, 3 × 0.35 kg/ha, min. 7-day interval between applications, PHI 0 days Number of trials: 7 in blueberries Sufficiently supported by data: No Specific comments/observations: An extrapolation from blueberries to elderberries is not foreseen in the Codex extrapolation rules. In the EU, the data would not be accepted (either residue trials in elderberries or additional trials on currants and/or grapes would be required).

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is not acceptable. Follow-up action: None
Guelder rose (cranberries)	**7**	0.01*	See elderberries
General comments	Information on the occurrence of PAM was reported in the detailed JMPR evaluations. However, information on metabolite 753-AOH, which is included in the EU residue definition for risk assessment, but not in the residue definition of JMPR is not available. Taking into account the metabolism studies and residue trials in fruits, metabolite 753-AOH is not expected to contribute significantly to the consumer exposure.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.24.5. Consumer risk assessment

Table 116: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The calculations are affected by additional, non-standard uncertainties, related to the levels of metabolites, PAM and 753-A-OH. Regarding the consumer exposure for the residue definition 1, the exposure may be underestimated as information was not available on the level of metabolite, 753-A-OH in the crops. However, this is not expected to significantly impact the risk assessment. The risk assessment was performed with the EU ARfD. The calculations are indicative, because there is no information on the specific level of all metabolites included in the EU RD. The consumer exposure for the residue definition 2 could not be performed as individual levels of PAM are not indicated in the JMPR Report.	**RA assumptions:** A long-term dietary risk assessment for both EU residue definitions were performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessments (EFSA, 2020r) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRLs are higher than the EU MRLs. The calculations are affected by additional, non-standard uncertainties, related to the levels of metabolite 753-A-OH. Regarding the consumer exposure for the residue definition 1, the exposure may be underestimated as information was not available on the level of metabolite, 753-A-OH in the crops. However, this is not expected to significantly impact the risk assessment. The risk assessment was performed with the EU ADI. The calculations are indicative, because not all metabolites were measured or reported. The consumer exposure for the residue definition 2 was updated with the levels of PAM which were derived from the JMPR evaluation.	**Specific comments:** Without data indicating the actual levels of metabolite PAM, the risk assessment in line with this residue definition could not be carried out. When the evaluation report will become available it has to be checked whether data is sufficient to carry out a risk assessment.
Results: **RD 1:** No short-term consumer health risk was identified for the crops under assessment. **RD 1:** highest result: Blackberries 6.86% of ARfD **RD 2:** highest result: Currants 1.4% of ARfD	**Results:** **RD 1:** No long-term consumer health risk was identified. **RD 1:** The overall chronic exposure accounted for 30% of the ADI; the overall contribution of the crops under consideration is max. 2% of the ADI Among the crops under consideration, raspberries was identified as the main contributor, accounting for up to 0.6% of the ADI. **RD 2:** The overall chronic exposure accounted for 60% of the ADI of PAM; the	**Results:** Long-term exposure: Max 8% of the JMPR ADI. Short-term exposure: Highest result up to 5% of ARfD.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
	overall contribution of the crops under consideration is max. 0.4% of the ADI Among the crops under consideration, currants were identified as the main contributor, accounting for up to 0.17% of the ADI.	

5.25. Fluxapyroxad (256) R/T

5.25.1. Background information

Table 117: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approved	Commission Implementing Regulation (EU) No 589/2012[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2012a)
MRL review performed	Yes, see comments	(EFSA, 2020e)
MRL applications/assessments	Yes, see comments	(EFSA, 2020a) (import tolerance for certain root crops) (EFSA, 2017i) (various crops) (EFSA, 2016c) (various crops) (EFSA, 2015q) (grapes and potatoes) (EFSA, 2011h) (various crops)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 589/2012 of 4 July 2012 approving the active substance fluxapyroxad, 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 175, 5.7.2012, p. 7–10.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.25.2. Toxicological reference values

Table 118: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.02 mg/kg bw per day	JMPR (2012) Rat, 2-year study, UF of 100	0.02 mg/kg bw per day	(EFSA, 2012a) Rat, 2-year study, UF 100	Yes
ARfD	0.3 mg/kg bw	JMPR (2012) Rat and rabbit developmental toxicity studies, UF of 100	0.25 mg/kg bw	(EFSA, 2012a) Rabbit (developmental effects), and rat (maternal effects) developmental toxicity studies; UF 100	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Conclusion/ comment	Parent: Regarding the derivation of the ADI, the JMPR and EU evaluations resulted in the same value, based on the same study. Regarding the derivation of the ARfD, both evaluations are based on the same NOAELs from the same studies, the difference being due to rounding. Metabolites: From the toxicological data available to the JMPR on metabolites **M700F001**, **M700F002** and **M700F048**, the JMPR considered these metabolites are not more toxic than fluxapyroxad. The EU assessment conclusions are reported below: **Metabolites M700F048 and M700F008:** The toxicological reference values of the parent are applicable to these 2 metabolites according to the EU assessment. **Metabolite M700F001:** An ADI of 0.25 mg/kg bw per day was derived by the EU assessment based on a developmental toxicity study in rabbits and UF of 1,000 applied; an ARfD was not derived as not necessary. **Metabolite M700F002:** An ADI of 0.3 mg/kg bw per day was derived by the EU assessment based on a developmental toxicity study in rabbits and UF of 1,000 applied; an ARfD was not derived as not necessary.				

5.25.3. Residue definitions

Table 119: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fluxapyroxad	Reg. 2018/685[(a)]: Fluxapyroxad Peer review (EFSA, 2012a): Fluxapyroxad (BAS 700F) – All crop categories	Yes
	Animal products	Fluxapyroxad The residue is fat soluble	Reg. 2018/685[(b)]: Fluxapyroxad Peer review (EFSA, 2012a): Fluxapyroxad (BAS 700F) The residue is fat soluble	Yes
RD RA	Plant products	Sum of fluxapyroxad and 3-difluoromethyl)-N-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-1-(ß-D-glucopyranosyl)-N-(3′,4′,5′-triflurobipheny-2-yl)-1H-pyrzaole-4-carboxamide (M700F048) and expressed as parent equivalents	Peer review (EFSA, 2012a): Fluxapyroxad (BAS 700F) – All crop categories	No
	Animal products	Sum of fluxapyroxad and 3-(difluoromethyl)-N-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) expressed as parent equivalents	Peer review (EFSA, 2012a): Fluxapyroxad (BAS 700F) and metabolite M700F008 expressed as parent equivalent	Yes
Conclusion, comments	The plant and animal RD for enforcement are comparable, as both refer to parent fluxapyroxad only. The RA residue definition in animal commodities is also comparable (both include the parent and the sum of M700F008 expressed as parent equivalent.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	For the plant risk assessment residue definition, the JMPR, in contrast to EU, has included two plant metabolites (M700F008 and M700F048). The overall contribution of metabolites is expected to be low. Using the risk assessment values derived by JMPR will lead to a slightly more conservative result.			

(a): Commission Regulation (EU) 2018/685 of 3 May 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products. OJ L 121, 16.5.2018, p. 1–29.

(b): Commission Implementing Regulation (EU) No 589/2012 of 4 July 2012 approving the active substance fluxapyroxad, 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 175, 5.7.2012, p. 7–10.

5.25.4. Codex MRL proposals

Table 120: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus fruit, Group of	1 (W)	0.01* except grapefruit and oranges with 0.4 and 0.3 resp.	The Codex proposal of 1 mg/kg from the previous JMPR meeting will be withdrawn, instead new Codex MRLs for the individual commodities of the citrus fruit group are proposed.
Lemons and Limes (including Citron), Subgroup of	**1**	0.01* (lemon, lime, kumquat)	cGAP: USA, 4 × 138 g/ha, 10-day interval, PHI 0 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: Residue trials were GAP compliant and analysed for fluxapyroxad and total fluxapyroxad. Residues of metabolites do not contribute significantly to the total residue. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Mandarins, Subgroup of	**1**	0.01*	cGAP: USA, 4 × 138 g/ha, 10-day interval, PHI 0 days Number of trials: 7 trials on lemons, extrapolated to mandarins Sufficiently supported by data: No Specific comments/observations: Mandarins are a major crop; no residue trials are available for mandarins; extrapolation from lemon is not in accordance with the agreed Codex extrapolation rules r the extrapolation from Lemon to Mandarin is not included in the extrapolation document from Codex (CXG 84, adopted in 2012 and amended in 2017). Since only 1 trial is available for mandarin, more trials would be required to set an MRL for the mandarin subgroup as proposed in the previous CCPR comments. However, based on the EU guidance on extrapolation (SANCO 7525/VI/95, Rev. 10.3), extrapolation from lemon to mandarin is possible and vice versa. Furthermore, according to the analyses conducted by the JMPR concerning the potential residue in citrus, residue levels in mandarin and in lemons following foliar application are comparable. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable although it is not fully in compliance with the JMPR extrapolation rules. Follow-up action: None

Commodity	Codex MRL proposal	EU MRL	Comment
Oranges, Sweet, Sour (including Orange-like hybrids), Subgroup of	**1.5**	0.3	cGAP: USA, 4 × 138 g/ha, 10-day interval, PHI 0 days Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: Residue trials were GAP compliant and analysed in oranges for Fluxapyroxad and total Fluxapyroxad. Residues of metabolites do not contribute significantly to the total residue. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Pummelo and Grapefruits (including Shaddock-like hybrids, among other Grapefruit), Subgroup of	**0.6**	0.4	cGAP: USA, 4 × 138 g/ha, 10-day interval, PHI 0 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Residue trials were GAP compliant and analysed in grapefruit for Fluxapyroxad and total Fluxapyroxad. Residues of metabolites do not contribute significantly to the total residue. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Citrus oil, edible	90	–	The proposal of 90 is derived from the PF of 59 from two processing studies. The previous proposal of 60 will be withdrawn. No EU MRLs are set for citrus oil.
Citrus pulp, dry	8	–	The PF of 4.8 is derived from two processing studies. No EU MRLs are set for citrus pulp.
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.25.5. Consumer risk assessment

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

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The acute exposure assessment was performed updating the most recent EFSA PRIMo rev. 3.1 which includes the MRL values which are already adopted. The HR values derived for total Fluxapyroxad were used for the citrus crops as input values. The risk assessment was performed with the EU ARfD.	**RA assumptions:** The chronic exposure assessment was performed using EFSA PRIMo rev. 3.1; the STMR values derived in the MRL review (EFSA, 2020e) and the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. For the citrus crops under assessment, the STMR values derived for total fluxapyroxad were used as input values. The risk assessment was performed with the EU ADI (same as the JMPR ADI).	**Specific comments:** JMPR did not provide an update of the consumer exposure.
Results: **No short-term consumer health risk was identified for the crops under assessment.** Oranges: 31% of ARfD Mandarins: 11% of ARfD Grapefruits: 8% of ARfD Lemons: 6% of ARfD Limes: 4% of ARfD Kumquat: 0.3% of ARfD	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 61% of the ADI. Among the crops under consideration, Oranges was identified as the main contributor, accounting for up to 8% of the ADI.	**Results:** –

5.26. Picoxystrobin (258)

5.26.1. Background information

Table 122: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	CZ	
Approval status	Not approved	Commission Implementing Regulation (EU) 2017/1455[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2016m)
MRL review performed	Yes, see comments	(EFSA, 2011o)
MRL applications/ assessments	Yes, see comments	(EFSA, 2014g) (sugar beet)
Classification of a.s. – cut-off criteria	Not assessed, not concluded	No harmonised classification.
Endocrine effects of a.s.	Not assessed/not concluded/ not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet.

(a): Commission Implementing Regulation (EU) 2017/1455 of 10 August 2017 concerning the non-renewal of approval of the active substance picoxystrobin, 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. C/2017/5541. OJ L 208, 11.8.2017, p. 28–30.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.26.2. Toxicological reference values

Table 123: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.09 mg/kg bw per day	JMPR (2013)	No toxicological reference values could be derived	Setting of reference values was postponed until conclusion on the genotoxic potential of picoxystrobin (EFSA, 2016m)	Not appropriate
ARfD	0.09 mg/kg bw	JMPR (2013)	No toxicological reference values could be derived	Setting of reference values was postponed until conclusion on the genotoxic potential of picoxystrobin (EFSA, 2016m)	Not appropriate
Conclusion/ comment	During the EU 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, 2016m). 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.				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
	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-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. In 2019, the EU submitted a concern form to JMPR; JMPR responded to the concerns raised by the EU, concluding that JMPR and EFSA differ in their interpretations of the genotoxicity data for picoxystrobin and IN-H8612 (JMPR 2019). A reassessment of the available genotoxicity data or new genotoxicity data has not been taken place at EU since the EFSA conclusion on picoxystrobin (EFSA, 2016m).				

5.26.3. Residue definitions

Table 124: 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	Reg. 396/2005: picoxystrobin Peer review: Picoxystrobin (pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites) (EFSA, 2016m)	Yes
	Animal products	Picoxystrobin The residue is fat soluble	Reg. 396/2005: picoxystrobin Peer review: Picoxystrobin (pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites) (EFSA, 2016m) The residue is fat soluble	Yes
RD RA	Plant products	Picoxystrobin	**Not proposed**, pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites (EFSA, 2016m)	Not applicable
	Animal products	Picoxystrobin	**Not proposed**, pending conclusion on the toxicological profile of picoxystrobin and its main plant metabolites (EFSA, 2016m)	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.			

5.26.4. Codex MRL proposals

Table 125: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Sorghum Grain	**0.02**	0.01*	cGAP: USA, 3 × 0.22 kg/ha, last application not to be applied after flowering. Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** Although a sufficient number of residue trials is available, the proposed Codex MRL is not acceptable since a consumer risk assessment cannot be conducted. Follow-up action: None
Cottonseed	**2**	0.01*	cGAP: USA, 3 × 0.22 kg/ha, PHI 7 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: Results from trials performed at higher application rate were scaled-down according to the proportionality principle (scaling factor of 0.44). **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. Follow-up action: None
Coffee bean	0.04	0.05*	cGAP: Brazil, 3 × 0.1 kg/ha, PHI 40 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: – **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. Follow-up action: None
Tea, Green, Black (black, fermented and dried)	**15**	0.05*	cGAP: China, 2 × 0.0225 kg/hL, PHI 10 days Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: Tea is a major crop in the Codex; the number of trials required for major crops is not clearly specified in the JMPR rules. At EU level, at least 8 trials are required. **Conclusion:** Codex MRL is not acceptable since a consumer risk assessment cannot be conducted. In addition, the number of residue trials is insufficient to derive an MRL proposal. Follow-up action: None
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 0.01 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.
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)	**0.02 (fat)**	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.

Commodity	Codex MRL proposal	EU MRL	Comment
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.
Alfalfa fodder	10 (dw)	–	–
Sorghum straw and fodder, dry	1 (dw)	–	–
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.26.5. Consumer risk assessment

Table 126: Summary of the consumer risk assessment

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:** JMPR updated the TTC calculations for the three metabolites IN-H8612, IN-QDK50 and IN-U3E08 performed in 2017, including the new uses. The exposure was found to be below the TTC threshold for Cramer Class III compounds.
Results: –	**Results:** –	**Results:** 0–0.2% of ADI 0–2% of ARfD

5.27. Benzovindiflupyr (261) R

5.27.1. Background information

Table 127: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approved	Commission Implementing Regulation (EU) 2016/177[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2015e)
MRL review performed	Not required	
MRL applications/assessments	Yes, see comments	(EFSA, 2016q) (Import tolerance request on various plant and animal commodities) Ongoing: modification of the existing MRLs in leek and spring onions, green onions and Welsh onions
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	

(a): Commission Implementing Regulation (EU) 2016/177 of 10 February 2016 approving the active substance benzovindiflupyr, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 35, 11.2.2016, p. 1–5.

5.27.2. Toxicological reference values

Table 128: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.05 mg/kg bw per day	JMPR (2013) Rat, 2-year study, UF of 100	0.05 mg/kg bw per day	(EFSA, 2015e) Rat, 2-year study, UF of 100	Yes
ARfD	0.1 mg/kg bw	JMPR (2013) Rat, acute neurotoxicity study, UF of 100	0.1 mg/kg bw	(EFSA, 2015e) Rat, acute neurotoxicity study, UF of 100	Yes
Conclusion/ comment	Parent: The JMPR and EU evaluations resulted in the same toxicological reference values, based on the same studies. Metabolites: **SYN545720 (CSCD465008):** The EU assessment derived an ADI of 0.3 mg/kg bw per day, based on the developmental toxicity study in rabbits, with an uncertainty factor (UF) of 1000 applied to account for the limited database available; ARfD not established, not needed. **NOA449410 (CSAA798670):** The EU assessment derived an ADI of 0.25 mg/kg bw per day, based on the developmental toxicity study in rabbits, 1000 UF applied to account for the limited database available; ARfD not established, not needed. **SYN546039 (CSCD695908):** A negative Ames test and an acute oral toxicity study in rat showing that the metabolite presents a low acute toxicity were available to the EU peer review; in 2015 (EFSA, 2015e) no data gap was identified for this metabolite. However, according to the current scientific approach, additional data would be required to conclude on the genotoxic potential (clastogenic and aneugenic potential) and on its general toxicity in comparison with the parent benzovindiflupyr. It appears that the toxicological data available on metabolites was not the same for the EU peer review and the JMPR.				

5.27.3. Residue definitions

Table 129: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Benzovindiflupyr	Reg. 396/2005: Benzovindiflupyr Peer review (EFSA, 2015e): Benzovindiflupyr	Yes
	Animal products	Benzovindiflupyr The residue is fat soluble	Reg. 396/2005: Benzovindiflupyr Peer review (EFSA, 2015e): Benzovindiflupyr The residue is not fat soluble	Yes
RD RA	Plant products	Benzovindiflupyr	Peer review (EFSA, 2015e): Benzovindiflupyr	Yes
	Animal products	Benzovindiflupyr	Peer review (EFSA, 2015e): Benzovindiflupyr and mono-hydroxylated benzovindiflupyr, free and conjugated (SYN546039) expressed as benzovindiflupyr	No
Conclusion, comments	**Plant commodities:** The residue definitions for enforcement and risk assessment set by JMPR and at EU level are identical. **Animal commodities:** The residue definition for enforcement set by JMPR and at EU level are identical. For risk assessment, the residue definition at EU level is more comprehensive and includes the mono-hydroxylated metabolite SYN546039 (free and conjugated). In the metabolism study in goats, the metabolite represented 22%–50% total radioactive residue			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	(TRR) in tissues and milk. A conversion factor of 2 was proposed to be used consumer risk assessment for animal commodities to account for the contribution of residues of this metabolite. At EU level, the residues were not considered fat soluble.			

5.27.4. Codex MRL proposals

Table 130: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Bulb onion, Subgroup of (includes all commodities in this subgroup)	**0.02**	Garlic: 0.01* Onion: 0.01* Shallot: 0.01*	cGAP: US, foliar, 4 × 76 g a.i./ha, interval 7 days, PHI 7 days Number of trials: 8 on bulb onions Sufficiently supported by data: Yes Specific comments/observations: For bulb onions, 5 trials are sufficient according to JMPR rules. At EU level, 8 trials would be required. Extrapolation from onions to garlic and shallots is acceptable **Conclusion:** The proposed Codex MRL is acceptable and covers onions, garlic and shallots. Follow-up action: None
Sugar cane	**0.4**	0.04	cGAP: US, foliar, 3 × 76 g a.i./ha, interval 14 days, PHI 30 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: see general comments below. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: –
Sugar cane, molasses			2 processing trials. PF 0.04
Sugar cane refined sugar			2 processing trials. PF 0.09
General comments	According to the OECD guidance document, by-products of sugar cane are used as feed items (sugarcane tops, molasse and bagasse). JMPR reported that the previous dietary burden calculations were updated, including STMRs for sugar cane tops and molasses. However, in the calculations reported in Annex 6, these feed items are not listed. While, the contribution from residues in sugar cane molasse is irrelevant, the statement that the residues in sugar cane tops do not significantly increase the livestock burden and the potential contribution of residues in sugar can bagasse (both feed items in non-EU livestock diets) are not substantiated. JMPR concluded that there is no need for updating the MRLs for animal products. Follow-up action: To check in the JMPR evaluation the dietary burden calculation regarding the inclusion of sugar cane tops and molasses and to verify the conclusion that no modification of the MRLs for animal products are required.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.27.5. Consumer risk assessment

Table 131: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 The calculation is based on the HR values for garlic, onions, shallots and sugar cane for which the Codex MRL proposal is higher than the existing EU MRL. To calculate the dietary exposure to cane sugar, the processing factor of 0.04 was used. The risk assessment was performed with the EU/JMPR ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The calculation is based on the STMR values for garlic, onions, shallots and sugar cane for which the Codex MRL proposal is higher than the existing EU MRL, and the STMR values derived in previous assessments (EFSA, 2016q; JMPR, 2016). To calculate the exposure to cane sugar, the processing factor of 0.04 was used. For products of animal origin, the conversion factor of 2 was used to take into consideration residues of SYN546039. For other commodities, EFSA assumed no uses are authorised. The risk assessment was performed with the EU/JMPR ADI.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Garlic: 0.05% of ARfD Onions: 0.34% of ARfD Shallots: 0.04% of ARfD Sugar canes (raw): 0.05% of ARfD Sugar cane (sugar): 0.03% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 5% of the ADI. Among the crops under consideration, sugar cane was identified as the main contributor, accounting for up to 0.27% of the ADI (raw commodity).	**Results:** Long-term exposure: Max 2% of the JMPR ADI. Short-term exposure: Highest result for sugar cane: 1% of ARfD (children), 2% of ARfD (all general population)

5.28. Fluensulfone (265) R

5.28.1. Background information

Table 132: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	No RMS assigned	
Approval status	Not approved	Not assessed in the EU
EFSA conclusion available	No	
MRL review performed	No	
MRL applications/ assessments	No	
Classification of a.s. – cut-off criteria	Not assessed, not concluded	No harmonised classification
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific

		Comments, references
		criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.28.2. Toxicological reference values

Table 133: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.01 mg/kg bw per day	JMPR (2013)	–	No EU assessment	Not appropriate
ARfD	0.3 mg/kg bw	JMPR (2013)	–	No EU assessment	Not appropriate
Conclusion/ comment	In 2017, the EU made a reservation in the CCPR meeting, related to the questions on the residue definition (results of metabolism studies did not reflect results from the field trials) and concern over the genotoxic potential of the MeS metabolite. In response to the concern on genotoxicity of MeS, the JMPR outlined that though there was a weakly positive result in the Ames test, the absence of genotoxicity was supported by negative results in in-vivo studies (micronucleus and liver unscheduled DNA synthesis). However, it is noted that the negative micronucleus assay with MeS must not be used as an argument for the assumption that the metabolite was not genotoxic. Similarly, a negative UDS assay is not considered sufficient for this purpose any longer. The appropriate tests to clarify the mutagenic potential of MeS in vivo would have been either the Comet assay or a study in transgenic rodents. Since the original studies (Ames test and in vivo studies) are not available in the EU for a detailed assessment, a final conclusion on the possible genotoxic potential cannot be derived. JMPR assessed MeS using the TTC approach (Cramer class III). A precondition for using the TTC for Cramer class III is clarity on the absence of a genotoxic potential.				

5.28.3. Residue definitions

Table 134: 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	Default residue definition	No
	Animal products	Fluensulfone The residue is fat soluble	Default residue definition	Yes
RD RA	Plant products	Fluensulfone	–	Not appropriate
	Animal products	Fluensulfone	–	Not appropriate
Conclusion, comments	Since the active substance has never been assessed at EU level and no specific MRLs are established in Annex II or III, currently the default residue definition covering the parent compound only is applicable. A default MRL of 0.01 mg/kg according to Art. 18(1)(b) Reg. 396/2005 is applicable for all commodities. The JMPR residue definitions were proposed in 2014 and modified in 2016: According to the plant metabolism studies assessed by the JMPR in 2014, the main plant metabolites of fluensulfone following the soil/early foliar treatment are thiazole sulfonic acid (TSA, M3625) and butane sulfonic acid (BSA, M3627). Parent fluensulfone was present at trace levels only; TSA was also found to accumulate in rotational crops. In residue trials submitted in 2016, fluensulfone was found in significant concentrations, and therefore, JMPR decided to include also the parent compound in the residue definitions.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	The JMPR did not include TSA in the risk assessment and enforcement residue definition for plants because of its low toxicological relevance and since it is accumulating in rotational crops, thus being not a proper marker for the use of fluensulfone. For metabolite BSA additional toxicity studies were assessed by the JMPR 2016 and it was concluded its residues are unlikely to be of toxicological relevance. However, it was considered as appropriate marker compound for the use of fluensulfone and therefore included in the enforcement residue definition. Metabolite M-3626 (MeS) has not been identified in primary and rotational crop metabolism studies but was detected in residue trials (< 0.01–0.08 mg/kg in cucumber, summer squash, melons, tomatoes and sweet and chilli peppers trials). For plant commodities evaluated by the JMPR (2016, 2019), no residue information on the occurrence of MeS has been provided. However, JMPR considered that MeS is not expected in permanent crops and that based on rotational crop metabolism studies it is not expected in sugar cane and cereal grains. Since metabolite MeS is not covered by the toxicological endpoints, the JMPR applied the TTC approach for the assessment of MeS. Based on the available residue data from field trials (see above) as assessed by JMPR (2014, 2016), the JMPR concluded as to no risk for public health. The same conclusion was derived for the current assessment, although new information on MeS was not provided. The exposure assessment for MeS as estimated by the JMPR is affected by uncertainties since for the majority of crops on which the use of fluensulfone has been reported, no information on MeS residues is available. In 2017, the EU made a reservation in the CCPR meeting related the residue definition; it was noted that the results of metabolism studies did not reflect results from the field trials; hence, it might be expected that additional metabolites occur in treated crops to which consumers might be exposed which have not been identified in the metabolism studies and for which no toxicological information is available. No new information has been provided regarding residue definitions. MS to discuss whether the previous EU position should be maintained (the metabolism studies seem to be not sufficiently reliable and representative for the residue behaviour observed in trials; in residue trials metabolites were detected that were not found in significant levels in the metabolism study. Thus, the information currently available is not sufficient to derive sound residue definitions or whether the proposed residue definitions are considered acceptable.			

5.28.4. Codex MRL proposals

Table 135: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	Default EU MRL	Comment
Citrus fruit, Group of	**0.2**	0.01	cGAP: USA, 1 × (soil, preflowering) 3.92 kg/ha, PHI 60 days Number of trials: 22 trials (8 on oranges, 3 on mandarins, 5 on lemons and 6 on grapefruit). Sufficiently supported by data: Yes Specific comments/observations: Since the application of a.s. takes place before flowering and the data sets are of the same population, the JMPR merged residue data on oranges, lemons, mandarins and grapefruits to derive group MRL. Since mandarins are a major crop in Codex, additional trials would be required. If the trials on the different citrus crops are assessed separately, the following MRL proposals would be derived: oranges 0.09 mg/kg, grapefruit 0.15 mg/kg and lemons 0.3 mg/kg. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions and the lack of residue trials in mandarins. Follow-up action: None

Commodity	Codex MRL proposal	Default EU MRL	Comment
Pome fruit, Group of (except Persimmon, Japanese)	**0.2**	0.01 (Pome fruits, kaki and azaroles)	cGAP: USA, 1 × (soil, preflowering) 3.92 kg/ha Number of trials: Apples (16) and pears (8), trials from USA/CAN Sufficiently supported by data: Yes Specific comments/observations: Codex MRL proposal based on a merged residue data set on apples and pears (populations similar). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Stone fruit, Group of	**0.09**	0.01	cGAP: USA, 1 × (soil, preflowering) 3.92 kg/ha Number of trials: Cherries (5), peaches (9), plums (5) Sufficiently supported by data: No Specific comments/observations: Cherries and plums are major crops in Codex. Hence, the number of trials is not be sufficient. The use on peaches is sufficiently supported and would require an MRL of 0.10 mg/kg. According to EU rules, all these crops are major crops for which 8 trials per each crop would be required. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions and the lack of residue trials for cherries and plums. Follow-up action: None
Small fruit vine climbing, Subgroup of	**0.7**	0.01 (table grapes and wine grapes)	cGAP: USA, 1 × (soil, preflowering) 3.92 kg/ha Number of trials: 9 (grapes) Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Sugar cane	**0.06**	0.01	cGAP: USA, 1 × (soil; at planting) 3.92 kg/ha Number of trials: sugar cane (11) (AUS/USA) Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Tree nuts, Group of	**0.025***	0.01	cGAP: USA, 1 × (soil, preflowering) 3.92 kg/ha Number of trials: Almonds (5), pecans (5) Sufficiently supported by data: Yes Specific comments/observations: Residues in all trials were below the LOQ. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Coffee bean	**0.05**	0.01	cGAP: Brazil, 1 × (row soil treatment) 0.96 kg/ha Number of trials: 8 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	Default EU MRL	Comment
			Specific comments/observations: None **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Wheat, similar grains and pseudo cereals without husks, Subgroup of	**0.08 (R)**	0.01	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 90 days. Number of trials: 15 (wheat) Sufficiently supported by data: Yes Specific comments/observations: The CXL MRL proposal based on the total fluensulfone residues in rotational crop wheat (grain) and takes into consideration the US fluensulfone label requirement to respect the PBI of 90 days for rotational crop wheat. The residues calculated using OECD MRL calculator. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Barley, similar grains and pseudo cereals with husks, Subgroup of	**0.08 (R)**	0.01	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 90 days. Number of trials: 15 (wheat) Sufficiently supported by data: Yes Specific comments/observations: The CXL MRL proposal based on the total fluensulfone residues in rotational crop wheat (grain) and takes into consideration the US fluensulfone label requirement to respect the PBI of 90 days for rotational crop barley. The residues calculated using OECD MRL calculator. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Maize cereals, Subgroup of	**0.15 (R)**	0.01	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months. Number of trials: 18 (maize) Sufficiently supported by data: Yes Specific comments/observations: The CXL MRL proposal is based on the total fluensulfone residues in rotational crop maize (grain), extrapolated to maize and sweetcorn subgroups. The CXL MRL proposal is derived using the data from PBI of 10 months. The residues calculated using OECD MRL calculator. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Sweet corns, Subgroup of	**0.15 (R)**	0.01 (sweet corn and baby corn)	
Rice cereals, Subgroup of	**0.04 (R)**	0.01	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months Number of trials: 11 (rice)

Commodity	Codex MRL proposal	Default EU MRL	Comment
			Sufficiently supported by data: Yes Specific comments/observations: The CXL MRL proposal is based on the total fluensulfone residues in rotational crop rice (grain). The CXL MRL proposal is derived using the data from PBI of 10 months. The residues calculated using OECD MRL calculator. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Sorghum grain and millet, Subgroup of	**0.04 (R)**	0.01	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months Number of trials: 9 (sorghum) Sufficiently supported by data: Yes Specific comments/observations: The CXL MRL proposal is based on the total fluensulfone residues in rotational crop sorghum (grain). The CXL MRL proposal is derived using the data from PBI of 10 months. The residues calculated using OECD MRL calculator. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the previously raised reservation on the residue definitions. Follow-up action: None
Hay or fodder (dry) of grasses except maize fodder and rice straw and fodder, dry	15 (dw)	–	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months Number of trials: 15 (wheat) Sufficiently supported by data: Yes Specific comments/observations: The CXL MRL proposal is based on the total fluensulfone residues observed in wheat hay when wheat is grown as rotational crop (PBI 3 months). The CXL MRL proposal takes into consideration 88% DM content. The residues calculated using OECD MRL calculator. For feed, MRLs are not set in the EU. Follow-up action: None
Maize fodder	0.6 (dw)	–	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months Number of trials: 20 (maize) Sufficiently supported by data: Yes Specific comments/observations: For feed, MRLs are not set in the EU.
Rice straw and fodder, dry	0.06 (dw)	–	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months Number of trials: 11 (rice) Sufficiently supported by data: Yes Specific comments/observations: For feed, MRLs are not set in the EU.
Straw or fodder (dry) of cereal grains (except maize fodder and rice straw and fodder, dry)	6 (dw)	–	cGAP: None. Rotational crop field trials: soil treatment with fluensulfone at 3.6–4.2 kg/ha, PBI 3 and 10 months Number of trials: 15 (wheat) Sufficiently supported by data: Yes Specific comments/observations: For feed, MRLs are not set in the EU.

Commodity	Codex MRL proposal	Default EU MRL	Comment
Almond hulls	7 (dw)	–	cGAP: USA, 1 × (soil, preflowering) 3.92 kg/ha Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: MRL not set in EU for almond hulls.
Citrus pulp, dry	1.5	–	Processing studies from the JMPR 2017. The CXL MRL proposal derived for the RAC (0.2 mg/kg), multiplied by the PF of 6.3 (derived from 2 processing studies; individual PF 12 and 0.72 (> 50% difference)) and rounded to nearest MRL class. See comments on the CXL MRL proposal for citrus fruits.
Citrus oil, edible	1.5	–	Processing studies from the JMPR 2017. The CXL MRL proposal derived for the RAC (0.2 mg/kg), multiplied by the PF of 5.7 (derived from 2 processing studies) and rounded to nearest MRL class. See comments on the CXL MRL proposal for citrus fruits.
Apple juice	0.4	–	The CXL MRL proposal derived for the RAC (0.2 mg/kg), multiplied by the PF of 1.7 (derived from 2 processing studies) and rounded to nearest MRL class. Supported.
Apples, dried	1	–	The CXL MRL proposal derived for the RAC (0.2 mg/kg), multiplied by the PF of 4.8 (derived from 2 processing studies) and rounded to nearest MRL class. Supported.
Prunes	**0.3**	–	The CXL MRL proposal derived for the RAC (0.09 mg/kg), multiplied by the PF of 2.9 (derived from 2 processing studies) and rounded to nearest MRL class. Supported.
Dried grapes	2	–	The CXL MRL proposal derived for the RAC (0.7 mg/kg), multiplied by the PF of 2.4 (derived from 1 processing study) and rounded to nearest MRL class. Not fully supported (1 processing study only).
Sugar cane molasses	0.5	–	The CXL MRL proposal derived for the RAC (0.06 mg/kg), multiplied by the PF of 7.4 (derived from 1 processing study) and rounded to nearest MRL class. Not fully supported (1 processing study only).
General comments	Currently, no specific MRLs are established in Annex II or III of Regulation (EC) No 396/2005. Thus, the default MRLs are applicable in the EU. The primary crop samples derived from trials submitted for the JMPR 2019 assessment were analysed for fluensulfone and its metabolite BSA. The JMPR 2019 also evaluated rotational crop field studies with cereals. The plant-back intervals (PBIs) were 3 months for winter wheat and 10 months for maize, rice, sorghum and spring wheat. Samples were analysed for fluensulfone and metabolite BSA. Fluensulfone residues were detected only in wheat hay (0.02 mg/kg) in the 3-month PBI, whereas BSA was present above LOQ in all commodities. The samples were not analysed for other compounds (TSA, MeS). Based on total residues determined in various cereal products, the JMPR proposed MRLs for cereal crops grown in crop rotation. Pending a decision on reliable residue definitions, a conclusion on the acceptability of the proposed Codex MRLs is not possible. At EU level, risk managers should discuss the possibility to include the metabolites identified in the metabolism studies/residue trials performed with fluensulfone in the EU residue definition (e.g. BSA, TSA and MeS), considering that parent fluensulfone is not a reliable marker for use of fluensulfone. It is noted that MRLs derived from rotational crop studies are specifically labelled – (R). This element is increasing the transparency and should be considered for other substances as well. (R): MRL proposal derived from rotational crop field studies		

*: Indicates that the MRL is proposed at the limit of quantification.

5.28.5. Consumer risk assessment

Table 136: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The risk assessment was performed with the JMPR ARfD. The calculations are indicative, because the residue definitions derived by the JMPR are not acceptable.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values were the STMR values as derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The risk assessment was performed with the JMPR ADI. The calculations are indicative, because the residue definitions derived by the JMPR are not acceptable.	**Specific comments:** –
Results: **No short-term consumer health risk was identified for the crops under assessment.** Oranges: 3% of ARfD Sweet corn: 2% of ARfD	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 2% of the ADI.	**Results:** Long-term exposure: Max 3% of the JMPR ADI. Short-term exposure: 1% of ARfD

5.29. Tolfenpyrad (269) R

5.29.1. Background information

Table 137: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	First evaluated by JMPR in 2013 (toxicology and residues)
Type of JMPR evaluation	New use	
RMS	no RMS assigned	Not assessed at EU level
Approval status	Not approved	Not notified and not authorised in the EU
EFSA conclusion available	No	–
MRL review performed	No	–
MRL applications/ assessments	No	No MRL applications, but comments were prepared for previous Codex MRL proposals (CCPR 2014 and CCPR 2017); NL informed EFSA that an MRL application is under assessment.
Classification of a.s. – cut-off criteria	Not assessed/not concluded	No harmonised classification
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.29.2. Toxicological reference values

Table 138: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.006 mg/kg bw per day	JMPR (2013)	–	–	Not appropriate
ARfD	0.01 mg/kg bw	JMPR (2013)	–	–	Not appropriate
Conclusion/ comment	In 2013 JMPR concluded that the ADI and ARfD are also applicable to the metabolites PT-CA and OH-PT, which showed similar toxicity to tolfenpyrad in LD_{50} studies but lower toxicity in a 4- week dietary study. In addition, JMPR considered the ADI and ARfD applicable to all the livestock metabolites: OH-PT-CA, PT-CA conjugates and OH-PT-CA conjugates.				

5.29.3. Residue definitions

Table 139: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Tolfenpyrad	Default residue definition under Art. 18(1)(b)	Yes
	Animal products	Sum of tolfenpyrad, and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl) carbonylaminomethyl]phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3(1-hydroxyethyl) -1-methylpyrazol-5-yl] carbonylaminomethyl]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad The residue is not fat soluble	Default residue definition under Art. 18(1)(b)	No
RD RA	Plant products	Tolfenpyrad	–	Not appropriate
	Animal products	Sum of tolfenpyrad, and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl) carbonylaminomethyl]phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3(1-hydroxyethyl) -1-methylpyrazol-5-yl] carbonylaminomethyl]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad	–	Not appropriate
Conclusion, comments	Since no specific MRLs are established in the EU, the default residue definition covering only parent compound are used for enforcement purposes. See also (EFSA, 2014i).			

5.29.4. Codex MRL proposals

Table 140: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
Lemons and Limes, Subgroup of	**0.9**	0.01 Lemons, limes	cGAP: USA, 1 × 0.31 kg/ha, PHI 3 days Number of trials: 8 trials on lemon Sufficiently supported by data: Yes Specific comments/observations: The STMR/HR were derived using a peeling processing factor of oranges (2 processing studies, PF 0.32).

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
			Conclusion: The proposed Codex MRL is acceptable.However, see also general comment on processing. Follow-up action: None
Mandarins, Subgroup of	**0.9**	0.01	cGAP: USA, 1 × 0.31 kg/ha, PHI 3 days Number of trials: 8 trials on lemon Sufficiently supported by data: No Specific comments/observations: Residue trials on mandarins not available. Although not foreseen in the Codex principles for extrapolation, the JMPR proposed to extrapolate residues from lemon to mandarin. According to the EU guidelines, the number of trials on lemons would be sufficient for extrapolation to mandarins. See also Fluxapyroxad (256) proposed extrapolation of residues from lemons to Subgroup of Mandarins. The STMR/HR were derived using a peeling processing factor of oranges (2 processing studies, PF 0.32). **Conclusion:** The proposed Codex MRL is not acceptable because the estimated acute dietary exposure to residues of tolfenpyrad exceeds the toxicological reference value (ARfD). Follow-up action: None
Oranges, Sweet, Sour, Subgroup of	**0.6**	0.01	cGAP: USA, 1 × 0.31 kg/ha, PHI 3 days Number of trials: 11 on orange Sufficiently supported by data: Yes Specific comments/observations: The STMR/HR were derived using a peeling processing factor of oranges (2 processing studies, PF 0.32). **Conclusion:** The proposed Codex MRL is not acceptable because the estimated acute dietary exposure to residues of tolfenpyrad exceeds the toxicological reference value (ARfD). Follow-up action: None
Pummelo and Grapefruits, Subgroup of	**0.6**	0.01	cGAP: USA, 1 × 0.31 kg/ha, PHI 3 days Number of trials: six trials on grapefruit Sufficiently supported by data: Yes Specific comments/observations: The STMR/HR were derived using a peeling processing factor of oranges (2 processing studies, PF 0.32). **Conclusion:** The proposed Codex MRL is acceptable.However, see also general comment on processing. Follow-up action: None
Bulb Onions, Subgroup of	**0.09**	0.01 Garlic, onions, shallots	cGAP: USA, 1 × 0.28 kg/ha, PHI 7 days Number of trials: 6 trials Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal for Subgroup 009A, Bulb Onions, would be applicable to the EU classification for garlic (220010), onions (220020) and shallots (220030). **Conclusion:** The proposed Codex MRL is acceptable.However, see also general comment on processing. Follow-up action: None
Tomatoes, Subgroup of	**0.7**[(b)]	0.01	cGAP: USA, 2 × 0.25 kg/ha, interval 14 days, PHI 1 day Number of trials: 12 trials on tomato (including cherry tomato) Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
			Specific comments/observations: The JMPR concluded that the estimated acute dietary exposure to residues of tolfenpyrad for the consumption of tomatoes may present a public health concern. **Conclusion:** The proposed Codex MRL is not acceptable because the estimated acute dietary exposure to residues of tolfenpyrad exceeds the toxicological reference value (ARfD). Follow-up action: None
Peppers, Subgroup of (except okra, martynia and roselle)	**0.5**	0.01	cGAP: USA, 2 × 0.25 kg/ha, interval 14 days, PHI 1 day Number of trials: eleven trials on peppers (including chilli peppers, n = 3) Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal for peppers (VO 0051) excluding martynia, okra and roselle, would be applicable to the EU classification for sweet peppers/bell peppers (0231020). **Conclusion:** The proposed Codex MRL is not acceptable because the estimated acute dietary exposure to residues of tolfenpyrad exceeds the toxicological reference value (ARfD). Follow-up action: None
Eggplants, Subgroup of	**0.7**[(b)]	0.01	cGAP: USA, 2 × 0.25 kg/ha, interval 14 days, PHI 1 day Number of trials: twelve trials on tomato (including cherry tomato) Sufficiently supported by data: Yes Specific comments/observations: According to the Codex principles, residue trials on tomato are suitable for extrapolation to eggplants (VO 2046). The JMPR concluded that the estimated acute dietary exposure to residues of tolfenpyrad for the consumption of eggplants may present a public health concern. **Conclusion:** The proposed Codex MRL is not acceptable because the estimated acute dietary exposure to residues of tolfenpyrad exceeds the toxicological reference value. Follow-up action: None
Citrus pulp, dry	**6**	–	A concentration of residues occurs in citrus dried pomace and the JMPR evaluation derived a processing factor on the basis of a single value reviewed in 2013 (PF = 8.9). EU MRLs are not set for processed commodities/by-products, such as citrus dried pomace.
Citrus oil, edible	**80**	–	A concentration of residues occurs in citrus oil and the JMPR evaluation derived a processing factor on the basis of a single value reviewed in 2013 (PF = 83). EU MRLs are not set for processed commodities/by-products, such as citrus oil.
Peppers chilli, dried	**5**	–	A default concentration factor of 10 was used to derive the Codex MRL proposal for dried chilli peppers. EU MRLs are not set for processed products, such as dried chilli peppers.
Milks	0.01*	0.01	The JMPR calculated the dietary burden for livestock on the basis of residues in feed crops under assessment and their by-products (tomato wet pomace and dried citrus pulp), and residues in previously assessed feed crops and their by-products (potato, STMR and HR = 0; JMPR 2016). The max estimated burden for cattle was calculated for AUS dairy cattle. The MRL proposal was derived from the lactating-cattle feeding study.

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
			Conclusion: The proposed Codex MRL is acceptable. Follow-up action: None
Mammalian fats except milk fats	0.01*	0.01	See milks
Meat (from mammals other than marine mammals)	0.01*	0.01	See milks
Edible offal (mammalian)	**0.4**	0.01	At the expected dietary burden residues are expected in liver according to the feeding study of 0.38 mg/kg. The proposed Codex MRL is acceptable.
Eggs	0.01*	0.01	No feed items in the livestock dietary burden for poultry for the crops under assessment and their by-products. The JMPR considered the dietary burden for poultry to be currently zero, and therefore, the JMPR estimated MRLs at the LOQ of 0.01 mg/kg for all poultry commodities. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry, edible offal of	0.01*	0.01	See eggs
Poultry fats	0.01*	0.01	See eggs
Poultry meat	0.01*	0.01	See eggs
General comments	(a): Default MRL of 0.01 mg/kg according to Art. 18(1)(b) Reg 396/2005. (b): On the basis of the information provided the JMPR concluded that the estimated acute dietary exposure to residues of tolfenpyrad for the consumption of these commodities may present a public health concern. Processing data: Data on the nature of residues in processed products has not be reported (neither in 2020 JMPR assessment nor in 2013 and 2016 assessment).		

*: Indicates that the MRL is proposed at the limit of quantification.

5.29.5. Consumer risk assessment

Table 141: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities for which the Codex MRL proposal is higher than the existing EU default MRL of 0.01 mg/kg. The toxicological reference values have not been evaluated at EU level. The risk assessment was performed with the JMPR ARfD. The risk assessment is affected by additional non-standard uncertainties related to the use of processing factors derived for oranges which were extrapolated to other citrus crops. In addition, no information is available on the nature of residues in processed products (e.g. pasteurised citrus juices).	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The STMR values derived by JMPR were used. The toxicological reference values have not been evaluated at EU level. The risk assessment was performed with the JMPR ADI. The risk assessment is affected by additional non-standard uncertainties related to the use of processing factors derived for oranges which were extrapolated to other citrus crops. In addition, no information is available on the nature of residues in processed products (e.g. pasteurised citrus juices).	**Specific comments:** JMPR concluded that the estimated acute dietary exposure to residues of tolfenpyrad for the consumption of tomatoes and eggplants may present a public health concern.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: **The calculated short-term exposure exceeded the ARfD for several crops under assessment.** Commodities exceeding the ARfD in children and adult diets (IESTI calculation) Tomatoes: 291% of ARfD (BE toddler) Peppers: 190% of ARfD (DE child) Oranges: 172% of ARfD (UK infant) Eggplants: 135% of ARfD (NL general) and 125% of ARfD (UK child) Mandarins: 107% of ARfD (NL toddler) Commodities where IESTIs were below 100% ARfD in children and adult diets (rank order) Grapefruits: 78% of ARfD (child) Lemons: 62% of ARfD (child) Limes: 36% of ARfD (child) Bovine, Liver: 31% of ARfD (child) Bovine, Edible offals (other than liver and kidney): 28% of ARfD (child) Bovine, Kidney: 14% of ARfD (child)	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for up to 20% of the ADI (NL toddler). Among the crops under consideration, tomato was identified as the main contributor, accounting for up to 7.8% of the ADI (GEMS/Food G06 diet).	**Results:** Long-term exposure: Max 1–20% of the JMPR ADI. Short-term exposure: Highest result for eggplant: 240% of ARfD (CN child), and tomato: 190% of ARfD (CN child).

5.30. Mesotrione (277) R/T

5.30.1. Background information

Table 142: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	UK (BE co-RMS)	
Approval status	Approved	Commission Implementing Regulation (EU) 2017/725[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2016e) (EFSA, 2018ad) (confirmatory data)
MRL review performed	Yes, see comments	(EFSA, 2015b)
MRL applications/ assessments	No	
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione 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 107, 25.4.2017, p. 24–28.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.30.2. Toxicological reference values

Table 143: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.5 mg/kg bw per day	JMPR (2014)	0.01 mg/kg bw per day	(EFSA, 2016e) (mouse multigeneration study and 200 UF) confirmed in (European Commission, 2017a)	No
ARfD	Unnecessary	JMPR (2014)	0.02 mg/kg bw	(EFSA, 2016e) (mouse multigeneration study and 100 UF) confirmed in (European Commission, 2017a)	No
Conclusion/ comment	At the EU level the ADI is 0.01 mg/kg body weight (bw) per day, based on decreased organ weights in pups in the mouse multigeneration study with an NOAEL of 2 mg/kg bw per day, applying an increased uncertainty factor (UF) of 200 to account for the increased tyrosinaemia at the NOAEL whereas JMPR set the ADI of 0.5 mg/kg bw per day based on decreased body weight, body weight gain and feed efficiency in male mice in the 18-month mice study. An UF of 100 was applied. The differences between EU peer review and JMPR can be allocated to different NOAEL setting in the critical study in the EU peer review (i.e. The NOAEL for offspring toxicity in the mouse multigeneration study was set by JMPR at higher dose levels than in EU). It is not clear from the JMPR report how the relevance of decreased weights in pups was assessed by JMPR. At the EU level the acute reference dose (ARfD) is 0.02 mg/kg bw, based on the NOAEL of 2 mg/kg bw per day (i.e. NOAEL for offspring toxicity the mouse multigeneration study) as developmental effects may be relevant to acute exposure, standard UF of 100 applied; whereas JMPR considered not necessary to set an ARfD. The differences between EU peer review and JMPR can be allocated to different NOAEL setting in the critical study in the EU peer review (i.e. The NOAEL for offspring toxicity in the mouse multigeneration study was set by JMPR at higher dose levels than in EU). At the EU level toxicological studies were submitted on metabolites MNBA and AMBA. – MNBA is of low acute toxicity by the oral and dermal routes; it is unlikely to be genotoxic and presented a lower toxicity profile compared with mesotrione. – AMBA is of low acute oral toxicity and did not present mutagenic potential in an Ames test; however, AMBA gave positive results in an *in vitro* cytogenetic assay, and no *in vivo* genotoxicity follow up testing were available; repeated dose toxicity would also have to be addressed as this metabolite is relevant to consumer risk assessment. In 2019, JMPR assessed additional studies on metabolite MNBA and AMBA that allowed them to conclude that metabolites MNBA and AMBA are unlikely to be genotoxic and unlikely to be of safety concern. Additional data available to JMPR have not been peer reviewed at EU, therefore a firm conclusion on the toxicological profile of AMBA cannot be drawn.				

5.30.3. Residue definitions

Table 144: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Mesotrione	Reg. 396/2005: Mesotrione Peer review (EFSA, 2016e): Mesotrione (cereals and pulses/oilseeds only) MRL review Art. 12 (EFSA, 2015b): Mesotrione (cereals and pulses/oilseeds only)	Yes, considering the residue definition in legislation
	Animal products	Mesotrione The residue is not fat soluble	Reg. 396/2005: Mesotrione Peer review (EFSA, 2016e): Not required for the representative use (provisional)	Yes, considering the residue definition in the legislation

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			MRL review Art. 12 (EFSA, 2015b): AMBA (free and conjugated) (ruminants) The residue is not fat soluble	
RD RA	Plant products	Mesotrione	Peer review (EFSA, 2016e): Mesotrione (cereals and pulses/oilseeds only) MRL review Art. 12 (EFSA, 2015b): Mesotrione (cereals and pulses/oilseeds only).	Yes, for cereals and pulses/ oilseeds only
	Animal products	Mesotrione	Peer review (EFSA, 2016e): Not required for the representative use (provisional) MRL review Art. 12 (EFSA, 2015b): AMBA (free and conjugated) (ruminants)	No
Conclusion, comments	Plant commodities The residue definitions derived in the MRL review is based on metabolism studies with maize (soil and foliar application) and peanuts (soil application). JMPR evaluated a wider range of metabolism studies (cranberries (foliar application), soybean (tolerant) and maize (soil and foliar application), rice and peanut (soil treatment)). The study with cranberries indicates that in berries the parent mesotrione and its metabolite AMBA are relevant residues. Maize, soya and rice feed commodities contained MNBA and AMBA > 10% TRR in most cases. During the peer review for the renewal of mesotrione, metabolism studies with maize (soil and foliar application) and peanuts (soil application) were reassessed and an additional metabolism study on soybean (tolerant) was evaluated. Based on the studies on conventional crops, the residue definition for risk assessment in feed commodities was provisionally proposed as mesotrione and AMBA (including its conjugates), pending on the toxicological profile of AMBA conjugates. Animal commodities The residue definitions for animal commodities proposed by the MRL review is based on a study with lactating cow dosed with AMBA. JMPR assessed additional metabolism studies with lactating cows, swine and poultry, each dosed with mesotrione. Results indicate that AMBA > 10% is present only in kidney of cow, whereas mesotrione is the main component of the TRR in cow liver and kidney, tissues of swine and poultry and in eggs. During the peer review for the renewal, the residue definitions for animal commodities were not derived as livestock metabolism studies were not triggered for the representative use.			

5.30.4. Codex MRL proposals

Table 145: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus fruit, Group of (includes all commodities in this group)	0.01*	Citrus fruits: 0.01* Kumquat: 0.01*	cGAP: USA, 2 × 210 g a.i./ha, PHI of 1 day (application at the basis of the tree) Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: Combined data set of trials performed on orange (11), grapefruit (6) and lemon (5), approximating the GAP but with a shorter interval between applications, extrapolated to the whole group of citrus fruit. Residues were always below the LOQ of 0.01 mg/kg. Results from the trials confirmed by 6 additional trials on fruit trees (including citrus) conducted at an exaggerated rate (3×) for the purpose of studying processing. At EU level, the discussion on the relevance of AMBA as regards inclusion in the residue definition and its toxicological properties is not yet finalised.

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is acceptable. Follow-up action: None
Pome fruits, group of (includes all commodities in this group)	0.01*	Pome fruits: 0.01* Azaroles, kaki: 0.01*	cGAP: USA, 2 × 210 g a.i./ha, PHI of 30 days (application at the basis of the tree). Number of trials: 18 Sufficiently supported by data: Yes Specific comments/observations: Combined data set of trials performed on apples (12) and pears (6), approximating the GAP but with a shorter interval between applications, extrapolated to the whole group of pome fruits. Residues were always below the LOQ of 0.01 mg/kg. Results from the trials confirmed by 6 additional trials on fruit trees (including pome) conducted at an exaggerated rate (3×) for the purpose of studying processing. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Stone fruits, Group of (includes all commodities in this group)	0.01*	0.01*	cGAP: USA, 2 × 210 g a.i./ha, PHI of 30 days (application at the basis of the tree). Number of trials: 21 Sufficiently supported by data: Yes Specific comments/observations: Combined data set of trials performed on cherries (6), peaches (9) and plums (6), approximating the GAP but with a shorter interval between applications, extrapolated to the whole group of stone fruit. Residues were always below the LOQ of 0.01 mg/kg. Results from the trials confirmed by 6 additional trials on fruit trees (including stone fruits) conducted at an exaggerated rate (3×) for the purpose of studying processing. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Tree nuts Group of (includes all commodities in this group)	0.01*	0.01*	cGAP: USA, 2 × 210 g a.i./ha, PHI of 30 days (application at the basis of the tree). Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: Combined data set of trials performed on almonds (5) and pecans (5), approximating the GAP but with a shorter interval between applications, extrapolated to the whole group of stone fruit. Residues were always below the LOQ of 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Almond hulls	0.04 (dw)	–	
General comments	Due to differences in enforcement and risk assessment residue definitions between EU and the JMPR for plant commodities, in principle the derived Codex MRL proposals should not be taken over in EU legislation. However, considering that in the GAPs assessed by the JMPR, the application is done at the basis of the tree and the low to moderate persistence of mesotrione and AMBA in soil, significant residues of metabolite AMBA are not expected in the fruit crops under assessment. Nevertheless, it should be confirmed that the application is done by using a proper equipment to avoid spray drift of the crops.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.30.5. Consumer risk assessment

Table 146: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities under assessment. The calculations are affected by additional, non-standard uncertainties, related to the lack of residue trials analysing for metabolite AMBA and a firm conclusion on the toxicological profile of AMBA. The risk assessment was performed with the EU ARfD. The calculations are indicative, since the consumer exposure to metabolite AMBA (relevant for the fruit crops) could not be assessed. However, if it is confirmed that the application is done by using a proper equipment to avoid spray drift of the crops, significant residues of metabolite AMBA are not expected in the fruit crops under assessment.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2015b) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The calculations are affected by additional, non-standard uncertainties, related to the lack of residue trials analysing for metabolite AMBA and a firm conclusion on the toxicological profile of AMBA. The risk assessment was performed with the EU ADI. The calculations are indicative, since the consumer exposure to metabolite AMBA (relevant for the fruit crops) could not be assessed. However, if it is confirmed that the application is done by using a proper equipment to avoid spray drift of the crops, significant residues of metabolite AMBA are not expected in the fruit crops under assessment.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Pears, oranges: 7% of ARfD Apples, peaches: 5% of ARfD Grapefruits: 4% of ARfD Mandarins: 3% of ARfD Plums, apricots, lemons: 2% of ARfD Quinces, limes: 1% of ARfD Cherries, medlar, loquats, tree nuts: < 1% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 3% of the ADI. Among the crops under consideration, apples were identified as the main contributor, accounting for up to 1% of the ADI.	**Results:** Long-term exposure: Max 0% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.31. Acetochlor (280) R/T

5.31.1. Background information

Table 147: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status	Not approved	Commission Implementing Regulation (EU) No 1372/2011[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2011d) Application for renewal of the approval has been withdrawn

		Comments, references
MRL review performed	Yes, see comments	(EFSA, 2013j)
MRL applications/ assessments	Yes, see comments	(EFSA, 2015r) (import tolerance application for soyabeans and cotton) Import tolerance request for soyabeans (ongoing, additional data requested)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 1372/2011, concerning the non-approval of the active substance acetochlor, 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 Commission Decision 2008/934/EC. OJ L 341, 22.12.2011, p. 45–46.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.31.2. Toxicological reference values

Table 148: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.01 mg/kg bw per day	JMPR (2015)	0.0036 mg/kg bw per day	(EFSA, 2011d) (78-week mice study and 300* UF) confirmed in (European commission, 2011c)	No
ARfD	1 mg/kg bw	JMPR (2015)	1.5 mg/kg bw	(EFSA, 2011d) (acute neurotoxicity rat study and 100 UF) confirmed in (European Commission, 2011c)	No
Conclusion/ comment	*: Additional safety factor of 3 because of the use of an LOAEL. During the **EU evaluations**, the metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and N-oxamic acid were considered covered by the toxicological reference values of the parent (EFSA, 2011d). Additionally, an isomer ratio 1:1 for t-sulfonic acid and s-sulfonic acid was also considered covered by the parent. For the metabolite t-norchloro acetochlor, genotoxic and carcinogenic properties could not be excluded on the basis of the available data (EFSA, 2015r). However, in the metabolism study with soybeans t-norchloro acetochlor was not detected (ongoing IT application). In the **JMPR evaluation**, the metabolites *tert*-sulfinyllactic acid and 1-hydroxyethyl sec-oxanilic acid were concluded unlikely to be genotoxic. For chronic toxicity, a threshold of toxicological concern (TTC) of 1.5 μg/kg bw per day applies. However, the information provided in the JMPR report was insufficient to conclude definitively on the general toxicity of these metabolites relative to that of acetochlor.				

5.31.3. Residue definitions

Table 149: 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 compounds hydrolysable with base to 2-ethyl-6-methylaniline (EMA) and 2-(1-hydroxyethyl)-6-methylaniline (HEMA), expressed in terms of acetochlor The residue is not fat soluble	Reg. 396/2005: Acetochlor MRL review Art. 12 (EFSA, 2013j): No final recommendation Peer review (EFSA, 2011d): Sum of all compounds forming EMA and HEMA on hydrolysis, expressed as acetochlor The residue is not fat soluble	No (compared with current RD set in MRL Reg.)
	Animal products			No (compared with current RD set in MRL Reg.)
RD RA	Plant products	Sum of compounds hydrolysable with base to 2-ethyl-6-methylaniline (EMA) and 2-(1-hydroxyethyl)-6-methylaniline (HEMA), expressed in terms of acetochlor The residue is not fat soluble	Peer review (EFSA, 2011d): All compounds forming EMA and HEMA on hydrolysis plus N-oxamic acid, expressed as acetochlor (applicable to cereal grains and rotational crops). No residue definition was proposed for animal commodities.	Yes
	Animal products			Yes
Conclusion, comments	The residue definitions for enforcement for plants and animal products established by JMPR and in the EU MRL legislation are not compatible. It is noted that the existing residue definition is acetochlor, which is unlikely to be present due to rapid and extensive degradation. Therefore, at EU level the revision of the residue definition should be considered as recommended in the EFSA MRL review (EFSA, 2013j).			

5.31.4. Codex MRL proposals

Table 150: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Alfalfa hay	30 (dw)	–	cGAP: USA, preplant/at-planting/pre-emergence and post-emergence (up to or at the 4th-trifoliate stage – new stands – or following spring green-up – fall-planted or established stands – or between cuttings), with a max rate of 3.4 kg a.i./ha per year and a PHI of 20 days. Number of trials: 8 (forage and hay) Sufficiently supported by data: Yes **Conclusion:** EU MRLs are currently not set for animal feed items. Follow-up action: None
Legume animal feed, except alfalfa hay	3 (dw)	–	The old CXL for legume animal feed (3 mg/kg (dw) is replaced by a new Codex MRL proposal at the same level, excluding alfalfa hay, since a new Codex MRL is proposed for alfalfa (see above).
Soyabean (dry)	**1.5**	0.01*	cGAP: USA, preplant/pre-emergence and post-emergence (before the R2 growth stage, full flowering) at up to 1.7 kg a.i./ha (max. rate per year of 3.4 kg a.i./ha). Number of trials: 13 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: The number of residue trials would be sufficient to derive an MRL proposal. However, several deficiencies were noted in the ongoing import tolerance application for a comparable GAP which is currently on clock-stop. The following data were requested: – standard hydrolysis study; – fully validated analytical method for livestock). According to the data submitted in support of the EU import tolerance application, 8 more trials are available; based on the complete data set (13 + 8 trials) an MRL of 1 mg/kg would be sufficient (STMR of 0.19 mg/kg, HR is unaffected). **Conclusion:** The proposed Codex MRL is not acceptable because the residue definitions are currently not compatible. In addition, the nature of residues in processed products should be investigated, by providing standard hydrolysis studies. Follow-up action: None
Edible offal (mammalian)	**0.05**	0.01*	cGAP: Australian livestock dietary burden (highest max DB: 16.57 DM/kg beef cattle; Highest mean 6.29 DM/kg beef cattle) Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is not acceptable because the residue definitions are currently not compatible.In addition, deficiencies were identified for the Codex MRL proposal on soyabeans which would be also relevant for soya meal used as feed and consequently for food of animal origin. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.31.5. Consumer risk assessment

Table 151: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The calculations are affected by additional, non-standard uncertainties, due to the different residue definitions established by JMPR and at EU level and the fact that the toxicological profile of certain metabolites was not fully characterised. Furthermore, the potential formation of additional degradation products which may be of toxicological relevance cannot be excluded. The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The EU MRLs were used for the input values, and/or the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The calculations are affected by additional, non-standard uncertainties; see acute exposure assessment. The risk assessment was performed with the EU ADI.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the commodities under assessment.	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted	**Results:** Long-term exposure: Max 4% of the JMPR ADI.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Bovine liver: 0.02% of ARfD Soybeans: 0.02% of the ARfD	for 35% of the ADI (NL toddler). Among the crops under consideration, soybeans were identified as the main contributor, accounting for up to 15.5% of the ADI (GEMS/Food G11).	Short-term exposure: Highest result: 0% of ARfD

5.32. Flonicamid (282) R

5.32.1. Background information

Table 152: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	FI	
Approval status	Approved	Commission Directive 2010/29/EU[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2010a)
MRL review performed	Yes, see comments	(EFSA, 2014j)
MRL applications/ assessments	Yes, see comments	(EFSA, 2020h) (Confirmatory data following Art. 12 review) (EFSA, 2020l) (import tolerances in various crops and animal products) (EFSA, 2019h) (strawberries and small fruits) (EFSA, 2018v) (various root crops) (EFSA, 2018u) (various crops) (EFSA, 2017d) (various commodities) (EFSA, 2016k) (herbs and edible flowers) (EFSA, 2015l) (several crops)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): 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.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.32.2. Toxicological reference values

Table 153: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.07 mg/kg bw per day	JMPR (2015)	0.025 mg/kg bw per day	(European Commission, 2010a) (Rabbit developmental, and 100 UF) confirmed in (EFSA, 2014j)	No
ARfD	Unnecessary	JMPR (2015)	0.025 mg/kg bw		No
Conclusion/ comment	–				

5.32.3. Residue definitions

Table 154: 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
	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. These compounds were identified in metabolism studies in cereals, root crops and fruits (peach and pepper). The current EU MRLs include these compounds as they were considered relevant marker compounds. Since the ratios of parent, TFNA and TFNG are not stable enough, robust conversion factors could not be established. Therefore, the Codex MRL proposals derived are not compatible with the EU residue definitions.			

5.32.4. Codex MRL proposals

Table 155: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Lemons and Limes, subgroup of (includes all commodities in this subgroup)	**1.5**	0.15	cGAP: 3 × 100 g a.s./ha; PHI 0 days (USA) Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is not acceptable because the residue definitions are not compatible. Follow-up action: None
Oranges, Sweet, Sour, subgroup of (includes all commodities in this subgroup)	**0.4**	0.15	cGAP: 3 × 100 g a.s./ha; PHI 0 days (USA) Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is not acceptable because the residue definitions are not compatible. Follow-up action: None
Pumelo and grapefruit (including Shaddock-like hybrids) Subgroup of (including all commodities in this subgroup)	**0.3**	0.15	cGAP: 3 × 100 g a.s./ha; PHI 0 days (USA) Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: The EU rules for extrapolations allow extrapolating trials from oranges to grapefruits 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 are not compatible. Follow-up action: None

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus pulp, Dry	3 (dw)	–	The JMPR estimated a processing factor for flonicamid (parent only) of 1.8 for citrus dry pulp based on one processing study. The maximum residue level of 3 mg/kg for citrus pulp, dry was estimated on the basis of the processing factor of 1.8 for orange pulp, dry and the maximum residue level for lemon of 1.5 mg/kg.
General comments	The EMS noted that previously the EU has raised concerns for residue trials with PHI of 0 days, because residues may increase over time. In the current case however, considering that the trials were performed with performed with 3 applications, EFSA is of the opinion that residue trials with a short PHI are sufficient.		

5.32.5. Consumer risk assessment

Table 156: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (lemons and limes, oranges, pumelo and grapefruit). The consumer exposure was assessed considering the HR for each crop. No refinement was performed. The risk assessment was performed with the EU ARfD. The calculations are indicative, because information on the magnitude of metabolites TFNA and TFNG, expected to be a significant part of the residues, is not available.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2020l) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (lemons and limes, oranges, pumelo and grapefruit). The risk assessment was performed with the EU ADI. The calculations are indicative, because information on the magnitude of metabolites TFNA and TFNG, expected to be a significant part of the residues, is not available.	**Specific comments:** Only long-term dietary exposure assessment was performed as JMPR (2015) decided that an ARfD for flonicamid was unnecessary.
Results: The calculated short-term exposure exceeded the ARfD for one crop under assessment. Oranges: 127% of ARfD Lemons: 97% of ARfD Limes: 57% of ARfD Grapefruits: 41% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 31% of the ADI. Among the crops under consideration, orange was identified as the main contributor, accounting for up to 1.9% of the ADI.	**Results:** Long-term exposure: Max 10% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.33. Fluazifop-p-butyl (283) R

5.33.1. Background information

Table 157: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approved	Commission Implementing Regulation (EU) No 201/2013[(a)]

		Comments, references
EFSA conclusion available	Yes, see comments	(EFSA, 2010m)
MRL review performed	Yes, see comments	(EFSA, 2015s)
MRL applications/ assessments	Yes, see comments	(EFSA, 2018f) (tomato) (EFSA, 2017g) (various products of plant and animal origin) (EFSA, 2016l) (pumpkin seeds) (EFSA, 2015h) (several commodities)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 201/2013 of 8 March 2013 amending Implementing Regulations (EU) No 788/2011 and (EU) No 540/2011 as regards an extension of the uses for which the active substance fluazifop-P is approved. OJ L 67, 9.3.2013, p. 6–9.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.33.2. Toxicological reference values

Table 158: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.004 mg/kg bw per day	JMPR (2016)	0.01 mg/kg bw per day	(EFSA, 2010m) (2-year rat study with fluazifop acid supported by 81-weeks mice and multigeneration studies in rats (uncertainty factor 100); the ADI expressed as fluazifop acid)	No
ARfD	0.4 mg/kg bw	JMPR (2016)	0.017 mg/kg bw	(EFSA, 2010m) (2-year rat study with fluazifop acid supported by 81-weeks mice and multigeneration studies in rats (uncertainty factor 100); ARfD expressed as fluazifop acid)	No
Conclusion/ comment	–				

5.33.3. Residue definitions

Table 159: 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 fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop	Yes, see the comments below
	Animal products	Sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid The residue is fat soluble	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop The residue is fat soluble	Yes, see comments below

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL),5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop	No
	Animal products	Sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop	Yes, see comment below
Conclusion, comments	The EU residue definition covers the R-enantiomer (fluazifop-P) and all constituent isomers. JMPR restricted the residue definition to fluazifop-P butyl, fluazifop-P-acid and their conjugates. The analytical methods used for enforcement do not discriminate between fluazifop-P and fluazifop-S (and the related metabolites). Hence, the EU and JMPR residue definitions are considered comparable. It is noted that JMPR included two metabolites in the risk assessment residue definition for plants which are not covered by the EU residue definition (i.e. 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL) and 5-trifluoromethyl-2-pyridone (X)). Since these metabolites were not analysed in the residue trials, JMPR used adjustments factors derived from the metabolism studies and molecular weight correction factors to cover their contribution to the risk exposure calculation (see also the risk consumer section). 5-Trifluoromethyl-2-pyridone (X) metabolite was found in significant amounts in the rational crop studies, representing > 60% in most crop commodities. The inclusion of this metabolite in the EU residue definition should be considered. For animal commodities, although JMPR restricted the residue definitions to the active isomer only (fluazifop-P), the residue definition at EU and JMPR level are considered comparable.			

5.33.4. Codex MRL proposals

Table 160: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cane berries, Subgroup of	**0.08**	0.01* (blackberries, dewberries, raspberries)	cGAP: USA, 2 × 0.42 kg/ha, RTI 14 days, PHI 1 day Number of trials: 3 (blackberry), 2 (raspberry) Sufficiently supported by data: Yes Specific comments/observations: All the residues were below 0.05 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Currants, black, red, white	0.01* (W)	0.1	The existing CXL will be replaced by the proposed Codex MRL for the Subgroup of bush berries. (See below, bush berries)
Gooseberry	0.01*(W)	0.1	The existing CXL will be replaced by the proposed Codex MRL for the Subgroup of bush berries. (See bush berries below)
Bush berries, Subgroup of	**0.3**	0.1 (blueberries, currants, gooseberries, rose hips)	cGAP: USA, 2 × 0.42 kg/ha, RTI 14 days, PHI 1 day Number of trials: 7 in blueberries Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL for whole group of bush berries covers blueberries, currants, gooseberries and rose hips. According to Codex extrapolation rules, blueberry trials are acceptable to derive the group MRL. In the EU additional trials on currants and/or on grapes would be needed. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

Commodity	Codex MRL proposal	EU MRL	Comment
Elderberries	**0.3**	0.1	cGAP: USA, 2 × 0.42 kg/ha, RTI 14 days, PHI 1 day The USA GAP on bush berries covers also high bush cranberries and elderberry. No trials were submitted. JMPR extrapolated the residue trials from blueberries to elderberries. Sufficiently supported by data: No Specific comments/observations: An extrapolation from blueberries to elderberries is not foreseen in the Codex extrapolation rules. In the EU, the data would not be accepted either (residue trials in elderberries or additional trails on currants and/or grapes would be required) **Conclusion:** The proposed Codex MRL is not acceptable. Follow-up action: none
Guelder rose	**0.3**		See the elderberries
Strawberry	**3**	0.3	cGAP: USA: 1 × 0.28, PHI 14 days Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: Strawberries are a major crop in Codex (crop for which refinement criteria applied). In the EU, strawberries are major crops and therefore 8 residue trials would be needed. **Conclusion:** The proposed Codex MRL is not acceptable because an acute risk to the European consumer has been identified (see below) and because the number of trials is insufficient. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.33.5. Consumer risk assessment

Table 161: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. It should be noted that JMPR used additional factors to compensate the contribution of the metabolites included in the RA residue definition that were not analysed in the field trials. These factors were derived from the metabolism studies and the molecular weight. Since the metabolites are not included in the EU residue definition, the input values are slightly higher than required for the EU RD. The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2018f) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. It should be noted that JMPR used additional factors to compensate the contribution of the metabolites included in the RA residue definition that were not analysed in the field trials. These factors were derived from the metabolism studies and the molecular weight. The risk assessment was performed with the EU ADI.	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: The calculated short-term exposure exceeded the ARfD for one of crops under assessment. Strawberries: 144% of ARfD; Currants: 12% of ARfD Blueberries: 9% of ARfD Gooseberries: 9% of ARfD Blackberries: 5% of ARfD Raspberries: 4% of ARfD Dewberries: 0.8% of ARfD	**Results:** The calculated long-term exposure exceeded the ADI. The overall chronic exposure accounted for 142% of the ADI. It is noted that the exceedance is mainly attributed to soyabeans (GEMS diets). Further refinements of the exposure calculations might be possible. Among the crops under consideration, strawberries were identified as the main contributor, accounting for up to 3.4% of the ADI.	**Results:** Long-term exposure: Max 63% of the JMPR ADI. It is noted that JMPR decided to withdraw the CXL in sweet potato and yam since they resulted in a chronic risk to the consumer. Short-term exposure: Highest result for strawberry: 6% of ARfD

5.34. Flupyradifurone (285) R

5.34.1. Background information

Table 162: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/2084[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2015d) (EFSA, 2017l) (confirmatory data M-Tox and Phys/chem)
MRL review performed	Yes, see comments	In the framework of the EU pesticides peer review
MRL applications/ assessments	Yes, see comments	(EFSA, 2021g)[(c)] (okra/lady's finger) (EFSA, 2020s) (rapeseed mustard seeds) (EFSA, 2020k) (assessment of confirmatory data, import tolerances and MRL modifications) (EFSA, 2016g) (strawberries, blackberries and raspberries)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): 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.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.
(c): The assessment performed in the recently published reasoned opinion could not be taken into account for the assessment in this report.

5.34.2. Toxicological reference values

Table 163: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.08 mg/kg bw per day	JMPR (2015)	0.064 mg/kg bw per day	(EFSA, 2015d) (rat two-generation study and 100 UF) confirmed in (European Commission, 2015)	No
ARfD	0.2 mg/kg bw	JMPR (2015)	0.15 mg/kg bw	(EFSA, 2015d) (rabbit developmental toxicity study and 100 UF) confirmed in (European Commission, 2015)	No
Conclusion/ comment	Reference values of the parent are applicable to the metabolite difluoroacetic acid (DFA).				

5.34.3. Residue definitions

Table 164: 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 The residue is not fat soluble	Reg. 396/2005: 1) Flupyradifurone 2) Difluoroacetic (DFA) (expressed as DFA)	No
	Animal products	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.	Reg. 396/2005: 1) Flupyradifurone 2) Difluoroacetic (DFA) (expressed as DFA) The residue is not fat soluble	No
RD RA	Plant products	Sum of flupyradifurone, difluoroacetic acid and 6-chloronicotinic acid, expressed as parent equivalents.	Peer review (EFSA, 2015d): Sum flupyradifurone and DFA expressed as flupyradifurone	No
	Animal products	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.	Peer review (EFSA, 2015d): Sum of flupyradifurone and DFA, expressed in flupyradifurone	Yes
Conclusion, comments	In the EU, a separate enforcement residue definition for plant and animal commodities is set that refers to a soil metabolite difluoroacetic acid (DFA, expressed as DFA). Thus, the EU and JMPR residue definitions are not compatible. Since detailed information on DFA residues in the crops assessed by JMPR was reported in the JMPR evaluation, Codex MRL proposals for DFA in plant commodities could be derived. The different residue definitions for animal commodities set in the EU and by JMPR are not relevant, since no Codex MRL proposals for animal products are under assessment. The RA residue definition derived by the JMPR for plant commodities includes also 6-CNA metabolite, which was not considered relevant by the EU pesticides peer review. Thus, the exposure calculated for this residue definition of JMPR would be overestimated to a certain extent. However, 6-CNA is minor metabolite.			

5.34.4. Codex MRL proposals

Table 165: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Avocado	**0.6**	0.01*	cGAP: USA, 2 × 205 g/ha, 14-day interval, PHI 1 day Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Information on DFA residues is not available from the JMPR report. If details are reported in the JMPR evaluation, the corresponding DFA MRL could be derived. **Conclusion:** The proposed Codex MRL for RD 1 is acceptable, but no MRL proposal was derived for the second EU RD (DFA). Follow-up action: To check details in JMPR evaluation.
Cocoa beans	0.01*	0.05*	cGAP: Ghana, 4 × 15 g/ha, PHI 7 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: The same GAP and residue trials are assessed by EFSA under currently ongoing MRL application on import tolerances. The residue data on DFA indicate that existing EU MRL set at the LOQ of 0.1* can be modified to 0.06 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Cane berries	**6**	blackberries and raspberries: 1.5; dewberries: 0.01*	cGAP: USA, 2 × 205 g/ha, 7-day interval, PHI 10 days Number of trials: 10 (4 blackberries + 6 raspberries) Sufficiently supported by data: Yes Specific comments/observations: Information on DFA residues is not available from the JMPR report. If details are reported in the JMPR evaluation, the corresponding DFA MRL could be derived. **Conclusion:** The proposed Codex MRL for RD 1 is acceptable, but no MRL proposal was derived for the second EU RD (DFA). Follow-up action: To check details in JMPR evaluation.
Coffee beans	0.9	1	cGAP: Brazil, 1 × 600 g/a (drench)+3 × 200 g/ha (foliar), 15-day interval, PHI 21 days Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The same GAP and 13 residue trials were assessed by EFSA for setting an import tolerance. The residue data indicate that for flupyradifurone an MRL of 0.2 mg/kg required for DFA. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Hops, dry	**10**	4	cGAP: USA, 1 × 154 g/ha, PHI 21 day Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Information on DFA residues is not available from the JMPR report. If details are reported in the JMPR evaluation, the corresponding DFA MRL could be derived. It is noted that the same GAP supported by only 3 residue trials was submitted to EFSA in an import tolerance application, EFSA concluded that since the number of trials is insufficient, no MRL proposal can be derived for the import tolerance application. **Conclusion:** The proposed Codex MRL for RD 1 is acceptable, but no MRL proposal was derived for the second EU RD (DFA). Follow-up action: To check details in JMPR evaluation.
General comments	Information on the residue concentrations on metabolite DFA is not available in the JMPR report. Risk managers to decide if EFSA should be mandated with deriving MRL proposals for DFA for avocado, cane berries, hops, if sufficient information is available in the JMPR evaluation. The residue data submitted for coffee and cocoa beans for the EU assessment allow derivation of CXL proposals for DFA in these commodities.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.34.5. Consumer risk assessment

Table 166: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The calculation can be slightly overestimated, considering the contribution of 6-CNA metabolite. The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment performed for the ongoing MRL application (reasoned opinion on the import tolerances, EU uses and Article 12 confirmatory data), were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The calculation can be slightly overestimated, considering the contribution of 6-CNA metabolite. The risk assessment was performed with the EU ADI.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Among the crops under assessment, the highest exposure was calculated for blackberries: 31% of the ARfD.	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 50% of the ADI. Among the crops under consideration, coffee beans were identified as the main contributor, accounting for up to 3% of the ADI.	**Results:** Long-term exposure: Max 20% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.35. Isofetamid (290) R/T

5.35.1. Background information

Table 167: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	–
Type of JMPR evaluation	Follow-up evaluation due to an EU comment in 2018 CCPR	The EU noted that for bush berries an MRL of 4 instead of 5 mg/kg would be sufficient. For dry beans and dry peas the OECD MRL calculator would suggest an MRL of 0.09 mg/kg (instead of 0.05 mg/kg).
RMS	BE	–
Approval status	Approved	Commission Implementing Regulation (EU) 2016/1425[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2015w)
MRL review performed	No	Not foreseen, since MRLs were set in the framework of the first approval
MRL applications/ assessments	Yes, see comments	(EFSA, 2019i) (CCPR 51) (EFSA, 2018j) (tomatoes, peppers, aubergines, okra and cucurbits with edible peel) Ongoing: modification of the existing MRLs in blackberries, dewberries and raspberries

		Comments, references
Classification of a.s. – cut-off criteria	No	–
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2016/5398. OJ L 231, 26.8.2016, p. 30–33.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.35.2. Toxicological reference values

Table 168: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.05 mg/kg bw per day	JMPR (2016)	0.02 mg/kg bw per day	(EFSA, 2015w) (1-year dog study, UF 100)	No
ARfD	3 mg/kg bw	JMPR (2016)	1 mg/kg bw	(EFSA, 2015w) (developmental toxicity study with rabbit, UF 100)	No
Conclusion/ comment	The ADI established by JMPR is 0.05 mg/kg bw per day, based on the NOAEL of 5.34 mg/kg bw per day for liver toxicity in the 90-day and 1-year toxicity studies in dog and applying an uncertainty factor (UF) of 100. The EU evaluation derived a different ADI (0.02 mg/kg bw per day) based on the NOAEL of 1.57 mg/kg bw per day for effects on body weight and body weight gain in the 1-year toxicity study in dog and applying an UF of 100. The ARfD established by JMPR is based on the NOAEL of 300 mg/kg bw per day for skeletal anomalies in the developmental toxicity study in rabbit and applying an UF of 100. The EU evaluation derived a different ARfD (1 mg/kg bw) based on the NOAEL of 100 mg/kg bw per day based on skeletal variations observed in the developmental study in rabbit and applying an UF of 100. According to (EFSA, 2015w), the reference values of parent compound (isofetamid) are applicable. to metabolites and therefore also for metabolite GPTC (*N*-{1-[4-(β-D-glucopyranosyloxy)-2-methylphenyl]-2-methyl-1-oxopropan-2-yl}-3-methylthiophene-2-carboxamide) which was included in the risk assessment residue definition for plants.				

5.35.3. Residue definitions

Table 169: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Isofetamid	EU Reg. 2018/1514[(a)]: Isofetamid	Yes
	Animal products	Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isofetamid The residue is fat soluble	EU Reg. 2018/1514[(b)]: Isofetamid Peer review (EFSA, 2015w): Isofetamid (provisional, not required) Fat solubility open (pending confirmation by livestock feeding study, not required at this stage)	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Isofetamid	Peer review (EFSA, 2015w) Art 10 MRL (EFSA, 2018j): Sum isofetamid and *N*-{1-[4-(β-D-glucopyranosyloxy)-2-methylphenyl]-2-methyl-1-oxopropan-2-yl}-3-methylthiophene-2-carboxamide (GPTC), expressed as isofetamid	No
	Animal products	Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido) propanoyl] phenoxy] propanoic acid (PPA), expressed as isofetamid	Peer review (EFSA, 2015w): Sum isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido)propanoyl] phenoxy]propanoic acid (PPA), expressed as isofetamid	Yes
Conclusion, comments	Plant commodities: The plant residue definitions for enforcement are identical, as both refer to the parent isofetamid only. For the plant risk assessment residue definition, the JMPR, in contrast to the EU, does not include the plant metabolite GPTC. EFSA previously derived conversion factors (CF) for risk assessment for peaches, plums, grapes (CF 1.1) and lettuce (CF 1.3) (EFSA, 2015w). A conversion for risk assessment was not deemed necessary for strawberries, tomatoes, aubergines, peppers, okra and cucurbits with edible peel (CF 1.0 and/or GPTC < LOQ) (EFSA, 2015w, 2018j)). For apricots, cherries and rapeseed, CFs could not be derived in the framework of the EU peer review, because residue levels of parent and GPTC were < LOQ (EFSA, 2015w). For bush berries the CF derived for grapes could be used. For pulses, considering metabolism studies in French beans, GPTC is not expected to occur and therefore no CF is deemed necessary. Animal commodities: See (EFSA, 2019i).			

(a): Commission Regulation (EU) 2018/1514 of 10 October 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, Pasteuria nishizawae Pn1, talc E553B and tebuconazole in or on certain products. OJ L 256, 12.10.2018, p. 8–32.

(b): Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2016/5398. OJ L 231, 26.8.2016, p. 30–33.

5.35.4. Codex MRL proposals

Table 170: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Bush berries, Subgroup of	**4**	0.01* (blueberries, currants, gooseberries and rose hips)	cGAP: Canada, 3 × 496 g/ha, 7-day interval, PHI 7 days Number of trials: 10 trials on blueberry conducted at higher application rates of 650 g/ha (1.31N) and scaled using the proportionality approach. Sufficiently supported by data: Yes Specific comments/observations: The extrapolation from blueberries to bush berries (subgroup) is in line with the agreed Codex extrapolations. According to the EU classification, the number of trials would not be sufficient to support extrapolation to the group of small fruit and berries. Last year it was noted that one residue trial outlier value of 3 mg/kg (scaled value) affects the MRL calculation (without the outlier, the calculated MRL would be 1.5 mg/kg) (EFSA, 2019i).

Commodity	Codex MRL proposal	EU MRL	Comment
			The Codex MRL for bush berries (subgroup) would be applicable also to currants (154030), gooseberries (154040), rose hips (154050) and other small fruit and berries (154990). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Dry beans (except soyabeans), Subgroup of	**0.09**	0.01* Dry beans, dry lupins	cGAP: Canada and USA, 2 × 500 g/ha, 7-day interval, PHI 30 days Number of trials: 8 trials on beans and 11 trials on peas Sufficiently supported by data: Yes Specific comments/observations: Residues from dry beans and dry peas were similar (Mann–Whitney test) and data sets could be combined. The Codex MRL would be applicable also to dry lupin (300040) and other dry pulses (300990). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Dry peas, Subgroup of	**0.09**	0.01* Dry peas, dry lentils	cGAP: Canada and USA, 2 × 500 g/ha, 7-day interval, PHI 30 days (FAO, 2018) Number of trials: 11 trials on peas and 8 trials on beans Sufficiently supported by data: Yes Specific comments/observations: See comments on dry beans (except soyabeans), subgroup of (above). The MRL proposal for dry peas would be also applicable to dry lentils (300020) and other dry pulses (300990). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.35.5. Consumer risk assessment

Table 171: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities for which the Codex MRL proposal is under consideration, using HR/STMR values derived by JMPR. The calculations are affected by additional non-standard uncertainties due to the lack of information on residue levels of the plant metabolite GPTC measured in residue trials, which is included in the EU residue definition for risk assessment. CF for bush berries were used to compensate for this deficiency. For pulses a CF is not necessary. The risk assessment was performed with the EU ARfD.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (refined calculation mode). The input values of the most recent long-term risk assessment (EFSA, 2019i) are still applicable (including the STMR values derived by JMPR for the crops under assessment). The calculations are affected by additional non-standard uncertainty due to the lack of information on residue levels of the plant metabolite GPTC measured in residue trials, which is included in the EU residue definition for risk assessment. Instead, CF were used. The risk assessment was performed with the EU ADI. The calculations are indicative because information is not available on the contribution of the plant metabolite GPTC, which is included in the EU residue definition for risk assessment.	**Specific comments:** The JMPR exposure assessment according to the residue definition for risk assessment for plant commodities covers isofetamid (only) whereas the EU residue definition includes also the plant metabolite GPTC.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
	EFSA applied the previously derived conversion factor (CF) for risk assessment (CF = 1.1) (EFSA, 2015w) to the STMR values derived by the JMPR for peaches (also used for apricots), cherries and plums. The same CF was applied for blueberries, currants, gooseberries, rose hips and other small fruit and berries. A conversion factor (CF) for risk assessment was not available for other commodities under consideration. The risk assessment was performed using the STMR values for isofetamid (only) derived by the JMPR for pome fruit, blackberries, dewberries, raspberries, other cane fruit, azarole, kaki, beans (with pods), peas (with pods), beans, lentils, peas, lupins and other pulses.	
Results: No short-term consumer health risk was identified for the crops under assessment. The commodities under consideration leading to highest exposure are: Currants: 2.60% of ARfD Blueberries: 1.97% of ARfD Gooseberries: 1.94% of ARfD Beans (dry): 0.02% of ARfD Lentils (dry): 0.01% of ARfD Peas (dry): 0.01% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 24% of the ADI. Among the crops under consideration, apples were identified as the main contributor, accounting for up to 8% of the ADI.	**Results:** Long-term exposure: Max 0–6% of the JMPR ADI (FAO, 2018). Short-term exposure: Highest result for peaches: 3% of the JMPR ARfD (FAO, 2018).

5.36. Pendimethalin (292) R

5.36.1. Background information

Table 172: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	SE	
Approval status	Approved	Commission Implementing Regulation (EU) 2017/1114[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2016f)
MRL review performed	Yes, see comments	(EFSA, 2012c)
MRL applications/ assessments	Yes, see comments	(EFSA, 2018w) (confirmatory data following Art.12 review) (EFSA, 2015u) (lettuce) (EFSA, 2014c) (various crops) (EFSA, 2013g) (various crops)
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded	

(a): Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017 renewing the approval of the active substance pendimethalin, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 162, 23.6.2017, p. 32–37.

5.36.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0–0.1 mg/kg bw per day	JMPR (2016)	0.125 mg/kg bw per day	(EFSA, 2016f) (dog, 2-year study and 100 UF) confirmed in (European Commission, 2017b)	No
ARfD	1 mg/kg bw	JMPR (2016)	0.3 mg/kg bw	(EFSA, 2016f) (rabbit, developmental toxicity study and 100 UF) confirmed in (European Commission, 2017b)	No
Conclusion/ comment	–				

5.36.3. Residue definitions

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	Pendimethalin The residue is fat soluble	Reg. 396/2005: Pendimethalin Peer review (EFSA, 2016f): Pendimethalin MRL review Art. 12 (EFSA, 2012c): Pendimethalin	Yes
	Animal products		Reg. 396/2005: Pendimethalin Peer review (EFSA, 2016f): Pendimethalin MRL review Art. 12 (EFSA, 2012c): Pendimethalin The residue is fat soluble	Yes
RD RA	Plant products		Peer review (EFSA, 2016f): Pendimethalin MRL review Art. 12 (EFSA, 2012c): Pendimethalin	Yes
	Animal products		Peer review (EFSA, 2016f): Pendimethalin MRL review Art. 12 (EFSA, 2012c): Pendimethalin	Yes
Conclusion, comments	The proposed residue definitions for enforcement and risk assessment are comparable between the JMPR and EU evaluations.			

5.36.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Cane berries, subgroup of (includes all commodities in this subgroup)	0.05*	0.05* (blackberries, raspberries, dewberries)	cGAP: US GAP, Soil application, 1x6.7 kg a.s./ha, PHI 30 days. Number of trials: 4 GAP-compliant residue trials on blackberries and 2 GAP-compliant residue trials on raspberries. Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL refers to blackberries, raspberries, dewberries. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Bush berries, Subgroup of (includes all commodities in this subgroup)	0.05*	0.05* (blueberries, currants, gooseberries, rose hips)	cGAP: US GAP, Soil application, 1x6.7 kg a.s./ha, PHI 30 days. Number of trials: 7 GAP-compliant residue trials on blueberries supported by acceptable storage stability data. According to the current EU guidelines on extrapolation, 4 trials on currants (black, red and white) and 2 trials on any representative of the 'other small fruits and berries' are in principle required to be extrapolated to the whole subgroup of 'other small fruits and berries'. Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL refers to blueberries, currants, gooseberries and rose hips. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Mints	0.2	Corresp. EU MRL: basil and edible flowers: 0.6	cGAP: US GAP, soil application, 1x2.24 kg a.s./ha, PHI of 90 days. Number of trials: 4 residue trials 'approximating' the US GAP. Sufficiently supported by data: Yes Specific comments/observations: It is noted that the EU MRL is higher compared to the Codex MRL proposal. This can be explained by the fact that this MRL supports an EU GAP (i.e. Foliar spray treatment, 1 × 1.59 kg a.s./ha, PHI 42 days) that is more critical compared to the US GAP. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Strawberries	0.05*	0.05*	cGAP: US GAP: soil application, 1x3.2 kg a.s./ha, PHI 35 days. Number of trials: 8 residue trials 'approximating' the US GAP are available. Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Peppermint Oil, edible	6	–	Codex MRL proposals for processed products are not taken over in the EU legislation.
General comments	None		

*: Indicates that the MRL is proposed at the limit of quantification.

5.36.5. Consumer risk assessment

Table 176: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The most recent risk assessment performed in the framework of the assessment of Art. 12 confirmatory data (EFSA, 2018w) is still valid since the proposed Codex MRLs are all lower or at the same level as the EU MRLs.	**RA assumptions:** The most recent risk assessment performed in the framework of the assessment of Art. 12 confirmatory data (EFSA, 2018w) is still valid since the proposed Codex MRLs are all lower or at the same level as the EU MRLs.	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
The risk assessment was performed with the EU ARfD.	The risk assessment was performed with the EU ADI.	
Results: No short-term consumer health risk was identified for the crops under assessment. IESTI for the crops under consideration: < 1% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 1.6% of the ADI.	**Results:** Long-term exposure: Max 0% of the JMPR ADI. Short-term exposure: Highest result for the crops under consideration: 0% of ARfD

5.37. Cyclaniliprole (296) R

5.37.1. Background information

Table 177: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	AT	
Approval status	Not approved	Commission Implementing Regulation (EU) 2017/357[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2016i)
MRL review performed	No	
MRL applications/assessments	No	
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): 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. C/2017/1280. OJ L 54, 1.3.2017, p. 4–5.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.37.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.04 mg/kg bw per day	JMPR (2017)	0.0043 mg/kg bw per day	(EFSA, 2016i) (1-year dog study, uncertainty factor 300)	No
ARfD	Unnecessary	JMPR (2017)	–	Not allocated	Yes
Conclusion/ comment	ADI: In 2016, EFSA derived an ADI which is one order of magnitude lower than the ADI derived by JMPR. Tox info on NK-1375 is not available in the EU. Hence, it is not possible to conclude on whether the reference values of the parent can be used for NK-1375. In the comments for the 2018 CCPR, EFSA noted that for establishing the ADI for cyclaniliprole, the EU assessment interpreted the effects observed in the toxicological studies differently: 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				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
	albumin in females. The basis of an LOAEL to set the ADI implied an additional uncertainty factor of 3 (overall 300). In 2017, the JMPR considered that the ADI of the parent applies also 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). ARfD: Not derived. The TRV derived by EFSA are not formally approved in EU (not included in the pesticides database)				

5.37.3. Residue definitions

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	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
RD RA	Plant products	Cyclaniliprole + 3-bromo-2 ((2-bromo-4H-pyrazolo[1,5d] pyrido[3,2-b]-[1,4]oxazin4-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 (EFSA, 2016i): 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	Not appropriate since the EU is only provisional
	Animal products	Cyclaniliprole	Peer review (EFSA, 2016i): 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	RD enf and RA (plant commodities): only comparable for RAC. RA RD in EU for RAC is only provisional. European assessment on processed commodities not finalised. RD RA (animal commodities): EU residue definition includes also two metabolites: NSY-28 and NK-1375. 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 be finalised. The data gaps regarding the toxicological studies and residue levels of metabolites are considered a serious concern which would be a sufficient reason to make a reservation for the proposed Codex MRL proposals.			

5.37.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
Almonds	**0.03**	0.01*	cGAP: Canada, 3x80 g a.i./ha, RTI 14 days, PHI 30 day Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 12–15 days, PHI 30 day. Proportionality principle (0.8 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Almond hulls	6	–	No MRLs are set in the EU for processed commodities/by-products.
Bush berries, Subgroup of	**1.5**	0.01* (blueberries, currants, gooseberries, rose hips)	cGAP: Canada, 3 × 80 g a.i./ha, RTI 5 days, PHI 1 day Number of trials: 10 (trials on blueberries) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 5 days, PHI 1 day. Proportionality principle (0.8 scaling factor) applied. According to EU extrapolation rules, trials on currants are needed to set MRL for the whole subgroup of other small fruits and berries (0154000). However, according to Codex, the extrapolation from blueberry to the subgroup of bush berries is possible. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: To discuss whether the extrapolation is acceptable.
Elderberries	**1.5**	0.01*	cGAP: Canada, 3 × 80 g a.i./ha, RTI 5 days, PHI 1 day Number of trials: 10 (trials on blueberries) Sufficiently supported by data: No Specific comments/observations: JMPR suggests extrapolating from blueberries. According to Codex extrapolation rules, trials on elderberry are needed. **Conclusion:** The proposed Codex MRL is not acceptable because it is not sufficiently supported by data (lack of residue trials in elderberries) Follow-up action: None
Guelder rose	**1.5**	(see elderberries)	cGAP: Canada, 3 × 80 g a.i./ha, RTI 5 days, PHI 1 day Number of trials: 10 (trials on blueberries) Sufficiently supported by data: No Specific comments/observations: JMPR suggests extrapolating from blueberries. According to Codex extrapolation rules, trials on elderberry are needed. **Conclusion:** The proposed Codex MRL is not acceptable because it is not sufficiently supported by data (lack of residue trials in elderberries). See also conclusion on residue definitions. Follow-up action: None
Cane berries, Subgroup of	**0.8**	0.01* Blackberries, dewberries, raspberries	cGAP: Canada, 3 × 80 g a.i./ha, RTI 5 days, PHI 1 day Number of trials: 5 (trials on raspberries) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 5–6 days, PHI 1 day. Proportionality principle (0.8 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
Cherries, Subgroup of	**0.7**	0.01*	cGAP: Canada, 3 × 80 g a.i./ha, RTI 7 days, PHI 7 day Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 7 days, PHI 7 day. Proportionality principle (0.7–0.8 scaling factor) applied. Residues measured in flesh, but it was considered that correction by the pit will leave to same MRL. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Cabbages, head	**0.7**	0.01*	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 10 (trials on cabbage with wrapper leaves) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 80 g/ha, RTI 6–8 days, PHI 1 day. Proportionality principle (0.6–0.98 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Cherry Tomato	**0.7 (W)**	0.01* (tomatoes)	Specific comments/observations: JMPR proposed to withdraw the existing CXL. A new MRL (0.08 mg/kg) for subgroup of tomatoes is proposed
Citrus fruit, Group of	**0.4**	0.01*	cGAP: USA, 3x80 g a.i./ha, RTI 7 day, PHI 1 day Number of trials: 23 (combined data set on lemons (n = 5), oranges (n = 12) and grapefruit (n = 6). Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 7 days, PHI 1 day. Proportionality principle (0.8 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Citrus oil, edible	50	–	Specific comments/observations: 1 processing study available. No MRLs are proposed in EU for processed commodities.
Cucumbers and summer squashes, Subgroup of	**0.05**	0.01* (cucurbitis with edible peel, except Armenian cucumbers)	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 18 (combined data set on cucumbers (9) and summer squashes (9)) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3x80 g/ha, RTI 7 days, PHI 1 day. Proportionality principle (0.75 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Tomato, dried	0.35	–	Specific comments/observations: 5 processing studies available. No MRLs are proposed in EU for processed commodities.
Edible offal (mammalian)	**0.2**	0.01*	JMPR calculated the dietary burden for livestock on the basis of residues in feed crops under assessment and their by-products. In addition, residues in rotational crops (straw, forage) were taken into account. The calculations were performed for parent cyclaniliprole; the metabolite NK-1375 was not considered. According to EFSA's view, the dietary burden calculation should

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
			be performed in accordance with the RD for risk assessment for plants (including metabolite NK-1375). Hence, it is expected that the overall dietary burden would be slightly higher than the one calculated by JMPR. Maximum DB (14.7 ppm DM) calculated for beef cattle not covered by the highest feeding study (11.6 ppm DM). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. See also conclusion on residue definitions. Follow-up action: None
Subgroup of Eggplants	**0.15**	0.01*	cGAP: Canada, 3x60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 12 (trials on bell peppers and non-bell peppers) Sufficiently supported by data: No Specific comments/observations: trials performed at 3x80 g/ha, RTI 6–8 days, PHI 1 day. Proportionality principle (0.74–0.99 scaling factor) applied. Since 2018 JMPR follows the approach to use residue trials from peppers or tomatoes (the data set leading to higher residues) to extrapolate to the subgroup Eggplant. The extrapolation from peppers to eggplants is not foreseen in EU. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Eggs	0.01*	0.01*	JMPR calculated the dietary burden for poultry on the basis of residues in feed crops under assessment and their by-products. In addition, residues in rotational crops (straw, forage) were taken into account. The calculations were performed for parent cyclaniliprole; the metabolite NK-1375 was not considered. According to EFSAs view, the dietary burden calculation should be performed in accordance with the RD for risk assessment for plants (including metabolite NK-1375). Hence, it is expected that the overall dietary burden would be slightly higher than the one calculated by JMPR. No feeding study with poultry. From metabolism study with laying hen, no residues expected in poultry eggs. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Flowerhead Brassicas, Subgroup of	**0.8**	0.01* (flowering brassica)	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day (GAP for Brassica head and stem vegetables) Number of trials: 10 (trials on broccoli) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3x80 g/ha, RTI 6–8 days, PHI 1 day. Proportionality principle (0.72–0.98 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Grapes	**0.6**	0.01*	cGAP: Canada, 3 × 80 g a.i./ha, RTI 7 days, PHI 7 days. Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 6 days, PHI 6–7 days. Proportionality principle (0.8 scaling factor) applied.

Commodity	Codex MRL proposal	EU MRL(a)	Comment
			Conclusion: The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Head Brassicas, Subgroup of	**0.7 (W)**	0.01*	Specific comments/observations: JMPR proposed to withdraw the existing CXL. An MRL of 0.7 mg/kg is proposed for head cabbage (see above).
Leafy greens, Subgroup of	**7**	0.01* (lamb's lettuces, lettuces, escaroles, spinaches and similar leaves subgroup of, chervil)	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 7 head lettuce, 10 leaf lettuce, 3 cos lettuce, 8 spinach Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3x80 g/ha, RTI 4–9 days, PHI 1 day. Proportionality principle (0.73–0.99 scaling factor) applied. JMPR indicated that residue levels from head lettuce, leaf lettuce, cos lettuce and spinach are not from the same population. JMPR proposed the MRL for the whole subgroup of leafy greens based on trials on spinach (n = 8) only. This is not fully matching EU extrapolations. Separated MRLs could be set for the individual crops. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. See also conclusions on residue definitions. Follow-up action: None
Leaves of Brassicaceae, Subgroup of	**10**	0.01* (leafy brassica subgroup of, land cresses, cress and other sprouts and shoots, rucola and red mustards)	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 5 (trials on mustard greens) Sufficiently supported by data: No Specific comments/observations: Chinese cabbage is a crop classified in the group of leaves of brassica, which is a major crop in Codex classification. Hence, 5 trials are not sufficient to derive an MRL proposal. The trials were performed at 3 × 80 g/ha, RTI 4–9 days, PHI 1 day. Proportionality principle (0.75–0.98 scaling factor) applied. JMPR extrapolated from mustard greens to the whole subgroup of leafy brassica, land cresses, rucola and red mustards. The extrapolation is in line with the Codex extrapolation rules, which differ from EU extrapolations for these crops. **Conclusion:** The proposed Codex MRL is not acceptable, because the number of residue trials is insufficient. See also conclusion on residue definitions. Follow-up action: None
Meat (from mammals other than marine mammals)	**0.25 (fat)**	0.01*	MRL derived from feeding study with cattle (see comments on edible offal). It is noted that EU MRL is derived for muscle, instead of meat. In muscle residues of 0.032 mg/kg were estimated from the max DB. Hence the MRL in muscle would be 0.05 mg/kg **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable (see edible offal). See also conclusion on residue definitions. Follow-up action: None
Low growing berries, Subgroup of (except cranberries)	**0.4**	0.01* (strawberries)	cGAP: Canada, 3 × 80 g a.i./ha, RTI 5 days, PHI 1 day. Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3x100 g/ha, RTI 4–6 days, PHI 1 day. Proportionality principle (0.8 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
Melons, pumpkins and winter squashes, Subgroup of	**0.1**	0.01* (cucurbitis with inedible peel)	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 10 (trials on melons, whole fruit) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3x80 g/ha, RTI 6–8 days, PHI 1 day. Proportionality principle (0.75 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Mammalian fats (except milk fats)	**0.25**	0.01*	MRL proposal derived from feeding study with cattle (see comments on edible offal). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable (see edible offal). See also conclusion on residue definitions. Follow-up action: None
Milks	0.01	0.01*	MRL proposal derived from feeding study with cattle (see comments on edible offal). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable (see edible offal). See also conclusion on residue definitions. Follow-up action: None
Milk fats	0.2	–	No MRLs are proposed in EU for milk fats.
Peppers, Subgroup of (except Martynia, Okra and Roselle)	**0.15**	0.01*	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 12 (trials on bell peppers and non-bell peppers) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 80 g/ha, RTI 6–8 days, PHI 1 day. Proportionality principle (0.74–0.99 scaling factor) applied. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Peppers, chilli, dried	1.5	-	Specific comments/observations: Proposed MRL was derived from residue trials in peppers, applying the default processing factor of 10. At EU level, MRLs are set only for fresh products, but not for processed chilli peppers
Peaches (including Apricots and Nectarines), Subgroup of	**0.3**	0.01* (peaches, apricots)	cGAP: Canada, 3 × 80 g a.i./ha, RTI 7 days, PHI 7 day Number of trials: 13 (trials on peaches) Sufficiently supported by data: Yes Specific comments/observations: application rate did not match the cGAP; proportionality principle (0.8–1.1 scaling factor) applied. Residues measured in flesh, but it was considered that correction by the pit will leave to same MRL. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Pome fruits	**0.3 (W)**	0.01*	JMPR proposed to withdraw the existing CXL and replace it with a new MRL of 0.2 mg/kg (see pome fruits below).
Pome fruits, Group of (excluding Japanese persimmons)	**0.2**	0.01* (Pome fruits and azaroles)	cGAP: Canada, 3 × 80 g a.i./ha, RTI 14 days, PHI 7 day Number of trials: 24 (combined data set on apple (16) and pear (8) Sufficiently supported by data: No Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 14 days, PHI 7 days (in the JMPR report it is erroneously reported that the trials were performed with a PHI of 1 day).

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
			Proportionality principle (0.8 scaling factor) applied. According to the RMS, the PHI reported in the 2019 report is a typo and should be corrected to 7 days. **Conclusion:** The proposed Codex MRL might not be acceptable because trials differ from GAP in two parameters (PHI and application rate). Hence, proportionality approach cannot be used to derive an MRL proposal. See also conclusion on residue definitions. Follow-up action: None
Plums, Subgroup of	**0.15**	0.01*	cGAP: Canada, 3 × 80 g a.i./ha, RTI 7 days, PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: application rate did not match the cGAP; proportionality principle (0.8–1.2 scaling factor) applied. Residues measured in flesh, but it was considered that correction by the pit will leave to same MRL. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Poultry, edible offal	0.01*	0.01*	MRL proposal derived from feeding study with laying hens (see comments on eggs). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable (see eggs). See also conclusion on residue definitions. Follow-up action: None
Poultry, fats	0.01*	0.01*	MRL proposal derived from feeding study with laying hens (see comments on eggs). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable (see eggs). See also conclusion on residue definitions. Follow-up action: None
Poultry, meat	0.01*	0.01*	MRL proposal derived from feeding study with laying hens (see comments on eggs). The corresponding MRL for poultry muscle is 0.01* **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable (see eggs). See also conclusion on residue definitions. **Follow-up action:** None
Tea, green, black (black, fermented and dried)	**50**	0.05*	cGAP: Japan, 1 × 4.5 g a.i./hL, PHI 3 days Number of trials: 6 (trials on tea, residues analysed in dried tea) Sufficiently supported by data: No; normally 8 trials would be required, but in exceptional cases 6 trials may be considered enough. Specific comments/observations: GAP compliant trials; **Conclusion:** Risk managers to discuss whether the number of trials is considered sufficient. See also conclusion on residue definitions. Follow-up action: None
Tomatoes, Subgroup of	**0.08**	0.01*	cGAP: Canada, 3 × 60 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 22 (combined data set on normal size and cherry tomato) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 80 g/ha, RTI 6–8 days, PHI 1 day. Proportionality principle (0.72–0.99 scaling factor) applied.

Commodity	Codex MRL proposal	EU MRL[(a)]	Comment
			Conclusion: The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Tuberous and corn vegetables, Subgroup of	0.01*	0.01* (potatoes, tropical root and tuber vegetables)	cGAP: Canada, 3 × 60 g a.i./ha, RTI 5 days, PHI 7 days Number of trials: 25 (trials on potatoes) Sufficiently supported by data: Yes Specific comments/observations: trials performed at 3 × 100 g/ha, RTI 4–6 days, PHI 6–7 days. All residues < 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, a general concern was noted (see conclusion on residue definitions). Follow-up action: None
Prunes	**0.6**	–	Specific comments/observations: 1 processing study available. No MRLs are proposed in EU for processed commodities.
Tomato	**0.1 (W)**	0.01*	Specific comments/observations: JMPR proposed to withdraw the existing CXL and replace it with a new MRL of 0.08 mg/kg (see tomato above).
General comments	(a): substance included in Annex V to Regulation (EC) No 396/2005. In 2017, JMPR derived MRL proposals for many of the crops assessed again by 2019 JMPR; CCPR 2018 decided to keep the MRL proposals at step 4 because JMPR used an approach outlined in the general considerations of the 2017 JMPR report (2.4 Field use pattern anticipated residue comparison model), which was not found acceptable by CCPR. In 2019, the applicant submitted revised GAPs to JMPR. Although the trials did not fully match the revised cGAPs, the trials could be used following scaling.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.37.5. Consumer risk assessment

Table 181: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was allocated.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1 based on the existing EU MRLs (all at the LOQ) and the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The risk assessment was performed with the EU ADI. The calculations are indicative, because final decision on RD at EU level is not yet taken.	**Specific comments:** –
Results: **Not relevant**	**Results:** The calculated long-term exposure exceeded the ADI. The overall chronic exposure accounted for 125% of the EU ADI (NL toddler). Among the crops under consideration, tea and spinaches were identified as the main contributor, accounting for up to 40% of the ADI, respectively.	**Results:** Long-term exposure: Max 10% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.38. Fenazaquin (297) R

5.38.1. Background information

Table 182: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	Other evaluation, see comment	Follow-up evaluation of additional uses
RMS	DE	
Approval status	Approved	Commission Implementing Directive 2011/39/EU[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013e) (application for amendment of approval conditions) EFSA Conclusion ongoing (AIR IV)
MRL review performed	Yes, see comments	(EFSA, 2020b)
MRL applications/ assessments	Yes, see comments	(EFSA, 2018o) (import tolerance in almonds) (EFSA, 2010f) (dried or fermented leaves and stalks of Camellia sinensis)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/60510) has not been performed yet.

(a): 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.

5.38.2. Toxicological reference values

Table 183: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0–0.05 mg/kg bw per day	JMPR (2017)	0.005 mg/kg bw per day	(EFSA, 2013e) (2-year oral rat study and 100 UF) confirmed in (European Commission, 2018b)	No
ARfD	0.1 mg/kg bw	JMPR (2017)	0.1 mg/kg bw	(EFSA, 2013e) (developmental rat study and 100 UF) confirmed in (European Commission, 2018b)	Yes
Conclusion/ comment	The ADI set at EU level is 10 times lower than the JMPR ADI. In addition, at the EU level, TRV have been set for plant metabolite TBPE: ADI of 0.002 mg/kg bw per day, ARfD of 0.002 mg/kg bw. This metabolite has not been assessed by JMPR in 2017 where it was concluded that TBPE was unlikely to be of greater toxicity than fenazaquin. JMPR agreed that the ADI and ARfD of fenazaquin can be applied to TBPE.				

5.38.3. Residue definitions

Table 184: 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 (EFSA, 2013e): Fenazaquin (applicable to fruit crops) Art. 10 (EFSA, 2018o): Fenazaquin (applicable to fruit crops) Art. 12 review (EFSA, 2020b): Fenazaquin (tentative for leafy vegetables)	Yes
	Animal products	Sum of fenazaquin and the metabolite 2-hydroxy-fenazaquin acid, expressed as fenazaquin equivalents The residue is fat soluble	Reg. 396/2005: Fenazaquin Peer review (EFSA, 2013e) and MRL review (EFSA, 2020b): Fenazaquin (ruminants) The residue is fat soluble	No
RD RA	Plant products	Fenazaquin	Peer review (EFSA, 2013e): Fenazaquin and TBPE (these RD are applicable to unprocessed and processed fruit). Art 12 (EFSA, 2020b) Fruits, leafy vegetables (tentative for leafy vegetables): 1) fenazaquin and 2) TBPE	No
	Animal products	Sum of fenazaquin and the metabolites 2-(4-{2-[(2-hydroxyquinazolin-4 yl)oxy] ethyl}phenyl)-2-methylpropanoic acid (2-hydroxy-fenazaquin acid) and quinazolin-4-ol and 3,4-dihydroquinazolin-4-one (tautomeric forms of 4-hydroxyquinazoline), expressed as fenazaquin equivalents	Peer review (EFSA, 2013e)and MRL review (EFSA, 2020b): Fenazaquin (ruminants)	No
Conclusion, comments	The EU and JMPR enforcement residue definitions for plants are identical, covering only parent fenazaquin. For risk assessment, a second residue definition was established in the EU which covers the metabolite TBPE. For animals there is a slight difference in the residue definition for enforcement and RA, since EFSA is proposing fenazaquin only (for ruminants), while JMPR proposes a wider RD which includes also metabolites, i.e. tautomeric forms of 4-hydroxyquinazoline (only for risk assessment) and 2-hydroxy-fenazaquin acid (for enforcement and risk assessment).			

5.38.4. Codex MRL proposals

Table 185: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Almonds hulls	**4** (dw)	–	cGAP: see almonds Specific comments/observations: Almond hulls are not a feed item in the EU livestock diet.

Commodity	Codex MRL proposal	EU MRL	Comment
			In the EU, no MRLs are established for animal feed. Follow-up action: None
Edible offal (Mammalian)	**0.02***	0.01*	JMPR calculated the dietary burden related to almonds hulls. In the feeding study in cattle performed at an exaggerated feeding level (100N), residues were below the LOQ in milk, muscle and kidney; low residues were found in liver and fat. At the calculated dietary burden, quantifiable residues are not expected. Sufficiently supported by data: Yes Specific comments/observations: The JMPR residue definition for enforcement and risk assessment differ from the EU RD for enforcement and RA. Currently, the EU MRLs and MRLs derived in the MRL review for livestock products are set at the LOQ of 0.01 mg/kg. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that it is not fully compatible with the EU residue definition. Follow-up action: None
Mammalian fats (except milk fats)	**0.02***	0.01*	See comments on edible offal (Mammalian).
Meat (from mammals other than marine mammals)	**0.02*** (fat)	0.01*	See comments on edible offal (Mammalian).
Milks	**0.02***	0.01*	See comments on edible offal (Mammalian).
Milk fats	0.02*	-	In the EU, MRLs are established only for milk, but not for milk fat.
Tree nuts, Group of (except coconut)	**0.02**	Almonds 0.02; Other tree nuts: 0.01*	cGAP: US, 1 × 504 g a.s./ha; PHI 7 days Number of trials: 9 trials on almonds, 5 trials on pecan Sufficiently supported by data: Yes Specific comments/observations: The same MRL value was proposed in an Art 10 application for almonds (EFSA, 2018o); the data set assessed at the EU level was slightly different (8 trials). Results for metabolite TBPE were all below the LOQ: 8 × < 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
General comments	The Codex MRL proposed for tree nuts is equivalent to the MRL of 0.02 mg/kg proposed in the MRL review (not legally implemented yet) for almonds (only authorised used for tree nuts). MRL derived in the Art. 12 (EFSA, 2020b) is fully supported by data and no risk to consumers is identified.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.38.5. Consumer risk assessment

Table 186: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: EFSA calculated the acute risk assessment for the proposed Codex MRL proposals that are higher than the existing EU MRLs (i.e. animal products and tree nuts). The calculation was	**RA assumptions:** The most recent EU risk assessment (EFSA, 2018o) was updated, including the STMR values derived by JMPR for animal products and for tree nuts.	**Specific comments on risk assessment:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
performed with EFSA PRIMo rev. 2, using the HR/STMR values derived by JMPR. The risk assessment was performed for fenazaquin; for the second residue definition proposed in the MRL review (TBPE), information on the residue levels were reported in the JMPR assessment only for few trials in almonds (residues not detected). Hence, this leads to additional, non-standard uncertainties in the risk assessment. The risk assessment is indicative, because only limited information on the residue concentrations related to the residue definition TBPE is available. The risk assessment was performed with the EU ARfD and the EFSA PRIMo rev. 2	The risk assessment is indicative, because only limited information on the residue concentrations related to the residue definition TBPE was reported in the JMPR evaluation. The risk assessment was performed with the EU ADI and the EFSA PRIMo rev. 2.	
Results: No short-term consumer health risk was identified for the crops under assessment. Milk and milk products: 2.5% of the ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 88% of the ADI (DE child).	**Results:** Long-term exposure: Max 0% of the JMPR ADI for the 17 GEMS/Food Consumption Cluster Diets using the STMR or SMTR-p values estimated by JMPR. Short-term exposure: Highest result for children and for general population: 0% of ARfD, using the HR/HR-p or STMR/SMTR-p values estimated by JMPR.

5.39. Fosetyl-Al (302) R

5.39.1. Background information

Table 187: Background information

		Comments, references
JMPR assessment	Extraordinary JMPR meeting May 2019	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approved	Commission Implementing Regulation (EU) 2019/168[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2006b) (corrigendum 2013) (EFSA, 2014f) (Statement dietary RA proposed temporary MRLs) (EFSA, 2018m) (corrigendum 2019)
MRL review performed	Yes, see comments	(EFSA, 2012k) Combined assessment of fosetyl and phosphonates is ongoing
MRL applications/ assessments	Yes, see comments	(EFSA, 2021d)[(c)] (potassium phosphonates in blueberries) (EFSA, 2020q) (potassium phosphonates in garlic, shallots, wine grapes, avocados, olives, horseradish) (EFSA, 2020i) (potassium phosphonates in flowering brassica, Chinese cabbages, kales and spinaches) (EFSA, 2020d) (fosetyl/phosphonic acid in various crops)

		Comments, references
		(EFSA, 2019d) (potatoes and wheat) (EFSA, 2018e) (tree nuts, pome fruit, peach and potato) (EFSA, 2015y) (in blackberry, celeriac and Florence fennel) Modification of the existing MRLs in table grapes and wine grapes (withdrawn) (2015) (EFSA, 2012l) (potato, kiwi and certain spices) Ongoing: modification of the existing MRLs in citrus Ongoing (additional data requested): modification of the existing MRLs in apricots, cherries and plums Ongoing: Art. 43 assessment
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Assessment ongoing	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) is ongoing, further data were requested (clock-stop)

(a): Commission Implementing Regulation (EU) 2019/168 of 31 January 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, Bacillus subtilis (Cohn 1872) Strain QST 713, Bacillus thuringiensis subsp. Aizawai, Bacillus thuringiensis subsp. israeliensis, Bacillus thuringiensis subsp. kurstaki, Beauveria bassiana, benfluralin, clodinafop, clopyralid, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, Lecanicillium muscarium, mepanipyrim, mepiquat, Metarhizium anisopliae var. Anisopliae, metconazole, metrafenone, Phlebiopsis gigantea, pirimicarb, Pseudomonas chlororaphis strain: MA 342, pyrimethanil, Pythium oligandrum, rimsulfuron, spinosad, Streptomyces K61, thiacloprid, tolclofos-methyl, Trichoderma asperellum, Trichoderma atroviride, Trichoderma gamsii, Trichoderma harzianum, triclopyr, trinexapac, triticonazole, Verticillium albo-atrum and ziram. OJ L 33, 5.2.2019, p. 1–4.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

(c): The assessment performed in the recently published reasoned opinion could not be taken into account for the assessment in this report.

5.39.2. Toxicological reference values

Table 188: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	1 mg/kg bw per day (Applies to fosetyl-aluminium and phosphonic acid, expressed as fosetyl-aluminium)	JMPR (2017)	1 mg/kg bw per day	(EFSA, 2018m) Rabbit, developmental. Developmental NOAEL and safety factor of 100) not been noted by the European Commission	No (yes, if new ADI will be adopted)
			3 mg/kg bw per day phosphonic acid: 2.25 mg/kg bw per day	(European Commission, 2006a)	
ARfD	Unnecessary	JMPR (2017)	Unnecessary	(European Commission, 2006a) and (EFSA, 2018m)	Yes
Conclusion/ comment	–				

5.39.3. Residue definitions

Table 189: 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 The residue is not fat soluble	Reg. 396/2005: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) Peer review (EFSA, 2018m): sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid	No
	Animal products	Phosphonic acid	Reg. 396/2005: Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl) Peer review (EFSA, 2018m): phosphonic acid The residue is not fat soluble	No
RD RA	Plant products	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	Peer review (EFSA, 2018m): sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid	Yes
	Animal products	Phosphonic acid	Peer review (EFSA, 2018m): phosphonic acid MRL review Art. 12 (EFSA, 2012k): Phosphonic acid; risk managers to decide whether a separate residue definition for fosetyl should be established	Yes
Conclusion, comments	The existing enforcement residue definitions set by JMPR and in the EU for plant and animal commodities are expressed differently, i.e. as fosetyl or as phosphonic acid. Conversion factors can be used to make the MRL proposals derived by JMPR compatible with the EU residue definitions. 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 residue definitions of enforcement and risk assessment in commodities of plant and animal origin proposed by the EU peer review are the same as the ones derived by the JMPR. However, these residue definitions have not been enforced yet. Therefore, 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. For the risk assessment, the residue definitions proposed by the peer review are applicable.			

5.39.4. Codex MRL proposals

Table 190: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal (as phosphonic acid)	EU MRL (expressed as fosetyl)	Comment
Blackberries	70	300	cGAP: DE, indoor, 2 × 1.78 kg/ha, interval 10–14 days, PHI 14 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: The indoor and outdoor residue trials were combined, justified by the fact that

Commodity	Codex MRL proposal (as phosphonic acid)	EU MRL (expressed as fosetyl)	Comment
			residue data sets were of similar populations and that properties of fosetyl-Al would not be affected by indoor/ outdoor conditions. No information was provided which trials were indoor and which outdoor. The Codex MRL proposal expressed as fosetyl would be 100 mg/kg, which is lower than the existing EU MRL. The existing EU MRL for blackberries was established in 2019, following an application submitted by a German growers' association. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Kiwifruit	**150**	150	cGAP: IT, 2 × 4 kg/ha, BBCH 69, 30-day interval, PHI 40 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: According to Codex classification, 5 trials are sufficient for kiwis. According to EU rules at least 8 residue trials would be required. The Codex MRL proposal expressed as fosetyl would be 200 mg/kg, which is higher than the existing EU MRL. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the chronic exposure exceeded the ADI (see below). Follow-up action: None
Pineapple	15	50	cGAP: Costa Rica, preplant dip at 0.24 kg/hL + 3 (foliar) × 3.6 kg/ha, 90-day interval, PHI 90 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: According to Codex classification, 5 trials are sufficient. According to EU rules at least 8 residue trials would be required to support the import tolerance. The Codex MRL proposal expressed as fosetyl would be 20 mg/kg, which is lower than the existing EU MRL. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Head Brassicas (sub-group)	0.2 (*)	Head cabbage:10 Bru. sprouts: 10 Chinese cabbage: 10	cGAP: UK, soil treatment (drench) at 9.3 kg/ha, 10–14 days before transplanting Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: Residue trials on cabbage. According to Codex food classification, the Codex MRL proposal applicable also to Brussels sprouts, Chinese cabbage. The Codex MRL proposal expressed as fosetyl would be 0.8* mg/kg, which is lower than the existing EU MRL **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Flowerhead Brassicas (sub-group)	0.2 (*)	10	cGAP: UK, soil treatment (drench) at 9.3 kg/ha, 10–14 days before transplanting Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: Trials on cauliflower. The Codex MRL proposal expressed as fosetyl would be 0.8* mg/kg, which is lower than the existing EU MRL. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

Commodity	Codex MRL proposal (as phosphonic acid)	EU MRL (expressed as fosetyl)	Comment
Kale	0.2 (*)	10	cGAP: UK, soil treatment (drench) at 9.3 kg/ha, 10–14 days before transplanting Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal expressed as fosetyl would be 0.8* mg/kg, which is lower than the existing EU MRL **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Coffee beans	**30**	5*	cGAP: Brazil, foliar, 2 × 1.6 kg/ha, 30-day interval, PHI 30 days Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: According to Codex rules, coffee bean is a major crop, therefore the number of trials on not sufficient. According to EU rules, at least 8 residue trials on coffee would be required. The Codex MRL proposal expressed as fosetyl would be 40 mg/kg, which is higher than the existing EU MRL. **Conclusion:** The proposed Codex MRL is not acceptable because it is not sufficiently supported by data. In addition, the long-term exposure exceeded the ADI Follow-up action: None
Mammalian fat (except milk fats)	0.3	1.5	Livestock exposure calculated by the JMPR 2017 was updated with intake of residues from head cabbage, kale and pineapple by-product (process waste). The highest calculated beef and dairy cattle dietary burden remains for Australian diet. In comparison with JMPR 2017 assessment, additional contribution of residues in from the intake of brassica and pineapple process waste indicate that a higher Codex MRL is necessary only for fat. The Codex MRL proposal expressed as fosetyl would be 0.4 mg/kg, which is lower than the existing EU MRL. Sufficiently supported by data: Yes **Conclusion:** The proposed Codex MRL is acceptable.
Poultry meat	0.05 (*)	0.7	In the previous JMPR evaluation of fosetyl-Al in 2017, no intake was calculated for poultry due to the lack of uses in feed commodities. Now, based on the intake of kale or cabbage, the poultry dietary burden was estimated for EU diet (only). Since it was 200-fold lower than lowest feeding level from poultry feeding study, Codex MRLs at the LOQ of 0.05 mg/kg were proposed for all poultry matrices and eggs. Sufficiently supported by data: Yes **Conclusion:** The proposed Codex MRL is acceptable.
Poultry, Edible offal of	0.05 (*)	0.7	
Poultry fat	0.05 (*)	0.7	
Eggs	0.05 (*)	0.7	
Edible offal (mammalian)	–	Swine liver: 0.8 Swine kidney: 6 Ruminant liver:1.5 Ruminant kidney: 8	Livestock exposure calculated by the JMPR 2017 was updated with intake of residues from head cabbage, kale and pineapple by-product (process waste). The highest calculated beef and dairy cattle dietary burden remains for Australian diet. The existing Codex MRLs for meat (from mammals), for edible offal and mammalian milks remain unaffected.
Meat (from mammals other than marine mammals)	–	0.7 (muscle)	

Commodity	Codex MRL proposal (as phosphonic acid)	EU MRL (expressed as fosetyl)	Comment
General comments	The only crops for which the proposed Codex MRL is higher than existing EU MRL are kiwi and coffee beans. The Codex MRL proposals are derived for phosphonic acid and, in order to be taken over in the EU MRL legislation, they would need to be converted to fosetyl by applying the molecular weight conversion factor of 1.34. The Codex MRL proposal for coffee beans is not supported by sufficient number of residue data also according to Codex rules for minor/major crops.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.39.5. Consumer risk assessment

Table 191: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since currently no ARfD is allocated.	**RA assumptions:** The most recent long-term dietary risk assessment performed using EFSA with PRIMo rev. 3.1 (EFSA, 2020i) (scenario 2b) was updated with the STMR values (expressed as fosetyl) for kiwi and coffee beans. Two exposure scenarios were calculated: Scenario 1: The risk assessment was performed with the EU ADI of 2.25 mg/kg bw day (for phosphonic acid) (European Commission, 2006a). Scenario 2: The risk assessment was performed with proposed ADI of 1 mg/kg bw day (for phosphonic acid) (EFSA, 2018m) The calculations under scenario 2 are indicative, because the proposed ADI is not yet formally taken note by European Commission.	**Specific comments:** None
Results: Not relevant	**Results:** Scenario 1: No long-term consumer health risk was identified. The overall chronic exposure accounted for 43% of the ADI. Contribution from residues in kiwi 1.4% of the ADI and from coffee beans 2.2% of the ADI. Scenario 2: No long-term consumer health risk was identified. The overall chronic exposure accounted for 98% of the ADI. Contribution from residues in kiwi accounted for 3% of the ADI and coffee beans 5% of the ADI.	**Results:** Long-term exposure: Max 30% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.40. Mandestrobin (307) T

5.40.1. Background information

Table 192: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	

		Comments, references
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/2085[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2015k)
MRL review performed	No	Not foreseen, since MRLs were set in the framework of the first approval
MRL applications/ assessments	Yes, see comments	(EFSA, 2018r) (strawberry and grapes) (EFSA, 2018d) (apricot, cherry, peach and plum)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2015/2085 of 18 November 2015 approving the active substance mandestrobin, 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. 93–96.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.40.2. Toxicological reference values

Table 193: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.2 mg/kg bw per day	JMPR (2018) (1-year toxicity study in dogs, safety factor 100)	0.19 mg/kg bw per day	(EFSA, 2015k) (52-week dog (uncertainty factor 100), supported by multigeneration rat (parental LOAEL, uncertainty factor 300)	Yes
ARfD	3 mg/kg bw	JMPR (2018) (developmental toxicity study in rats, safety factor 100)	Not required	(EFSA, 2015k)	No
Conclusion/ comment	The EU ADI is 0.19 mg/kg bw per day based on the 1-year dog study (applying an uncertainty factor of 100), supported by the parental LOAEL from the multigeneration rat study (applying an UF of 300). The 2018 JMPR proposed the same ADI also based on the 1-year dog study. The different ADI values are a result of different policies on rounding. In the EU evaluation, the derivation of an ARfD was considered not necessary on the basis of the low acute toxicity profile of mandestrobin by the peer review experts. 2018 JMPR proposed an ARfD of 3 mg/kg bw for women of childbearing age, based on an NOAEL of 300 mg/kg bw per day for malformations observed in a developmental toxicity study in rats and using a safety factor of 100. The JMPR concluded that it was not necessary to establish an ARfD for the remainder of the population. The same developmental NOAEL from this study was set by the EU peer review (based on foetal findings) but was not considered appropriate for the ARfD derivation. Moreover, in EU it is not a common practice to set separate ARfDs for the different populations. Metabolites assessed during the EU peer review: The plant metabolites 4-OH-S-2200 and De-Xy-S-2200 were considered to be covered by the toxicological profile of mandestrobin.				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
	The plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-mandestrobin), due to uncertainties with regard to its toxicological profile, was considered not covered by the toxicological studies. The toxicological properties of metabolite 2-CH2OH-S-2200 (conjugate) remains open. It is noted that in JMPR report (2019) a read-across approach was applied to 2-CH_2OH-mandestrobin, concluding its similarity with mandestrobin. The RMS supported the JMPR approach for read-across.				

5.40.3. Residue definitions

Table 194: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Mandestrobin	Reg. 396/2005 and peer review (EFSA, 2015k): Mandestrobin	Yes
	Animal products	Mandestrobin The residue is fat soluble	Reg. 396/2005 and peer review (EFSA, 2015k): Mandestrobin The residue is fat soluble	Yes
RD RA	Plant products	Mandestrobin	Peer review (EFSA, 2015k): Sum of mandestrobin, De-Xy-S-2200 (De–XY-mandestrobin), 4-OH-S-2200 conjugate (4–OH-mandestrobin conjugate), 2–CH_2OH-S-2200 conjugate (2–CH_2OH-mandestrobin conjugate), expressed as mandestrobin	No
	Animal products	The sum of parent + (2*RS*)-2-[2-(4-hydroxy-2,5-dimethylphenoxymethyl)phenyl)-2-methoxy-*N*-methylacetamide (4-OH-mandestrobin) + (2*RS*)-2-(2-hydroxymethylphenyl)-2-methoxy-*N*-methylacetamide (De-XY-mandestrobin) + (2*RS*)-2-[2-(2-hydroxymethyl-5-methylphenoxymethyl)phenyl]-2-methoxy-*N*-methylacetamide (2-CH_2OH-mandestrobin) + 2-({2-[(1*RS*)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (2-COOH-mandestrobin) + 3-({2-[(1*RS*)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (5-COOH-mandestrobin), and their conjugates, expressed as parent compound.	Peer review (EFSA, 2015k): Mandestrobin	No
Conclusion, comments	For enforcement, JMPR and EU residue definitions are identical (both plant and animal products). For risk assessment, the EU residue definition for plant products is wider compared with JMPR since it includes also the metabolites De-Xy-S-2200, 4-OH-S-2200 conjugate and 2-CH_2OH-S-2200 conjugate, expressed as mandestrobin.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal product commodities were not assessed during the EU peer review process. For animal products the EU residue definition for risk assessment is set as mandestrobin (only), whereas the JMPR residue definition for risk assessment is wider and includes the metabolites 4-OH-mandestrobin, De-XY-mandestrobin, 2-CH_2OH-mandestrobin, 2-COOH-mandestrobin, 5-COOH-mandestrobin and their conjugates, expressed as parent compound. However, since for animal products the Codex MRL proposals under discussion are proposed at the LOQ of 0.01 and the input values for risk assessment are all proposed to be 0 mg/kg, this discrepancy in the residue definition is of minor relevance for the current assessment.			

5.40.4. Codex MRL proposals

Table 195: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Grapes	**5**	0.01*	cGAP: Canada and the USA, foliar application, 3 × 0.42 kg/ha, interval 10 days, PHI 10 days Number of trials: 11 trials Sufficiently supported by data: Yes Specific comments/observations: EU import tolerance MRLs for table and wine grapes have been proposed by ESFA at 5 mg/kg on the basis of the Canada GAP but is not yet implemented in EU legislation (EFSA, 2018r). In the JMPR evaluation, residue trials data reported for parent mandestrobin (only) in accordance with the JMPR RD RA, whereas the EU RD RA includes also the metabolites De-Xy-S-2200, 4-OH-S-2200 conjugate and 2-CH_2OH-S-2200 conjugate. A conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment is available (CF = 1.06) (EFSA, 2018r). The plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-mandestrobin), which is included as conjugate in the EU RD RA, is not covered by the available toxicological studies. However, this metabolite was not detected at levels at or above the LOQ in the supervised crop field trials of grapes assessed in the framework of a previous EU MRL application (EFSA, 2018r). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Grapes, dried (=Currents, Raisins and Sultanas)	10	–	A concentration of residues occurs in dried grapes (currants, raisins, sultanas) and the JMPR evaluation derived a processing factor of 2.0 on the basis of one trial. A tentative processing factor of 1.93 was previously derived by EFSA from one processing study (EFSA, 2018r).
Mammalian fats (except milk fats)	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Milks	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A

Commodity	Codex MRL proposal	EU MRL	Comment
			Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Meat (from mammals other than marine mammals)	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Edible offal (mammalian)	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Eggs	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry fats	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry meat	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR.

Commodity	Codex MRL proposal	EU MRL	Comment
			Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry, edible offal of	0.01*	0.01*	cGAP: Livestock are not significantly exposed and therefore residues in animal commodities are not expected and were not calculated by JMPR. Number of trials: N/A Sufficiently supported by data: No Specific comments/observations: The JMPR estimated MRLs for animal commodities since a validated analytical method is available for determination of parent mandestrobin in animal commodities. The JMPR recommended a Codex MRL at the LOQ of 0.01 mg/kg based on an estimated STMR and HR of 0 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Strawberry	**3.0**	0.05*	cGAP: Canada and the USA, foliar application, 4 × 0.42 kg/ha, interval 7 days, PHI 0 days Number of trials: 8 trials Sufficiently supported by data: Yes Specific comments/observations: An EU import tolerance MRL for strawberry has been proposed by ESFA at 3 mg/kg on the basis of the Canada GAP but is not yet implemented in EU legislation (EFSA, 2018r). In the JMPR evaluation, residue trials data reported for parent mandestrobin (only) in accordance with the JMPR RD RA, whereas the EU RD RA includes also the metabolites De-Xy-S-2200, 4-OH-S-2200 conjugate and 2-CH_2OH-S-2200 conjugate. A conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment is available (CF = 1.10) (EFSA, 2018r). The plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-mandestrobin), which is included as conjugate in the EU RD RA, is not covered by the available toxicological studies. However, this metabolite was not detected at levels at or above the LOQ in two trials of strawberries (including data from an overdosed plot) assessed in the framework of a previous EU MRL application (EFSA, 2018r). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Rape seed	**0.2**	0.01*	cGAP: Canada and the USA, 1 × 0.42 kg/ha, at BBCH 62–65, PHI 35 days Number of trials: 9 trials Sufficiently supported by data: Yes Specific comments/observations: An EU MRL for rapeseeds/canola seeds was previously assessed by ESFA in the framework of the first approval on the basis of EU GAPs (NEU and SEU, 1 × 0.20 kg/ha, BBCH 63–67, PHI defined by growth stage) and the EU MRL was proposed and set at the LOQ of 0.01 mg/kg (EFSA, 2015k). In the JMPR evaluation, residue trials data reported for parent mandestrobin (only) in accordance with the JMPR RD RA, whereas the EU RD RA includes also the metabolites De-Xy-S-2200, 4-OH-S-2200 conjugate and 2-CH_2OH-S-2200 conjugate. A conversion factor to recalculate residues according to the residue definition for monitoring to the EU residue definition for risk assessment is not available.

Commodity	Codex MRL proposal	EU MRL	Comment
			The plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-mandestrobin), which is included as conjugate in the EU RD RA, is not covered by the available toxicological studies. In case this metabolite is detected in rapeseeds, then additional studies addressing the toxicological properties may be required. The EU RMS informed EFSA that metabolism studies in rapeseed suggest that residues of max 0.02 mg/kg for 2-CH2OH-S-2200 are expected. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Follow-up action: None
General comments			

*: Indicates that the MRL is proposed at the limit of quantification.

5.40.5. Consumer risk assessment

Table 196: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The calculations for rapeseed are affected by additional non-standard uncertainties due to the lack of information on the contribution of the plant metabolites De–Xy-S-2200, 4–OH-S-2200 conjugate and 2–CH_2OH-S-2200 conjugate, which are included in the EU residue definition for risk assessment. A conversion factor (CF) for risk assessment for rapeseed is not available. The risk assessment was performed using the STMR values for rapeseed derived by the JMPR for mandestrobin (only), which may lead to an underestimation of residue levels. For grapes and strawberry, EFSA applied the previously derived conversion factors (CFs) for risk assessment (EFSA, 2018r) to the STMR values derived by the JMPR. The EU peer review considered that an ARfD was not required; however, for indicative purposes, a risk assessment was performed with the JMPR ARfD for adults and children noting this was derived for women of childbearing age only. The calculations are indicative for rapeseed because the plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-mandestrobin), which is included as conjugate in the EU residue definition for risk assessment, is not covered by the available toxicological studies. For the purposes of the indicative risk assessment, EFSA assumed the toxicity of the plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2018r) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. The calculations are affected by additional non-standard uncertainties due to the lack of information for rapeseed on the contribution of the plant metabolites De–Xy-S-2200, 4–OH-S-2200 conjugate and 2–CH_2OH-S-2200 conjugate, which are included in the EU residue definition for risk assessment. A conversion factor (CF) for risk assessment for rapeseed is not available. The risk assessment was performed using the STMR values for rapeseed derived by the JMPR for mandestrobin (only), which may lead to an underestimation of residue levels. For grapes and strawberry, EFSA applied the previously derived conversion factors (CFs) for risk assessment (EFSA, 2018r) to the STMR values derived by the JMPR. The risk assessment was performed with the EU ADI. The calculations are indicative because the plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-mandestrobin), which is included as conjugate in the EU residue definition for risk assessment, is not covered by the available toxicological studies. For the purposes of the indicative risk assessment, EFSA assumed the toxicity of the plant metabolite 2–CH_2OH-S-2200 (2–CH_2OH-	**Specific comments:** The JMPR exposure assessment according to the residue definition for risk assessment for plant commodities covers mandestrobin (only) whereas the EU residue definition includes also the plant metabolites De–Xy-S-2200, 4–OH-S-2200 conjugate and 2–CH_2OH-S-2200 conjugate.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
mandestrobin) to be comparable with that of the parent mandestrobin. The metabolite 2–CH_2OH-S-2200 was not detected at levels at or above the LOQ in the supervised crop field trials of grapes and in two trials of strawberries (including data from an overdosed plot) assessed in the framework of a previous EU MRL application (EFSA, 2018r), and therefore, further consideration is not required for these commodities. In case the metabolite 2-CH_2OH-S-2200 is detected in commodities assessed in future MRL applications, then additional studies addressing the toxicological properties of this metabolite may be required.	mandestrobin) to be comparable with that of the parent mandestrobin. The metabolite 2–CH_2OH-S-2200 was not detected at levels at or above the LOQ in the supervised crop field trials of grapes and in two trials of strawberries (including data from an overdosed plot) assessed in the framework of a previous EU MRL application (EFSA, 2018r), and therefore, further consideration is not required for these commodities. In case the metabolite 2-CH_2OH-S-2200 is detected in rapeseed or other commodities assessed in future MRL applications, then additional studies addressing the toxicological properties of this metabolite may be required.	
Results: No short-term consumer health risk was identified for the crops under assessment. Table grapes: 10% of ARfD Strawberries: 1% of ARfD Wine grapes: 3% of ARfD Rapeseeds: < 0.01% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 2% of the ADI. Among the crops under consideration, wine grapes and table grapes were identified as the main contributors, accounting for up to 2% and 1% of the ADI, respectively.	**Results:** Long-term exposure: Max 2% of the JMPR ADI. Short-term exposure: Highest result for grapes (all commodities): 4% of ARfD (CA women, 15–49 years). Table grapes (all commodities): 2% of ARfD (DE Women, 14–50 years) Wine grapes (all commodities): 1% of ARfD (PRIMO-UK adult).

5.41. Pydiflumetofen (309) R

5.41.1. Background information

Table 197: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approval process ongoing	
EFSA conclusion available	Yes, see comments	(EFSA, 2019k)
MRL review performed	No	
MRL applications/ assessments	Yes, see comments	MRL application ongoing as part of the approval process for pome fruit, grapes, potatoes, tropical root and tuber vegetables, solanaceae, cucurbits, brassica and soybeans
Classification of a.s. – cut-off criteria	No	RAC (ECHA, 2019a)
Endocrine effects of a.s.	No	(EFSA, 2019k)

5.41.2. Toxicological reference values

Table 198: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.1 mg/kg bw per day	JMPR (2018) Rat, 2-year study, UF of 100	0.09 mg/kg bw per day	(EFSA, 2019k) Mouse, 18-month study, UF of 100	No
ARfD	0.3 mg/kg bw	JMPR (2018) Rat developmental toxicity study, UF of 100	0.3 mg/kg bw	(EFSA, 2019k) Rat, developmental toxicity study, UF of 100	Yes
Conclusion/ comment	The slight difference between the ADI established by the JMPR and EU assessments is mainly due to rounding since the 2-year rat and 18-month mouse studies present similar NOAELs of 9.9 and 9.2 mg/kg bw per day, respectively, values agreed within the two assessments. The same conclusion was reached with regard to the setting of the ARfD. The ADI/ARfD derived by JMPR applies to pydiflumetofen and the metabolites 2,4,6-TCP and SYN547897. Metabolites: The EU evaluation concluded differently with regard to metabolites: **CSAA798670** (CA4312; NOA449410; M700F001): – The EU assessment derived an ADI of 0.25 mg/kg bw per day based on a rabbit developmental toxicity study, UF 1000; An ARfD was not derived as not needed. – The JMPR evaluation concluded that the toxicological profile of the metabolite indicate that it is less potent than the parent compound. **SYN508272** (M700F007): – The EU assessment derived an ADI and ARfD of 0.04 mg/kg bw per day based on a 28-day toxicity study in rat and applying an UF of 1000. – The JMPR evaluation concluded that the toxicity of the metabolite is covered by the parent compound. **SYN545547**, **SYN548263** and **SYN547897**: – The EU assessment concluded that these metabolites are unlikely to be genotoxic; however, insufficient information is available to conclude on their general toxicity, or comparative toxicity with the parent compound. – The JMPR evaluation noted that no toxicological studies were provided on these metabolites. **2,4,6-TCP** (2,4,6-trichlorophenol): – The EU assessment concluded that the metabolite showed evidence for carcinogenic potential in rat and mouse, its genotoxic potential is inconclusive (data gap). – The JMPR evaluation concluded that the toxicity of the metabolite and its conjugates is covered by the parent compound, as this metabolite was identified as a major metabolite in rats.				

5.41.3. Residue definitions

Table 199: Comparison of the residue definitions derived by JtMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Pydiflumetofen	Peer Review proposal (EFSA, 2019k): Pydiflumetofen	Yes
	Animal products	Pydiflumetofen The residue is fat soluble	Peer Review (EFSA, 2019k): Pydiflumetofen The residue is fat soluble	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Pydiflumetofen	Peer Review (EFSA, 2019k): Pydiflumetofen (for all crops following foliar application)	Yes
	Animal products	Animal products other than mammalian liver and kidney: Sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen For mammalian liver and kidney: Sum of pydiflumetofen, 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates and 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl) ethyl]pyrazole-4-carboxamide(SYN547897) and its conjugates, expressed as pydiflumetofen	Peer Review (EFSA, 2019k): Pydiflumetofen and 2,4,6-TCP for all animal matrices (provisionally)	No
Conclusion, comments	The EU pesticides residue definition for enforcement in plant and animal products and for risk assessment in plant products is identical with the JMPR residue definition. As regards the residue definition for risk assessment (RA) in animal products (all matrices), a provisional residue definition as parent and 2,4,6-TCP was proposed in the peer review. The inclusion of SYN547897 for ruminant liver and SYN547897 and SYN548263 for ruminant kidney in the RA RD was discussed in an EFSA expert meeting, but it was supported by a minority of experts during the peer review only. In contrast, the JMPR residue definition for animal products for mammalian liver and kidney includes also conjugates of 2,4,6-TCP, and SYN547897 and its conjugates; for other products than mammalian liver and kidney the RD for RA includes 2,4,6-TCP and its conjugates. Thus, the JMPR residue definitions is wider than the provisional EU RD. The residue definitions for primary crops applies also to rotational crops. Pydiflumetofen is a very persistent compound (DT50=8540 days EU value), the accumulation of residue and consequently the uptake from the soil cannot be neglected (see also the general comment from the MRL assessment).			

5.41.4. Codex MRL proposals

Table 200: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Barley, similar grains and pseudocereals with husks, Subgroup of	**3**	0.01* (barley, buckwheat and oats)	cGAP: USA, 1 × 0.2/ha before BBCH 71 Number of trials: 14 barley and 24 oats Sufficiently supported by data: Yes Specific comments/observations: JMPR combined GAP compliant trials from barley and oat. The level of residues in relevant succeeding crops (wheat grains) was low (mean/highest residues < 0.02 mg/kg) compared to the residues following direct application (0.23 mg/kg), therefore the MRL was based only on direct treatment. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Barley straw and fodder, dry	50 (dw)	–	cGAP: USA: 1 × 0.2 kg/ha (do not apply after BBCH 71) Number of trials: 81 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
			Specific comments/observations: Residue data set in straw and hay of barley, oats and wheat. Residues uptake via sol were insignificant (succeeding crops) compared to the residues following direct application. **Conclusion:** In the EU no MRLs are set for feed items.
Brassica vegetables (except Brassica leafy vegetables), Group of	**0.1**	0.01* broccoli; cauliflower; Brussels sprouts, head cabbage, Kohlrabi)	The Codex MRL proposal was derived from rotational crop studies (spinach, lettuce and kale) Number of trials: 22 Specific comments/observations: MRL proposals derived in EU peer review: 0.07 mg/kg in cauliflower, 0.15 mg/kg in broccoli, 0.2 mg/kg in head cabbage and kohlrabi, 0.3 mg/kg in Brussels sprouts, 4 in Chinese cabbage (MRLs not yet discussed in PAFF). **Conclusion:** The proposed Codex MRL is acceptable. See also general comments. Follow-up action: None
Cotton seed	**0.3**	0.01*	The Codex MRL proposal was derived from rotational crop studies (wheat straw) Number of trials: 3 (wheat straw) Sufficiently supported by data: No Specific comments/observations: Rotational crop studies in wheat straw are not appropriate to derive an MRL proposal for oilseeds. At least 8 trials in oilseed rape or soybeans would be required). **Conclusion:** The proposed Codex MRL is not acceptable.See also general comments. Follow-up action: None
Dry beans, Subgroup of	**0.4**	0.01* (beans, lupins, soyabeans)	cGAP: Canada, 2 × 0.2 kg/ha, RTI 14 days, PHI 14 days Number of trials: 10 (beans), 21 (soyabeans), 10 (peas) Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal is based on combined residue data set on dry beans, soyabeans and peas. Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Dry peas, Subgroup of	**0.4**	0.01* (Peas, Lentils)	cGAP: Canadian (2 × 0.2 kg/ha, RTI 14 days, PHI 14 days) Number of trials: 10 (beans), 21 (soyabeans), 10 (peas) Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal is based on combined residue data set on dry beans, soyabeans and peas. Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Edible offal (Mammalian)	**0.1**	0.01*	The Codex MRL proposal is based on the maximum dietary burden calculated of 44 ppm (Australian diet). Residues in liver at the calculated dietary burden accounted for up to 0.05 mg/kg. The proposed Codex MRL is not acceptable because of open issues regarding the toxicological profile of 2,4,6-TCP. In addition, it is noted that a Codex MRL proposal of 0.05 mg/kg would be sufficient.

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
			Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the open issues regarding the toxicological profile of 2,4,6-TCP. In addition, it is noted that a Codex MRL proposal of 0.05 mg/kg would be sufficient.
Eggs	**0.02**	0.01*	The Codex MRL proposal is based on the maximum dietary burden calculated of 6.2 ppm (EU diet). The feeding studies covers the estimated dietary burden since were conducted at 3, 9 and 15 ppm. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the open issues regarding the toxicological profile of 2,4,6-TCP.
Fruiting vegetables, Cucurbits, Group of	**0.4**	0.01* (cucumbers, gherkins, courgettes, melons, pumpkins, watermelons)	cGAP: USA 2x0.13 kg/ha, PHI 0 days Number of trials: 21 (10 on cucumbers, 5 on summer squash, 6 on cantaloupe) Sufficiently supported by data: Yes Specific comments/observations: JMPR meeting combined trials on cucumber (3 indoor and 7 outdoor trials), summer squash and cantaloupe based on the similar population according to the statistical test (Kruskal–Wallis test). Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. MRL proposal derived in EU peer review: 0.15 mg/kg for cucumber and melons, **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Fruiting vegetables, other than Cucurbits, Group of (except Martynia, Okra and Roselle)	0.5	0.01* (tomatoes, sweet pepper/ bell pepper, aubergines/ eggplants)	cGAP: USA 2 × 0.13 kg/ha, PHI 0 days Number of trials: 21 (10 tomatoes, 2 cherry tomatoes, 9 peppers). Sufficiently supported by data: Yes Specific comments/observations: The CXL is based on combined residue data set on tomatoes and peppers. Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. MRL proposal derived in EU peer review: 0.8 mg/kg for tomatoes, 0.5 mg/kg for pepper, 0.15 mg/kg aubergines. The manufacturer should be encouraged to submit the more critical EU GAP to JMPR. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Leafy greens, Subgroup of	40	0.01* Lamb lettuce/ corn salad, lettuce, endives, land cress, spinach, purslane, chards/beet leaves, chervil,	cGAP: USA 2 × 0.2 kg/ha, PHI 0 days Number of trials: 24 (8 on head lettuce, 8 leaf lettuce and 8 on spinach) Sufficiently supported by data: No Specific comments/observations: JMPR combined residue on lettuce (leaf and head) and spinach; although the data sets belonged to different statistical populations, considering that the medians did not differ by more than a factor of 5. Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment **Conclusion:** The proposed Codex MRL is not acceptable because of an intake concern identified for several crops; JMPR also identified a public health concern. Follow-up action: None

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Leaves of Brassicaceae, Subgroup of	**0.1**	0.01* hinese cabbage, kale, rucola, cress, land cress	The Codex MRL proposal was derived from rotational crop studies (spinach, lettuce and kale). Number of trials: 22 (spinach, lettuce and kale succeeding crops) Sufficiently supported by data: Yes Specific comments/observations: In the peer review an MRL of 4 mg/kg was proposed for kale and Chinese cabbage based on the NEU GAP (2 × 70 g/ha, PHI 14 days). **Conclusion:** The proposed Codex MRL is acceptable.Considering that EU uses would require higher MRLs, the manufacturer should be encouraged to submit label information on EU uses to JMPR. See also general comment. Follow-up action: None
Leaves of root and tuber vegetables, Subgroup of (except leaves of tuber vegetables)	**0.07**	No corresponding crops in EU food classification (part A)	The Codex MRL proposal was derived from rotational crop studies (radish and carrots tops). Number of trials: 15 (radish and carrots top, succeeding crops) Sufficiently supported by data: Yes Specific comments/observations: Only few crops classified in the Codex classification in this group are all classified in part B of the EU food classification under spinaches, for which a higher Codex MRL proposal was derived (see Leafy greens, Subgroup of). **Conclusion:** The proposed Codex MRL is acceptable. See also general comments. Follow-up action: None
Legume animal feeds	30 (dw)	–	JMPR meeting derived the Codex MRL proposal from trials on peas hay (5), peanut hay (11). Sufficiently supported by data: Yes Specific comments/observations: Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. No MRLs are set for feed items in the EU.
Legume vegetables, Group of	**0.02**	0.01* (beans with pods, beans without pods, peas with pods, peas without pods, other legume vegetables)	The Codex MRL proposal was derived from rotational crop studies (fresh beans). Number of trials: 3 (all < 0.02 mg/kg) Sufficiently supported by data: No Specific comments/observations: The number of trials is not sufficient; according to OECD guidance nr 279, four residue trials from the succeeding crops would be needed. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the limited number of trials. See also general comments. Follow-up action: None
Maize cereals, Subgroup of	**0.04**	0.01* mg/kg (maize/corn)	cGAP: Canada and USA: 1 × 0.2 kg/ha, PHI 30 days Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: Residues in succeeding crops via soil uptake were taken into account for deriving the MRL proposal and the STMR/HR (for deriving the MRL the highest residue observed in rotational crop studies (Scaled value) was added to the MRL calculated from the primary crop residue trials; the HR was calculated by adding HR (primary crop) to HR (rotational crop). For the STMR the mean residue from rotational crops was added

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
			to the STMR derived from primary crop studies). **Conclusion:** It is recommended to discuss with MS whether the approach taken by JMPR to derive the Codex MRL is acceptable. See also general comments. Follow-up action: none.
Maize flour	0.07	–	JMPR proposed processing factors of 1.6 (dry milled) and < 0.42 (wet milled). No EU MRLs are set for processed maize.
Maize fodder	18 (dw)	–	cGAP: Canada and USA: 1 × 0.2 kg/ha, PHI 30 days Number of trials: 23 Sufficiently supported by data: Yes Specific comments/observations: 23 independent trials from Canada were submitted. The level of residues in succeeding crops (stover maize) accounted for up to 13 mg/kg. No MRLs are set for feed items in the EU.
Maize oil, edible	0.08	–	JMPR proposed processing factors of 1.9 (wet milled) and < 0.42 (dry milled). No EU MRLs are set for processed maize.
Martynia	0.02	–	The Codex MRL proposal was derived from rotational crop studies (tomatoes). Number of trials: 4 (tomatoes, all < 0.02 mg/kg) Sufficiently supported by data: Yes Specific comments/observations: Martynia is not listed in the EU food classification. **Conclusion:** The proposed Codex MRL is acceptable.It is noted that the Codex MRL proposal should be labelled with an asterisk, considering that in all residue trials the results were below the LOQ. Follow-up action: None
Mammalian fats (except milk fats)	**0.1**	0.01*	See edible offal.
Meat (from mammals other than marine mammals)	**0.1 (fat)**	0.01*	See edible offal.
Milks	0.01*	0.01*	The proposed Codex MRL is not acceptable because of open issues regarding the toxicological profile of 2,4,6-TCP.
Millet fodder, dry	0.3 (dw)	–	The Codex MRL proposal was derived from rotational crop studies (wheat straw). **Conclusion:** No MRLs are set for feed items in the EU.
Oat straw and fodder, dry	50 (dw)	–	See barley straw and fodder.
Okra	**0.02**	0.01*	The Codex MRL proposal was derived from rotational crop studies (tomatoes). Number of trials: 4 (all < 0.02 mg/kg) Sufficiently supported by data: Yes Specific comments/observations: In EU peer review, an MRL of 0.5 mg/kg was proposed for okra based on the indoor GAP on pepper (GAP: 2 × 70 g/ha, PHI 3 days). **Conclusion:** The proposed Codex MRL is acceptable.It is noted that the Codex MRL proposal should be labelled with an asterisk, considering that in all residue trials the results were below the LOQ. Follow-up action: None
Peanut	**0.05**	0.01*	cGAP: USA, 4 × 0.05 kg/ha, PHI 14 days Number of trials: 12

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
			Sufficiently supported by data: Yes Specific comments/observations: Residues in succeeding crops via soil uptake were taken into account for deriving the MRL proposal (5 rotational crop studies in soyabean seeds and dry beans, all results < 0.02 mg/kg). JMPR added the mean residue found in rotational crop studies to the STMR from primary crops to derive the risk assessment values for peanuts. The MRL was derived by adding the highest residue found in succeeding crop field trials to the calculated MRL derived from primary crop trials. **Conclusion:** It is recommended to discuss with MS whether the approach taken by JMPR to derive the Codex MRL is acceptable. See also general comments. Follow-up action: None
Peanut oil, edible	0.15	–	JMPR propose a PF of 2.4 derived from one study. In EU no MRL is in place for processed commodities.
Peppers, chilli, dried	5	–	Proposed MRL was derived from residue trials in peppers, applying the default dehydration factor of 10. At EU level, MRLs are set only for fresh products.
Potato, dried	0.5	–	Proposed MRL was derived from residue trials in potatoes by applying a processing factor of 4.3.
Poultry, Edible offal of	0.01*	0.01*	The Codex MRL proposal is based on the maximum dietary burden of 6.2 ppm calculated for the EU. The feeding studies cover the max DB where the residues were < 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable.
Poultry fats	0.01*	0.01*	See poultry edible offal.
Poultry meat	0.01*	0.01*	See poultry edible offal.
Rice cereals, Subgroup of	**0.03**	0.01*	The Codex MRL proposal was derived from rotational crop studies (wheat, barely grain). Number of trials: 3 wheat and 4 on barley (all below LOQ of 0.02/0.03 mg/kg). Sufficiently supported by data: yes Specific comments/observations: - **Conclusion:** The proposed Codex MRL is acceptable. See also general comments. Follow-up action: None
Rice straw and fodder, dry	0.3 (dw)	–	See millet straw and fodder.
Root vegetables, Subgroup of	**0.1**	0.01* (carrot, beetroot, celeriac, chicory roots, ginseng, horseradish, parsley roots, parsnip, radish, salsify, swedes, sugar beet, swedes, turnip)	The Codex MRL proposal was derived from rotational crop studies (carrots, radishes). Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: - **Conclusion:** The proposed Codex MRL is acceptable. See also general comments. Follow-up action: None
Roselle	0.02	0.01*	The Codex MRL proposal was derived from rotational crop studies (tomatoes). Number of trials: 4 (tomatoes, all < 0.02 mg/kg) Sufficiently supported by data: Yes Specific comments/observations: In the EU food classification no commodity corresponding to the roselle (fruit) is listed.

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
			Conclusion: The proposed Codex MRL is acceptable, but no corresponding commodity in EU food classification. It is noted that the Codex MRL proposal should be labelled with an asterisk, considering that in all residue trials the results were below the LOQ. Follow-up action: None
Rye straw and fodder, dry	50 (dw)	–	See barley straw and fodder.
Small seed oilseeds, Subgroup of	**0.9**	0.01* (borage seed, rapeseed, linseed, mustard seed, poppy seed, radish seed, sesame seed)	cGAP: Canada and USA: 1x0.2 kg/ha, PHI 30 days Number of trials: 18 Sufficiently supported by data: Yes Specific comments/observations: Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Sorghum Grain and Millet, Subgroup of	**0.03**	0.01* (millet, sorghum)	See rice cereals.
Sorghum straw and fodder, dry	0.3 (dw)	–	See millet straw and fodder.
Stems and petioles, Subgroup of	**15**	0.01* (cardoons, celery, rhubarb, fennel)	cGAP: USA 2 × 0.2 kg/ha, PHI 0 days Number of trials: 8 (celery) Sufficiently supported by data: Yes Specific comments/observations: Rotational crop data are not available for stalk and stem vegetables. Considering data from Brassica and leafy crops, residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. **Conclusion:** The proposed Codex MRL is not acceptable because of an acute intake concern identified for celeries and rhubarbs (see below results of risk assessment). For cardoons and fennels the proposed Codex MRL proposal would be acceptable. Follow-up action: None
Sunflower seeds, Subgroup of	**0.3**	0.01* (sunflower seeds)	The Codex MRL proposal was derived from rotational crop studies (wheat straw) Number of trials: 3 (wheat straw) Sufficiently supported by data: No Specific comments/observations: Rotational crop studies in wheat straw are not appropriate to derive an MRL proposal for oilseeds. At least 8 trials in oilseed rape or soybeans would be required). **Conclusion:** The proposed Codex MRL is not acceptable.See also general comments. Follow-up action: None
Sweet Corns, Subgroup of	**0.03**	0.01* sweet corn	cGAP: USA 2 × 0.1 kg/ha, PHI 7 days Number of trials: 12 (< 0.01 mg/kg) Sufficiently supported by data: Yes Specific comments/observations: Residues in succeeding crops via soil uptake were taken into account for deriving the MRL proposal. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. See general comments. Follow-up action: none.
Tomato, dried	7		JMPR proposed processing factors of 10.5 for dried tomatoes. No EU MRLs are set for processed commodities.

Commodity	Codex MRL proposal	EU MRL (default MRLs)	Comment
Triticale straw and fodder, dry	50 (dw)	–	See barley straw and fodder.
Tuberous and corm vegetables, Subgroup of	**0.1**	0.01 (arrowroots, cassava, Jerusalem artichoke, potatoes, sweet potato, yam)	cGAP: USA 3 × 0.38 kg/ha PHI of 7 days Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: 22 GAP compliant residue trials on potatoes were submitted. The level of residues from the succeeding crops were taken into account for deriving the risk assessment values for potatoes (mean residue and highest residue of succeeding crops was added to median and highest residue in potatoes, respectively). For deriving the MRL proposal the highest residue found in succeeding crop trials was added to the MRL proposal derived for potatoes (0.07 km/kg + 0.03 mg/kg). **Conclusion:** It is recommended to discuss with MS whether the approach taken by JMPR to derive the Codex MRL is acceptable. Follow-up action: None
Wheat bran, processed	1	–	JMPR proposed processing factor of 2.25 for wheat bran. No EU MRLs are set for processed commodities.
Wheat germ	0.6	–	JMPR proposed processing factors of 1.45 for wheat germ. No EU MRLs are set for processed commodities.
Wheat, similar grains and pseudocereals without husks, Subgroup of	**0.4**	0.01* (wheat, rye, amaranth, quinoa)	cGAP: USA, 1 × 0.2kg/ha (application before BBCH 71) Number of trials: 29 Sufficiently supported by data: Yes Specific comments/observations: Residues in succeeding crops via soil uptake were considered insignificant compared to residues following direct treatment. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Wheat straw and fodder, dry	50 (dw)	–	See barley straw and fodder.
General comments	Pydiflumetofen is very high persistent compound in the soil and therefore the uptake from the soil of residues into the cultivated crops was considered by JMPR. JMPR calculated the DT50 (geometric mean) of 603 days, which was used to estimate the plateau level in soil (591 g a.i./ha). In the EU peer review a different DT50 (geometric mean) (1334 days) and soil plateau concentration (3174 g a.i./ha; plateau not yet reached after 100 years). It is recommended to discuss with risk managers whether Codex MRL proposals are acceptable despite the different methodology to calculate the soil plateau levels.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.41.5. Consumer risk assessment

Table 201: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The risk assessment is indicative, since the JMPR residue definition for animal products differs from the EU	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The calculation was performed using the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (MRL proposals derived in the peer review.	**Specific comments:** JMPR concluded that the estimated acute dietary exposure to residues of pydiflumetofen for the consumption of Leafy greens may present a public health concern.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RD (proposed in the peer review). Considering that the residue definition derived by JMPR for animal products is wider than the EU residue definition, the exposure is likely to be overestimated for animal products. The risk assessment is affected by additional, non-standard uncertainties due to the provisional residue definition for animal products The risk assessment was performed with the EU ARfD.	The risk assessment is indicative, since the JMPR residue definition for animal products differs from the EU RD (proposed in the peer review). Considering that the residue definition derived by JMPR for animal products is wider than the EU residue definition, the exposure is likely to be overestimated for animal products The risk assessment is affected by additional, non-standard uncertainties due to the provisional residue definition for animal products The risk assessment was performed with the EU ADI.	
Results: The calculated short-term exposure exceeded the ARfD for several crops under assessment. 228% Escaroles 216% Lettuces 128% Spinaches 116% Celeries 115% Rhubarbs 107% Chards/beet leaves 55% Globe artichokes 50% Florence fennels < 50% for remaining crops	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 17% of the ADI. Among the crops under consideration, spinach was identified as the main contributor, accounting for up to 10% of the ADI.	**Results:** Long-term exposure: Max 20% of the JMPR ADI. Short-term exposure: Highest result for lettuce: 300% of ARfD. An acute risk consumer was identified for several commodities classified under green leaves (i.e. spinach, lettuce, endive).

5.42. Pyriofenone (310) R

5.42.1. Background information

Table 202: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New use	
RMS	LV	
Approval status	Approved	Commission Implementing Regulation (EU) No 833/2013[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013d)
MRL review performed	Yes, see comments	(EFSA, 2019f)
MRL applications/assessments	Yes, see comments	(EFSA, 2015i) (table grapes) (EFSA, 2013l) (cereals, grapes and animal products)
Classification of a.s. – cut-off criteria	No	RAC, (ECHA, 2019b)
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 833/2013 of 30 August 2013 approving the active substance pyriofenone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 233, 31.8.2013, p. 7–10.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.42.2. Toxicological reference values

Table 203: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.09 mg/kg bw per day	JMPR (2018)	0.07 mg/kg bw per day	(EFSA, 2013d) (2-year rat study with safety factor 100)	No
ARfD	Unnecessary	JMPR (2018)	Not applicable	(EFSA, 2013d)	Yes
Conclusion/ comment	Although ADI derived by EFSA is slightly lower than JMPR, the values are in the same order of magnitude. The acceptable daily intake (ADI) of pyriofenone is 0.07 mg/kg bw per day, based on the NOAEL of 7.25 mg/kg bw per day from the rat, 2-year study based on liver effects, applying the standard uncertainty factor (UF) of 100. The same 2-year rat study was considered by JMPR for the ADI derivation and the NOAEL is set at 9.13 mg/kg bw per day for chronic nephropathy in females. Actually, the NOAEL retained is the same (200 ppm) but JMPR considers the corresponding concentration expressed in mg/kg bw per day in females while the EU peer review considered that of males. In the EU peer review, 4HDPM did not present mutagenic potential and it was concluded that the reference values of the parent are applicable to the metabolite. No other information on other metabolites available.				

5.42.3. Residue definitions

Table 204: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Pyriofenone	EU Reg. 2016/1[(a)]: Pyriofenone	Yes
	Animal products	Pyriofenone No conclusion on fat solubility, due to the low residues in muscle and fat found in the metabolism study	EU Reg. 2016/1[(a)]: Pyriofenone Peer review (EFSA, 2013d): Not required, considering the representative uses; Provisional RD proposed for ruminant products: pyriofenone The residue is not fat soluble	Yes
RD RA	Plant products	Pyriofenone	MRL review (EFSA, 2019f) and peer review (EFSA, 2013d): Pyriofenone	Yes
	Animal products	Pyriofenone	MRL review (EFSA, 2019f): Pyriofenone Peer review (EFSA, 2013d): Not required, considering the representative uses.	Yes
Conclusion, comments	For plant commodities, the EU and JMPR residue definitions are the same. 2018 JMPR proposed the parent compound as the residue definition for animal products. The same RD is proposed in the current meeting. In the MRL review, pyriofenone was also considered to be the appropriate RD.			

(a): Commission Regulation (EU) 2016/1 of 3 December 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products. OJ L 2, 5.1.2016, p. 1–62.

5.42.4. Codex MRL proposals

Table 205: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats (except milk fats)	0.01*	0.01*	In 2018, JMPR calculated the dietary burden considering the use in grapes. Since no new Codex MRL proposals were derived in 2019 JMPR, the DB of 0.61 ppm calculated in 2018 remains unchanged. No livestock feeding studies were available. Based on the goat metabolism study performed with 10 ppm (nominal; actual levels 7.8–13 ppm; 13–21 N), pyriofenone is not expected to be present at levels higher than the LOQ of 0.01 mg/kg in any of the animal matrices. Therefore, the JMPR recommended an MRL of 0.01 mg/kg for mammalians tissues and milk. STMR of 0 mg/kg in mammalian meat (muscle, fat), mammalian fat, mammalian edible offal and milk were used. Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Milks	0.01*	0.01*	See comments on Mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.01*	0.01*	See comments on Mammalian fats (except milk fats).
Edible offal (mammalian)	0.01*	0.01*	See comments on Mammalian fats (except milk fats).
Eggs	0.01*	0.01*	JMPR considered that since poultry is not exposed and residues of pyriofenone are not expected in eggs and poultry, JMPR recommend the MRL at the LOQ of 0.01 mg/kg for eggs, poultry (meat/muscle), fat and poultry edible offal. STMR of 0 mg/kg in eggs, poultry meat (muscle, fat), poultry fat and poultry edible offal. Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry fats	0.01*	0.01	See comments on eggs.
Poultry meat	0.01*	0.01	See comments on eggs.
Poultry, edible offal of	0.01*	0.01	See comments on eggs.
General comments	The 2019 JMPR meeting noted that pyriofenone is registered in the USA for use on fruiting vegetables. The critical GAP is of 3 applications at 0.11 kg a.i./ha, with a minimum re-treatment interval of 7 days and a PHI of 0 days. Trials were conducted in the USA on tomatoes and peppers. None of these trials matched the critical GAP, since all trials were conducted at a lower dose rate of 0.090 kg a.i./ha and a higher number of applications (4 applications). The Meeting was unable to estimate maximum residue levels for tomatoes and peppers and no MRLs for plant commodities are recommended in the current meeting, but only for livestock commodities.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.42.5. Consumer risk assessment

Table 206: Summary of the consumer risk assessment

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 is deemed necessary	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2015i) were updated, including the Codex MRL proposals derived by JMPR for the animal products. The risk assessment was performed with the EU ADI. The calculations are indicative, because a final decision on the appropriate RD for animal commodities for risk assessment has not been derived. However, considering the low dietary burden and the fact that no significant residues are expected in animal products, the open issue regarding the residue definition is not expected to have a major impact on the results of the exposure calculation.	**Specific comments:** In 2018 The JMPR used the established ADI of 0–0.09 mg/kg to estimate an IEDI ranging from 0–0.5% of the maximum ADI. Since no MRL for plant commodities are recommended in the current meeting, JMPR concluded that the IEDI ranging from 0 to 0.5% of the maximum ADI remain unchanged.
Results: Not relevant since no ARfD was allocated.	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 1% of the ADI (Dutch toddler). Among the commodities under consideration, milk (cattle) was identified as the main contributor, accounting for up to 0.9% of the ADI.	**Results:** The long-term dietary exposure is unlikely to present a public health concern. Short-term exposure: Not relevant (JMPR did not derive an ARfD). Therefore, the acute dietary exposure to residues of pyriofenone from the uses assessed was considered unlikely to present a public health concern.

5.43. Afidopyropen (312) R/T

5.43.1. Background information

Table 207: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	
RMS	no RMS assigned	The a.s. has not been assessed at EU level
Approval status	Not approved	
EFSA conclusion available	No	
MRL review performed	No	
MRL applications/assessments	No	MRL application under assessment in the Netherlands
Classification of a.s. – cut-off criteria	Not assessed/not concluded	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet.

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.43.2. Toxicological reference values

Table 208: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.08 mg/kg bw per day	JMPR (2019)	–	–	Not appropriate
ARfD	0.2 mg/kg bw (for women of child-bearing age) 0.3 mg/kg bw (for general population)	JMPR (2019)	–	–	Not appropriate
Conclusion/ comment	JMPR concluded that the ADI derived for afidopyropen also applies to the metabolites M001, M007 and CPCA, expressed as afidopyropen (metabolites included in RD for plants and animal products). As regards metabolite M017 (included in the residue definition for liver) it is reported in the JMPR report (p. 53, 1st para) that its toxicity is covered by the toxicity of the parent, since it is a major metabolite observed in rats. However, in the summary of the rat metabolism study the occurrence of this metabolite was not reported; in addition, the toxicological assessment performed by JMPR no mention of this metabolite was found. Hence, further evidence is needed to verify that M017 is covered by the toxicological reference values derived for the parent compound.				

5.43.3. Residue definitions

Table 209: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Afidopyropen	–	Not appropriate
	Animal products	Afidopyropen The residue is not fat soluble	No EU assessment. Default residue definition (parent compound)	Not appropriate
RD RA	Plant products	Sum of afidopyropen + M007 (dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl) oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11Hnaphtho[2,1-b]pyrano[3,4-e] pyran-4-yl]methyl rac-cyclopropanecarboxylate), expressed as afidopyropen		Not appropriate
	Animal products	Animal commodities, except liver: Afidopyropen + M001 ((3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12btrimethyl–9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-decahydro-2H,11H-benzo- [*f*]pyrano[4,3-b]chromen-11-one) + CPCA (M061) (cyclopropane carboxylic acid) and its carnitine conjugate (CPCA-carnitine conjugate) (M060) ((2R)-3-carboxy-2-[(cyclopropyIcarbonyI)oxy]-N,N,N-trimethylpropan-1- aminium chloride), expressed as afidopyropen Liver: Afidopyropen + M001 ((3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12b-trimethyl–9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-decahydro-2H,11H-benzo- [*f*]pyrano[4,3-b]chromen-11-one)		Not appropriate

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		+ M017 ([(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3-(cyclopropylcarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-9-(1-oxidopyridin-3-yl)-11-oxo-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H, 11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropane-carboxylate) + CPCA (M061) (cyclopropane carboxylic acid) and its carnitine conjugate (CPCA-carnitine conjugate) (M060) ((2R)-3-carboxy-2-[(cyclopropyIcarbonyI)oxy]-N, N,N-trimethylpropan-1- aminium chloride), expressed as afidopyropen		
Conclusion, comments	Plant products: In metabolism studies, parent afidopyropen was the major compound in the majority of primary crop commodities (up to 61% TRR). However, in soyabean, parent afidopyropen was detected at very low concentrations in dry soyabean seed (0.4% TRR, 0.001 mg/kg). The metabolite trigonelline (M031) identified in soyabean seeds (47% TRR) is also a naturally occurring alkaloid in many plants. The dimer M007 was found in dry soyabean seeds at 1% TRR and 12% TRR, depending on the study. Animal products: Parent afidopyropen was the major compound in animal tissues, ranging from 17% TRR in goat kidney to 97% TRR in egg yolk and up to 6.8% TRR in milk. The ester cleavage metabolite M001 was a major metabolite in milk, liver, kidney and muscle, ranging from 24 to 66% TRR, and was also a minor metabolite in fat (4.6% TRR). M017 was a major metabolite in hen liver. The metabolic pathways in goat and hens are similar to that which is reported in rat. CPCA is a metabolite that is formed by cleavage of the cyclopropane carboxylic acid ester moieties from the parent molecule. Parent afidopyropen contains two CPCA groups. From livestock and rat metabolism studies it is known that metabolism can lead to the cleavage of only one or both CPCA ester moieties. Including CPCA in the residue definition (expressed as parent compound) seems problematic, since one molecule of afidopyropen may generate 1 or 2 molecules of CPCA. Hence the molecular weight conversion factor to recalculate the amount of CPCA to afidopyropen equivalents could be either 6.9 or 3.45. Hence, this leads to ambiguous results. See also comments on feeding study.			

5.43.4. Codex MRL proposals

Table 210: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL (default)	Comment
Almond hulls	0.6 (dw)	–	The JMPR evaluation derived a Codex MRL proposal for almond hulls on the basis of the same residue trials that were evaluated for tree nuts. EU MRLs are not set for processed commodities/ by-products, such as almond hulls.
Apple, dried (peeled)	0.02	–	A reduction of residues occurs in apple, dried (peeled) and the JMPR evaluation derived processing factors on the basis of two processing studies (PF enf = < 0.46 and PF RA = < 0.64). EU MRLs are not set for processed products, such as dried apple.
Cabbages, Head	**0.5**	0.01	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 19 trials on head cabbage (with wrapper leaves) in Australia and the USA performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials were

Commodity	Codex MRL proposal	EU MRL (default)	Comment
			considered representative for the cGAP; the splitting of the first application is expected to influence the final residues by less than 25%. Residues in head cabbage (with wrapper leaves) used for MRL estimation (parent afidopyropen only). Residues in head cabbage (without wrapper leaves) used for estimating STMR and HR for consumer risk assessment (parent afidopyropen and M007). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Cherries, Subgroup of	**0.03**	0.01	cGAP: Canada and the USA, foliar application, 2 × 11 g/ha, interval 7 days, PHI 7 days. Number of trials: 8 trials Sufficiently supported by data: Yes Specific comments/observations: Residues in five trials were below the LOQs of 0.01 mg/kg (RD enf) and 0.02 mg/kg (RD RA). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Citrus Fruit, Group of	**0.15**	0.01	cGAP: USA, foliar application, 2 × 51 g/ha, interval 7 days, PHI 0 days, seasonal maximum rate 103 g/ha. Number of trials: Trials on oranges (n = 11), grapefruits (n = 6) and lemons (n = 8) performed at 1 × 25 g/ha + 2 × 50 g/ha, interval mean 7 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the additional application of 1 × 25 g/ha at 14 days before harvest is not expected to contribute to more than 25% of the residues at harvest. Therefore, the residue trials are deemed acceptable. According to the Codex principles, trials on mandarins would be also required to derive a group MRL for citrus. JMPR considered that trials on lemons would be sufficient to cover also mandarins. According to the EU guidelines, the number of trials would be sufficient for extrapolation to the whole group Citrus fruits (0110000). The Codex MRL proposal for the Group of Citrus Fruit (FC 0001) would be applicable to the EU classification whole group Citrus fruits (0110000) and also to kumquats (0161040). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Citrus oil (based on processing studies on oranges)	0.7	–	A concentration of residues occurs in citrus oil and the JMPR evaluation derived processing factors on the basis of three processing studies on oranges (PF enf = 4.6 and PF RA = 4.2). EU MRLs are not set for processed commodities/by-products, such as citrus oil.
Citrus pulp, dry (based on processing studies on oranges)	0.4	–	A concentration of residues occurs in citrus dried pomace and the JMPR evaluation derived processing factors on the basis of three processing studies on oranges (PF enf = 2.5 and PF RA = 2.4). EU MRLs are not set for processed commodities/by-products, such as citrus dried pomace.
Coriander, leaves	**5**	0.01 (classified under celery leaves)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. Number of trials: 7 trials on mustard greens; no residue trials were submitted on herbs. Sufficiently supported by data: No Specific comments/observations: The JMPR considered mustard greens to be more representative for herbs than the trials in

Commodity	Codex MRL proposal	EU MRL (default)	Comment
			leaf lettuce or spinach. According to the agreed extrapolations (Appendix VIII of REP18/PR) trials on basil, mint, leaf lettuce or spinach could be used to derive an MRL for coriander leaves. Using residue trials in leaf lettuce and spinach a lower MRL proposal of 2 mg/kg is derived. According to the EU classification, coriander leaves (0256030-004) are classified under celery leaves (0256030). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that MRL was derived on the basis of a non-standard extrapolation. Follow-up action: None
Cotton gin trash	1.5	–	The JMPR evaluation derived a Codex MRL proposal for cotton gin trash on the basis of the same residue trials that were evaluated for cotton seed. EU MRLs are not set for processed commodities/by-products, such as cotton gin trash.
Cotton seed	**0.08**	0.01	cGAP: USA, foliar application, 2 × 51 g/ha, interval 7 days, PHI 7 days. Number of trials: 15 trials approximating the cGAP Sufficiently supported by data: Yes Specific comments/observations: Details on residue trial details were reported in JMPR evaluation. **Conclusion:** The proposed Codex MRL seems acceptable. Follow-up action: None
Cucumber	**0.7**	0.01	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 9 trials performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the application of 2 × 12.5 g at 21–14 days before harvest is not expected to contribute to more than 25% of the residues at harvest. Therefore, the residue trials are within 25% of the cGAP. The number of trials is sufficient to support the Codex MRL proposal for cucumbers (0232010). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Dill, leaves	**5**	0.01 (classified under celery leaves)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. Number of trials: 7 trials on mustard greens; no residue trials were submitted on herbs or celery leaves. Sufficiently supported by data: No Specific comments/observations: The JMPR considered mustard greens to be more representative for herbs than leaf lettuce or spinach. According to the agreed extrapolations (Appendix VIII of REP18/PR) trials on basil, mint, leaf lettuce or spinach could be used to derive an MRL for coriander leaves. Using residue trials in leaf lettuce and spinach a lower MRL proposal of 2 mg/kg is derived. According to the EU classification, dill leaves (0256030-006) are classified under celery leaves (0256030). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that MRL was derived on the basis of a non-standard extrapolation.

Commodity	Codex MRL proposal	EU MRL (default)	Comment
Edible offal (mammalian)	**0.2**	0.01	JMPR calculated the dietary burden for livestock on the basis of residues in feed crops under assessment and their by-products. Max estimated burden for cattle: 12.9 ppm dry matter (dairy cattle, Australia) (parent + M007 (dimer)). Feeding study available that covers the estimated burden for afidopyropen; samples were analysed for parent, M001, M003 (tissues only), M005 (milk only), CPCA-carnitine; tissues and milk were not analysed for M017; for liver a correction factor was applied to account for the occurrence of M017 (correction factor derived from metabolism study). Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Eggs	0.01*	0.01	JMPR calculated the dietary burden for livestock on the basis of residues in feed crops under assessment and their by-products. Max estimated burden for poultry, layer: 0.15 ppm dry matter (EU) (parent + M007 (dimer)). Feeding study available that covers the estimated burden for afidopyropen; samples were analysed for parent, M001, M003, CPCA-carnitine and M017 (liver only). Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Eggplants, Subgroup of	**0.15**	0.01	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 28 trials on tomato (n=25) and cherry tomato (n=3) in Brazil and the USA performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the application of 2 × 12.5 g at 21–14 days before harvest is not expected to contribute to more than 25% of the residues at harvest. Therefore, the residue trials seem acceptable. Extrapolation form tomatoes to eggplants is acceptable. However, trials on cherry tomatoes should be excluded from the data set. However, this approach would not have an impact on the MRL proposal. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Flowerhead Brassicas, Subgroup of	**0.4**	0.01 Broccoli and cauliflowers	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 10 trials on broccoli performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the deviation is not expected to contribute to more than 25% of the residues at harvest. According to the EU guidelines, the extrapolation to cauliflowers (0241020) and other flowering brassicas (0241990) would not be fully supported, because a minimum of 4 trials on cauliflower (0241020) + 4 trials broccoli (0241010) are required for

Commodity	Codex MRL proposal	EU MRL (default)	Comment
			extrapolation to the whole subgroup (a) flowering brassica (0241000). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Fruiting vegetables, Cucurbits – Melon, Pumpkins and Winter squashes, Subgroup of	**0.05**	0.01 (cucurbits with inedible peel subgroup of)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: Trials on melon (n = 8) and winter squash (n = 5), performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the deviation is not expected to have a major impact on the residue levels. Statistical analysis of variance indicates that residue levels from trials on melon and winter squash are from similar populations (Mann–Whitney U-test) and the JMPR combined data sets to derive MRL and risk assessment values (whole fruit). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Ginger, rhizome (fresh)	0.01*	0.01	cGAP: Canada, foliar application, two applications at maximum rate 50 g/ha, interval 7 days, PHI 7 days. Number of trials: no residue trials were submitted on ginger rhizome; trials on potatoes (see tuberous and corm vegetables) Sufficiently supported by data: No Specific comments/observations: Residue trials data are available for potato. The JMPR considered that afidopyropen is not systemic and residue levels in potato tubers were below the LOQ. The JMPR decided to extrapolate the proposed Codex MRL and risk assessment values from potato tubers to ginger rhizome, considering that in trials performed on potatoes at exaggerated application rates (6.25N cGAP for ginger rhizome, residues were below the LOQs of 0.01 mg/kg (RD enf) and 0.02 mg/kg (0.01 mg/kg for each analyte) (RD RA)). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL which was derived from non-standard extrapolation is acceptable. Follow-up action: None
Leafy greens, Subgroup of	**2**	0.01 (lamb's lettuces, lettuces, escaroles, spinaches and similar leaves subgroup of, chervil)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: Trials on lettuce, head (with wrapper leaves) (n = 9), lettuce, leaf (n = 7), cos lettuce (n = 1) and spinach (n = 8) performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the deviation is not expected to have a major impact on the residue levels. Statistical analysis of variance reported populations for head lettuce, leaf lettuce and cos lettuce to be similar (Kruskal–Wallis H test) and the combined lettuces data set to be similar to the spinaches data set. Therefore, data on lettuces and spinaches were combined for MRL estimation and derivation of risk assessment values.

Commodity	Codex MRL proposal	EU MRL (default)	Comment
			According to the Codex principles, head lettuce and/or leaf lettuce and spinach are suitable for extrapolation to the subgroup of Leafy greens (VL 2050). According to the EU guidelines, the number of trials would be sufficient for extrapolation to the EU crop groups of lettuces and salad plants (0251000) and spinaches and similar leaves. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Leaves of Brassicaceae, Subgroup of	**5**	0.01 (leafy brassica, cress, land cress, rucola, red mustards, baby leaf crops (including brassica species)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1×25 g/ha + 2×50 g/ha. Number of trials: 7 trials on mustard greens performed at 2×12.5 g/ha + 2×50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, the deviation is not expected to have a major impact on the residue levels. According to the Codex principles, mustard greens are a suitable commodity for extrapolation to the subgroup of Leaves of Brassicaceae (VL 0054), and the proposed extrapolation is acceptable. The estimated acute dietary exposure to residues of afidopyropen in leafy brassica kales (243020) exceeds the toxicological reference value (ARfD) (see below). **Conclusion:** The proposed Codex MRL is not acceptable due to intake concerns. Follow-up action: None
Mammalian fats (except milk fats)	0.01*	0.01	See comments on edible offal (mammalian). Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Meat (from mammals other than marine mammals)	0.01*	0.01	See comments on edible offal (mammalian). Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Milks	0.001*	0.01	See comments on edible offal (mammalian). Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Parsley, leaves	**5**	0.01	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. Number of trials: 7 trials in mustard greens; no residue trials were submitted on herbs. Sufficiently supported by data: No Specific comments/observations: The JMPR considered mustard greens to be more representative for herbs than leaf lettuce or spinach. According to the agreed extrapolations (Appendix VIII of REP18/PR) trials on basil, mint, leaf lettuce or spinach could be used to derive an MRL for coriander leaves. Using residue trials in leaf lettuce and spinach a lower MRL proposal of 2 mg/kg is derived.

Commodity	Codex MRL proposal	EU MRL (default)	Comment
			Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that MRL was derived on the basis of a non-standard extrapolation. Follow-up action: None
Peaches, Subgroup of	**0.015**	0.01 (peaches, apricots)	cGAP: Canada and the USA, foliar application, 2 × 11 g/ha, interval 7 days, PHI 7 days. Number of trials: Eleven trials on peaches in Canada and the USA Sufficiently supported by data: Yes Specific comments/observations: Residues in ten trials were below the LOQs of 0.01 mg/kg (RD enf) and 0.02 mg/kg (0.01 mg/kg for each analyte) (RD RA). The Codex MRL proposal for Peaches (FS 2001) would be applicable to the EU classification for apricots (0140010) and peaches (0140030). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Peppers, Subgroup of, excluding okra, martynia and roselle	**0.1**	0.01	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 8 trials on bell peppers and 3 on chilli peppers performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, deviation is not expected to have a major impact on the residue levels. The highest residue values were observed in the trials performed on chilli peppers. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Peppers, chilli dried	1	–	A concentration of residues occurs in dried chilli peppers, and the JMPR evaluation derived a Codex MRL proposal of 1 mg/kg for peppers chilli, dried, on the basis of a drying factor of 10. Processing studies were not reported in the JMPR evaluation and processing factors were not derived for chilli peppers, dried. EU MRLs are not set for processed products, such as dried chilli peppers.
Pome fruit, Group of, excluding persimmon	**0.03**	0.01 (Pome fruits and azaroles)	cGAP: USA, foliar application, 2 × 25 g/ha, interval 7 days, PHI 7 days, seasonal maximum rate 51 g/ha. Number of trials: 13 trials on apples and 7 on pears Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal for pome fruit (FP 0009) excluding persimmon, would be applicable to the EU classification for the Group of Pome fruits and azaroles/Mediterranean medlars. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Plums, Subgroup of	0.01*	0.01 (plums except Prunus Nadia)	cGAP: Canada and the USA, foliar application, 2 × 11 g/ha, interval 7 days, PHI 7 days. Number of trials: Nine trials in Canada and the USA Sufficiently supported by data: Yes Specific comments/observations: Residues in all trials were below the LOQs of 0.01 mg/kg (RD enf) and LOQ of 0.02 mg/kg (0.01 mg/kg for each analyte) (RD RA). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

Commodity	Codex MRL proposal	EU MRL (default)	Comment
Poultry, edible offal of	0.01*	0.01	See comments on eggs. Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry, fats	0.01*	0.01	See comments on eggs. Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Poultry, meat	0.01*	0.01	See comments on eggs. Sufficiently supported by data: Yes Specific comments/observations: None **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Soyabean (dry)	0.01*	0.01	cGAP: USA, foliar application, 2 × 11 g/ha, interval 7 days, PHI 7 days. Number of trials: 23 trials Sufficiently supported by data: Yes Specific comments/observations: Residues in all trials were below the LOQ of 0.01 mg/kg (RD enf) and LOQ of 0.02 mg/kg (0.01 mg/kg for each analyte) (RD RA). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Stem and Petioles, Subgroup of	**3**	0.01 (cardoons, celeries, Florence fennels and rhubarbs)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 9 trials on celery performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, deviation is not expected to have a major impact on the residue levels. According to the Codex principles, celery is a suitable commodity for extrapolation to the subgroup of Stems and petioles (VS 2080), and the proposed extrapolation is acceptable. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Summer squash	**0.07**	0.01 (Courgettes)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 5 trials on summer squash in the USA performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, deviation is not expected to have a major impact on the residue levels. According to the EU guidelines, summer squashes (courgettes) are a major crop in SEU and world productions and at least 8 trials would be required. According to the Codex criteria, summer squash (VC 0431) are classified as consumption category 3, and a minimum of five trials are required. Therefore, the number of trials on summer squash (n = 5) is acceptable.

Commodity	Codex MRL proposal	EU MRL (default)	Comment
			Conclusion: The proposed Codex MRL is acceptable. Follow-up action: None
Tomatoes, Subgroup of	**0.15**	0.01	cGAP: Canada, foliar application, up to four applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 0 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 25 trials performed on normal sized tomatoes and 3 in cherry tomatoes performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The residue trials are not fully GAP compliant; however, deviation is not expected to have a major impact on the residue level. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Tomatoes, dried	0.7	–	A concentration of residues occurs in dried tomatoes, and the JMPR evaluation derived processing factors on the basis of three processing studies on oranges (PF enf = 4.3 and PF RA = 5.8). EU MRLs are not set for processed products, such as dried tomatoes.
Tree nuts, Group of	0.01*	0.01	cGAP: USA, foliar application, 2 × 11 g/ha, interval 7 days, PHI 7 days. Number of trials: 13 trials (5 in almond, 5 in pecan and 3 in pistachio). Sufficiently supported by data: Yes Specific comments/observations: Residues in all trials were below the LOQs of 0.01 mg/kg (RD enf) and 0.02 mg/kg (0.01 mg/kg for each analyte) (RD RA). The JMPR considered the combined data set for the available trials on tree nuts suitable for extrapolation to the group of Tree nuts. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Tuberous and corm vegetables, Subgroup of	0.01*	0.01 (potatoes, tropical root and tuber vegetables)	cGAP: Canada, foliar application, up to 4 applications at maximum rate 50 g/ha with seasonal maximum rate 125 g/ha, interval 7 days, PHI 7 days. JMPR assumed cGAP is 1 × 25 g/ha + 2 × 50 g/ha. Number of trials: 23 trials on potatoes in Canada and the USA performed at 2 × 12.5 g/ha + 2 × 50 g/ha, interval 7 days, PHI 0 days. Sufficiently supported by data: Yes Specific comments/observations: The metabolism of afidopyropen in root crops was not reported in the JMPR evaluation but in three other crop groups. The residue trials are not fully GAP compliant, deviating in the PHI and the application rate. The deviation of in the application rates is expected to have a minor impact on the residue levels. The Codex MRL proposal for the subgroup Tuberous and corm vegetables (VR 2071) would be applicable to the EU classification subgroups (a) potatoes (0211000) and (b) tropical root and tuber vegetables (0212000). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the trials were not fully compliant with the GAP, considering that the MRL proposal is at the LOQ. Follow-up action: To check details on the residue trials in JMPR evaluation.

Commodity	Codex MRL proposal	EU MRL (default)	Comment
Turmeric, root (fresh)	0.01*	0.01	cGAP: Canada, foliar application, 2 applications at maximum rate 50 g/ha, interval 7 days, PHI 7 days. Number of trials: no residue trials were submitted on turmeric root, but trials on potatoes. Sufficiently supported by data: No Specific comments/observations: The metabolism of afidopyropen in root crops was not reported in the JMPR evaluation. Residue trials data are available for potato (details see tuberous and corm vegetables). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. Follow-up action: None
General comments	Default MRL of 0.01 mg/kg according to Art. 18(1)(b) Reg 396/2005 for all commodities.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.43.5. Consumer risk assessment

Table 211: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the Codex MRL proposals. The risk assessment was performed with the JMPR ARfD derived for women of child-bearing age.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The STMR values derived by JMPR were used for the risk assessment. The risk assessment was performed with the JMPR ADI.	**Specific comments:** The short-term risk assessment is reported based on the ARfD for general population of 0.3 mg/kg bw. The ARfD is lower for women of child-bearing age 0.2 mg/kg bw. The highest result for Chinese cabbages (raw)
Results: **The calculated short-term exposure exceeded the ARfD for one crop under assessment.** Kales: 106% of ARfD (DE child) Chinese cabbages/pe-tsai: 77% of ARfD (child) Escaroles/broad-leaved endives: 52% of ARfD (child) Lettuces: 49% of ARfD (child) Celeries: 41% of ARfD (child) Rhubarbs: 41% of ARfD (child) Spinaches: 29% of ARfD (child) Chards/beet leaves: 25% of ARfD (adult; child 20%) Florence fennels: 21% of ARfD (adult; child 18%) Cucumbers: 20% of ARfD (child) Cardoons: 11% of ARfD (adult) Cauliflowers: 10% of ARfD (child) Broccoli: 7% of ARfD (child) Oranges: 6% of ARfD (child) Lamb's lettuce/corn salads: 4% of ARfD (child) Melons: 4% of ARfD (child)	**Results:** **No long-term consumer health risk was identified.** The overall chronic exposure accounted for 5% of the ADI. Among the commodities under consideration, bovine milk and muscle/meat and spinaches and Chinese cabbages were identified as the main contributors, accounting for 0.6% to 1% of the ADI.	**Results:** Long-term exposure: Max 4% of the JMPR ADI. Short-term exposure: Highest result for Chinese cabbages (raw): 100% of ARfD (CN child; 50% general population).

5.44. Metconazole (313) R/T

5.44.1. Background information

Table 212: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	In 2008 JMPR assessed triazole metabolites
RMS	BE	
Approval status	Approved	Commission Directive 2006/74/EC[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2006c)
MRL review performed	Yes, see comments	(EFSA, 2011n)
MRL applications/ assessments	Yes, see comments	(EFSA, 2016h) (various crops) (EFSA, 2013f) (barley and oats) (EFSA, 2010d) (various crops)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Assessment ongoing, see comments	Assessment not finalised: following ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]), additional data are requested for ecotox assessment; no endocrine effects for humans. ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605) is ongoing, further data were requested (clock-stop)

(a): Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances. OJ L 235, 30.8.2006, p. 17–22.
(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.44.2. Toxicological reference values

Table 213: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Metconazole					
ADI	0.04 mg/kg bw per day	JMPR (2019)	0.01 mg/kg bw per day	(EFSA, 2006c) (developmental rabbit with 400 uncertainty factor)	No
ARfD	0.04 mg/kg bw	JMPR (2019)	0.01 mg/kg bw	(EFSA, 2006c) (developmental rabbit with 400 uncertainty factor)	No
Triazole alanine					
ADI	1 mg/kg bw per day	JMPR (2008, 2019)	0.3 mg/kg bw	(EFSA, 2018q) (rabbit developmental with 100 uncertainty factor)	No
ARfD	Unnecessary	JMPR (2008, 2019)	0.3 mg/kg bw	(EFSA, 2018q) (rabbit developmental with 100 uncertainty factor)	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Triazole acetic					
ADI	1 mg/kg bw per day	JMPR (2008, 2019)	1 mg/kg bw	(EFSA, 2018q) (2-generation and rabbit developmental with 100 uncertainty factor)	Yes
ARfD	Unnecessary	JMPR (2008, 2019)	1 mg/kg bw	(EFSA, 2018q) (2-generation and rabbit developmental with 100 uncertainty factor)	No
1,2,4-triazole					
ADI	0.2 mg/kg bw per day	JMPR (2008, 2019)	0.023 mg/kg bw per day	(EFSA, 2018q) (rat 12-month study with 300 uncertainty factor)	No
ARfD	0.3 mg/kg bw	JMPR (2008, 2019)	0.1 mg/kg bw per day	(EFSA, 2018q) (rabbit developmental study with 300 uncertainty factor)	No
Conclusion/ comment	For **metconazole**, EFSA established an ADI and ARfD, of 0.01 mg/kg bw per day from the developmental rabbit study with 400 uncertainty factor; EFSA applied an additional uncertainty factor of 4 based on the teratogenic effects (EFSA, 2006c). JMPR based the ADI and ARfD on the same study but did not consider the inclusion of this extra uncertainty factor (JMPR, 2019). JMPR concluded that the TRVs derived for metconazole apply also to **M1** (CL 359451) and **M12** (CL 359138). **M11** had an acute oral LD_{50} > 5000 mg/kg bw and was not mutagenic in an Ames test. **M21** and **M30** were negative in in-vitro genotoxicity studies, JMPR therefore concluded that the TTC approach (Cramer class III) can be applied. For **unidentified hydroxylated metabolites** which were found in residue studies and which were potential candidates to be included in the residue definition for risk assessment, JMPR concluded that the addition of a hydroxylated group is unlikely to add any alerts for genotoxicity and therefore the TTC approach (Cramer class III) was considered appropriate. For **triazole alanine** and **triazole acetic acid**, JMPR (JMPR, 2008, 2019) established a group ADI (alone or in combination) of 0–1.0 mg/kg bw based on an NOAEL of 100 mg/kg bw per day for developmental toxicity in a study of developmental toxicity in rats given triazole alanine, on the basis of delayed ossification seen in rats at the LOAEL 300 mg/kg bw per day, and using an UF of 100. JMPR considered unnecessary the establishment of an ARfD. For **1,2,4-triazole**, JMPR (JMPR, 2008, 2019) established an ADI of 0.2 mg/kg bw per day based on NOAEL of 16 mg/kg bw per day on the basis of testicular effects (sperm abnormalities, sperm counts) with 100 uncertainty factor. JMPR established an ARfD of 0.3 mg/kg bw per day based on an NOAEL of 30 mg/kg bw. JMPR did not consider the decrease in body weight for setting the LOAEL and identified the NOAEL on the basis of alterations of the urogenital system that occurred at the LOAEL of 45 mg/kg per day and applied 100 uncertainty factor. (EFSA, 2018q) derived the following TRV for TDMs: (1) **triazole alanine**: ADI of 0.3 mg/kg bw based on the NOAEL of 30 mg/kg bw per day, taking into account the increased incidence of hyoid angulated alae in fetuses observed in the newly submitted rabbit developmental study and applying an UF of 100 was applied, the same endpoint and the same UF was considered applicable for the derivation of the ARfD; the ADI and ARfD derived for triazole alanine is also applicable to **triazole lactic acid**, for which no TRV were derived by JMPR. (2) for **triazole acetic acid**: ADI of 1 mg/kg bw per day, based on the NOAEL of 100 mg/kg bw per day in the newly submitted rat two-generation and rabbit developmental studies (decreased body weight gain and food consumption for maternal and developmental toxicity, plus stomach mucosal erosions or ulceration for developmental toxicity), applying an UF of 100, the same endpoint and the same UF was considered applicable for the derivation of the ARfD. (3) **1,2,4-triazole:** ADI of 0.0023 mg/kg bw per day based on the no-observed-adverse-effect-level (NOAEL) of 6.9 mg/kg bw per day, considering the decreased body weight gain in the newly submitted 12-month rat study with 300 uncertainty factor to cover the lack of a developmental neurotoxicity (DNT) study and carcinogenicity and dog studies.				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
	ARfD of 0.1 mg/kg bw per day based on a decrease on body weight gain observed at the LOAEL of 30 mg/kg bw per day from a rabbit developmental study with 300 uncertainty factor. In the peer review for renewal (EFSA conclusion not yet finalised, but discussed in MamTox PREV 07 experts' meeting), it was concluded that the hydroxylated metabolites (and M30 ketone) are unlikely to be genotoxic and that their general toxicity is covered by the parent compound, i.e. they have to be assumed as equally toxic.				

5.44.3. Residue definitions

Table 214: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Metconazole (sum of cis and trans isomer)	Reg. 396/2005: Metconazole (sum of isomers)	Yes
	Animal products	Sum of metconazole (cis and trans-isomer) The residue is not fat soluble	Reg. 396/2005: Metconazole (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Metconazole (sum of cis and trans isomer)	MRL review Art. 12 (EFSA, 2011n): Metconazole (sum of isomers) Peer review (EFSA, 2006c): Metconazole (sum of isomers) (cereals and oilseed crops only) Separate RDs for TDMs	Yes
	Animal products	Sum of metconazole (cis and trans-isomer) and metabolites (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (M1) and (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (M12), expressed as metconazole	MRL review Art. 12 (EFSA, 2011n): Metconazole (sum of isomers) Peer review (EFSA, 2006c): Metconazole (sum of isomers) Separate RDs for TDMs	No
Conclusion, comments	JMPR assessed metabolism studies in fruits (banana and mandarins), oilseed (peas and rape seed) and cereals (wheat). **Metconazole** was the predominant residues (19–96% TRRs) in all crops except, wheat grain where it was not found. In addition, significant residues of hydroxylated metconazole metabolites and their conjugates were found in. **Triazole metabolites (TDMs**) were also found in significant amounts in wheat grain, oilseed rape seed and pea seeds. **M11, M21** and **M30** were identified in metabolism studies; in residue trials they were only found in cereals. In order to decide whether they need to be included in the RD, JMPR calculated the exposure and compared it with the TTC for Cramer Class III (see toxicological reference values). Individually the long-term exposure was below the TTC of 1.5 µg/kg bw per day (i.e. 0.81 µg/kg bw per day). Significant residues of unidentified **hydroxylated metconazole metabolites** and their conjugates were detected in mandarin fruit, pea seed and oilseed rape seed, ranging from 19% to 67% TRRs. Also for these compounds JMPR estimated the long-term exposure and compared it to the TTC for Cramer class III compounds. Since no residue data from treated crops were available, JMPR calculated the estimated concentration, taking into account the ratio of parent metconazole to these metabolites observed in metabolism studies. The exposure for the group of hydroxylated metconazole metabolites was 0.75 µg/kg bw per day. Based on overall results, JMPR proposed for plants, the enforcement and risk assessment residue definitions as metconazole (sum of isomers) only.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Currently, in the EU the residue definition for enforcement and the risk assessment (plant products) are similar with what JMPR proposed. In the ongoing EU peer review process a new residue definition for risk assessment is under discussion, i.e. metconazole (sum of isomers) and its monohydroxylated derivatives (free and conjugates). Triazole metabolites were also considered for the dietary exposure and consequently, it was proposed to be included separately in the RA RD: 1) triazole alanine (TA) and triazole lactic acid (TLA) as they share the same toxicity, 2) triazole acetic acid (TAA); 3) 1,2,4-triazole (T). For animal products, the enforcement residue definition proposed by the JMPR is similar with the one from EU (the existing and the agreed under the peer review process). For risk assessment the proposed JMPR residue definition is wider covering also the two monohydroxylated compounds M01 and M12 of metconazole. In the ongoing EU peer review process a new residue definition for risk assessment is under discussion, which is comparable with the JMPR RD. In the EU also the separate TDM residue definitions are relevant for risk assessment (/animal and plant products), 1) triazole alanine (TA) and triazole lactic acid (TLA) as they share the same toxicity; 2) triazole acetic acid (TAA); 3) 1,2,4-triazole (T). As regards, the fat solubility JMPR consider the residue of metconazole as not fat soluble while in EU is considered as fat soluble.			

5.44.4. Codex MRL proposals

Table 215: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Banana	0.1*	0.1	cGAP: Mexico, 3 × 90 g/ha, RTI 14 days, PHI 0 days Number of trials: 12 overdosed trials Sufficiently supported by data: Yes Specific comments/observations: The trials were conducted with 7x150 g/ha, RTI 11–15 days and harvested at 0 DALA in South and Central America. All the trials were below LOQ. **Conclusion:** The proposed Codex MRL is acceptable. See general comments Follow-up action: None
Blueberries	**0.5**	0.4	cGAP: Canada, 3 × 90 g a.i./ha, PHI 7 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: 11 GAP compliant trials conducted in Canada and USA were submitted. **Conclusion:** The proposed Codex MRL is sufficiently supported. See also general comments. Follow-up action: None
Beans with pods (Phaseolus spp.) immature pods and succulent seeds)	**0.05***	0.02*	cGAP: Brazil, 3 × 14 g a.i./ha, RTI 7 days and PHI 15 days Number of trials: 4 overdosed trials Sufficiently supported by data: No Specific comments/observations: The submitted trials were performed at higher rates (45–180 g/ha, RTI 7 days and PHI 14–15 days) with all residues < LOQ. The number of the trials is not sufficient according to JMPR rules; at least one additional trial is needed. In the EU, beans with pods are a major crop and therefore 4 additional trials would be needed. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable despite an incomplete data set, considering that the trials were all below the LOQ. See general comments Follow-up action: None

Commodity	Codex MRL proposal	EU MRL	Comment
Cotton seed	0.3	0.3	cGAP: USA, 3 × 92 g a.i./ha, RTI 7 days, PHI 30 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: The existing EU MRL is based on the same residue data set. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Edible offal (mammalian)	**0.04***	0.02*	The Codex MRL proposal is based on the maximum dietary burden calculated for the Australian diet. The feeding studies covers the estimated dietary burden. Specific comments/observations: At max feeding levels of 50 ppm (approx. 3N of max. dietary burden), residues of metconazole in milk and tissues were all < LOQ (0.04 mg/kg). **Conclusion:** The proposed Codex MRL are sufficiently supported. Follow-up action: None
Eggs	**0.04***	0.02*	CXL is based on the max dietary burden calculated for the EU. At max feeding levels of 20 ppm, residues of metconazole in eggs and poultry tissues were < 0.04 mg/kg. **Conclusion:** The proposed Codex MRL are sufficiently supported. Follow-up action: None
Garlic	**0.05***	0.02*	cGAP: Brazil, 3 × 90 g a.i./ha, RTI 7 days, PHI 14 days Number of trials: 6 (3 in bulb onion, 3 in garlic) Sufficiently supported by data: No Specific comments/observations: According to the JMPR rules five trials in garlic would be required. Using a combined data set with trials in garlic and bulb onion to derive an MRL for garlic is not fully in line with the agreed Codex extrapolation rules. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering that residues were below the LOQ in all trials.See general comments. Follow-up action: None
Tree nuts, Group of	0.04*	0.05* Almonds Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts/ cobnuts Macadamia Pecans Pine nut kernels Pistachios Walnuts	cGAP: USA, 4 × 123 g a.i./ha, RTI 7 days, PHI 25 days Number of trials: 10 overdosed trials (3 in pecan nuts and 7 in almonds) Sufficiently supported by data: Yes Specific comments/observations: Residues level were below LOQ in all trials. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Maize	0.015	0.1	cGAP: USA, 4 × 92 g a.i./ha, RTI 7 days, PHI 20 days Number of trials: 20 (highest residue 0.018 mg/kg) Sufficiently supported by data: Yes Specific comments/observations: The CXL is based on 20 GAP compliant trials conducted in USA. The same USA GAP and the same residue data set as examined by JMPR have been considered in the framework of EU MRL review (EFSA, 2011n), where an MRL proposal of

Commodity	Codex MRL proposal	EU MRL	Comment
			0.02 mg/kg was derived. The adoption of the higher EU MRL of 0.1 mg/kg seems to be an error. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Proposed follow-up action at EU level: reduction of EU MRL for maize grain to 0.02 mg/kg (or alternatively, to CXL level 0.015 mg/kg).
Mammalian fats (except milk fats)	**0.04***	0.02*	see edible offal (mammalian)
Meat (from mammals other than marine mammals)	**0.04***	0.02*	See edible offal (mammalian)
Milks	**0.04***	0.02*	See edible offal (mammalian)
Onion, bulb	**0.05***	0.02*	cGAP: Brazil, 3 × 90 g a.i./ha, RTI 7 days, PHI 14 days Number of trials: 6 (3 on bulb onions and 3 on garlic). Sufficiently supported by data: No Specific comments/observations: Bulb onions are a major crop in Codex. Hence, the number of trials in onions would not be sufficient. Using a combined data set of residue trials in garlic and bulb onion to derive an MRL for bulb onions is not fully in line with the agreed Codex extrapolation rules. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering that residues were below the LOQ Follow-up action: None
Peanut	0.04*	0.05*	cGAP: USA, 4 × 140 g a.i./ha, RTI 14 days, PHI 14 days Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: The submitted trials were conducted with 2x270-290 g/ha, and 13–15 DALA. Since residue levels were below LOQ, JMPR assumed that also from trials conducted according with the GAP the level will be below the LOQ. From additional trials performed at a 4X or 10X application rate were < LOQ or only slightly above. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Poultry, Edible offal of	**0.04***	0.02*	See eggs.
Poultry fats	**0.04***	0.02*	See eggs.
Poultry meat	**0.04***	0.02*	See eggs.
Rape seed	0.15	0.2	cGAP: UK, 2 × 72 g a.i./ha, BBCH 71, RTI 14 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: - **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Cherries, Subgroup of	**0.3**	0.2 Cherries	cGAP: USA, 3 × 140 g a.i./ha PHI 14 days, Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: The number of trials is in line with the JMPR rules. In the EU one additional trial would be needed. The same USA GAP as examined by JMPR has been considered in the framework of EU MRL review (EFSA, 2011n), and an import tolerance of 0.2 mg/kg was

Commodity	Codex MRL proposal	EU MRL	Comment
			derived on the basis of 9 trials. The JMPR report mentions only seven trials and as a consequence, a higher CXL (0.3 mg/kg) is derived. It may need to be verified why some trials were omitted (and/or not submitted to JMPR), as those additional trials could result in a lower CXL proposal (= EU MRL (IT)). **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: It should be verified why some trials were omitted (and/or not submitted to JMPR), as those additional trials could result in a lower CXL proposal.
Subgroup of dry beans except soyabeans	0.04*	0.15 (beans, cowpea, lupin)	cGAP: Canada and USA, 2 × 140 g a.i./ha, RTI 7 days, PHI 21 days Number of trials: 18 Sufficiently supported by data: Yes Specific comments/observations: In all residue trials, the residues were below LOQ. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Dry peas, Subgroup of	0.15	0.15 (peas and lentils)	cGAP: Canada and USA, 2 × 140 g a.i./ha, RTI 7 days, PHI 21 days Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: The same residue data set was submitted to support the current EU MRL for beans and peas. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Peaches, Subgroup of	**0.2**	0.1 (peaches, apricots)	cGAP: USA, 3 × 140 g a.i./ha (foliar application), PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The residue trials are sufficient according with the JMPR rules. In the EU trials in apricots would be requested too. According to OECD calculator an MRL of 0.15 mg/kg is sufficient. The same USA GAP as examined by JMPR has been considered in the framework of EU MRL review (EFSA, 2011n). The HR derived by JMPR for metconazole only is the same as the one derived by (EFSA, 2011n), although the residue data set seems different. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that a slightly lower value would be sufficient for the critical GAP assessed by JMPR. Follow-up action: None
Plums, Subgroup of	**0.1**	0.02* (plums)	cGAP: USA, PHI 14 days, 3 × 140 g a.i./ha Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: According to JMPR rules, plums are a major crop for which refinement criteria applied. The number of submitted trials is therefore not sufficient. **Conclusion:** The proposed Codex MRL is not acceptable because the number of trials is not sufficient. See also

Commodity	Codex MRL proposal	EU MRL	Comment
			general comments. Follow-up action: None
Sunflower seeds, Subgroup of	**1.5**	0.7 (sunflower seeds) 0.05* (safflower seed)	cGAP: Canada and USA, 2 × 140 g a.i./ha, RTI 7 days, PHI 21 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: The number of trials is in line with the JMPR rules. In the EU sunflowers are a major crop and one additional trial would be required. The same GAP as examined by JMPR has been considered in the framework of the setting of an import tolerance request (EFSA, 2016h); an IT of 1 mg/kg was derived on the basis of 9 trials, but the IT was eventually set at 0.7 mg/kg (= tolerance in CA). The JMPR report mentions only 7 trials and as a consequence, a higher CXL (1.5 mg/kg) is derived. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: It should be verified why some trials were omitted (and/or not submitted to JMPR), as those additional trials could result in a lower CXL proposal.
Tuberous and corm vegetables, Subgroup of	0.04*	0.04* (arrowroots potatoes, cassava, Jerusalem artichoke, sweet potato, yams	cGAP: USA, 4 × 140 g a.i./ha, RTI 7 days, PHI 1 day Number of trials: 14 trials in potatoes Sufficiently supported by data: Yes Specific comments/observations: - **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Sugar beet	**0.07**	0.06	cGAP: Canada, 2 × 113 g a.i./ha, RTI 14 days, PHI 14 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: The same GAP as examined by JMPR has been considered in the framework of EU MRL review (EFSA, 2011n). On the basis of a data set of 12 trials (instead of 11 trials mentioned by JMPR), an import tolerance of 0.06 mg/kg was derived, which is slightly below the CXL derived by JMPR (0.07 mg/kg). **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Soyabean (dry)	0.04	0.05*	cGAP: USA, 2 × 63 g a.i./ha, RTI 10 days, PHI 30 days Number of trials: 21 overdosed trials (scaling factor of 0.8) Sufficiently supported by data: Yes Specific comments/observations: - **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Sugar cane	**0.06**	0.02*	cGAP: USA, 4 × 91 g a.i./ha, RTI 14 days, PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Sweet corn (Corn-on–the-cob)	0.015*	0.02* (sweet corn and baby corn)	cGAP: USA, 4 × 92 g a.i./ha, RTI 7 days, PHI 7 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: According to the OECD

Commodity	Codex MRL proposal	EU MRL	Comment
			calculator an MRL of 0.015 mg/kg is derived; the asterisk should be deleted. **Conclusion:** The proposed Codex MRL is sufficiently supported. See general comments. Follow-up action: None
Prunes, dried	0.5	–	JMPR propose a PF of 2.3 based on one study.
General comments	**General comments:** No residue data were reported for the TDMs. Hence, a risk assessment according to the additional EU risk assessment residue definitions for TDMs cannot be performed. According to JMPR, in animal commodities, metconazole residues were not stable in muscle and liver, while for fat stability was demonstrated only for 3 months during storage at −20°C. M1 is stable during the storage for 9 months in liver and for at least 8 months in the other tissues; M12 is stable in liver and kidney for at least 8 and 9 months, respectively. The RMS BE clarified that in the framework of the AIR peer review, it was concluded that the feeding studies are fully reliable with respect to reported residue results for metconazole; the main uncertainties related to stability and analytical recovery of metabolites. The broader residue definition for risk assessment for products of plant origin agreed upon at EU level in the framework of the AIR EU peer review implies that the exposure of the consumer to the monohydroxylated derivatives of metconazole will have to be taken into account as well in the future. This has not been the case in the consumer risk assessment conducted by EFSA (which only considered metconazole). Unfortunately, only a few tentative (and conservative) conversion factors could be derived from the metabolism studies in the AIR peer review framework (e.g. 1.4 for whole fruits, 3.3 for oilseeds, 1.0 for cereal grains), to make a rough estimate of exposure according to the newly agreed EU RD for RA.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.44.5. Consumer risk assessment

Table 216: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. EFSA used the HR/STMR values derived by JMPR; however, for crops where JMPR suggested the HR/STMR being 0, in accordance with the EU practice, EFSA used the proposed Codex MRLs (at the LOQ).	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (normal mode calculation). The input values of the most recent long-term risk assessment (EFSA, 2016h) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL. For crops/commodities for which JMPR proposed an STMR of 0, EFSA used the proposed Codex MRL (LOQ).	**Specific comments:** –
Additional uncertainty of the assessment (lack of reported residue values for the metabolites included in the EU RD for RA and open issues related to storage stability.	Additional uncertainty of the assessment (lack of reported residue values for the metabolites included in the EU RD for RA and open issues related to storage stability.	
The risk assessment was performed with the EU ARfD.	The risk assessment was performed with the EU ADI.	
No risk assessment can be performed for TDMs since no information on the occurrence of TDMs in the crops under consideration are provided.	No risk assessment can be performed for TDMs since no information on the occurrence of TDMs in the crops under consideration are provided.	

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: The calculated short-term exposure exceeded the ARfD for one under assessment. Bananas: 97% of the ARfD Peaches: 81% of the ARfD Potatoes: 62% of the ARfD Milk: 50% of the ARfD Apricots: 30% of the ARfD Plums: 19% of the ARfD Blueberries: 20% of the ARfD Cherries: 17% of ARfD Other crops/commodities: < 15% of ARfD As for banana and peaches, the calculated short-term exposure to the parent only was close to the ARfD (97% and 81%, respectively), further consideration is needed whether an acute consumer concern can be excluded. As regards bananas, residues were < LOQ (< 0.1 mg/kg) in all trials (with higher number of applications); considering a worst-case CF of 1.4 to account for metabolites included in the new EU RDRA and assuming lower residue levels in the banana pulp (cf. peeling factor expected in range 0.4–0.9 in banana metabolism study), an acute consumer concern is rather unlikely. Peaches: Considering metconazole only, IESTI accounted for 81% ARfD. However, considering a worst-case CF of 1.4 to account for metabolites included in the new EU RDRA, IESTI accounted for 113% ARfD. It is therefore recommended that risk managers should discuss a general reservation to the proposed CXLs.	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 44% of the ADI. Among the crops under consideration, Milk: Cattle was identified as the main contributor, accounting for up to 24% of the ADI., followed by bananas (5% of the ADI) and potatoes (2% of ADI)	**Results:** Long-term exposure: Max 2% of the JMPR ADI. Short-term exposure: Highest result for Banana: 20% of ARfD

5.45. Pyflubumide (314) R/T

5.45.1. Background information

Table 217: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	
RMS	no RMS assigned	
Approval status	Not approved	No application for approval submitted in the EU.
EFSA conclusion available	No	
MRL review performed	No	
MRL applications/assessments	No	

		Comments, references
Classification of a.s. – cut-off criteria	Not assessed/not concluded	No harmonised classification
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet.

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.45.2. Toxicological reference values

Table 218: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.0007 mg/kg bw per day	JMPR (2019)	–	–	Not appropriate
ARfD	0.008 mg/kg bw	JMPR (2019)	–	–	Not appropriate
Conclusion/ comment	The ADI value proposed by JMPR was derived from the NOAEL of 0.7 mg/kg bw/day based on the findings in liver, hearth and adrenals in the 2-year study of toxicity and carcinogenicity in rats, using a safety factor of 100. The ADI was supported by the parental and offspring NOAELs in the two-generation study in rats (0.8 mg/kg bw per day) and by the NOAEL in the one-year study in dogs (1.1 mg/kg bw per day). This active substance is not registered in EU and therefore the available toxicological data set has not been reviewed by EFSA. EFSA does not have specific comments on the evaluation made by JMPR. The ARfD value proposed by JMPR was derived from the offspring NOAEL of 0.8 mg/kg bw/day for lung lesions occurred as acute effect in the two-generation rat study, using a safety factor of 100. This active substance is not registered in EU and therefore the available toxicological data set has not been reviewed by EFSA. EFSA does not have specific comments on the evaluation made by JMPR. EFSA notes that based on JMPR assessment, the active substance might have Endocrine Disrupting properties relevant for human health: '*Thyroid effects such as organ weight increase or follicular cell hyperplasia could be clearly attributed to inhibition of thyroid peroxidase (TPO) resulting in a lower availability of iodine, reduced concentrations of circulation triiodothyronine (T3) and thyroxine (T4) and, because of hormonal feedback regulation, an increase in thyroid stimulating hormone (TSH) release.*' JMPR concluded that the ADI and ARfD are applicable to the metabolites **pyflubumide-NH** (P-NH, metabolite B) and **pyflubumide-RfOH** (P-RfOH, metabolite U). Regarding metabolites relevant for residues, based on the JMPR report, metabolite **pyflubumide-NH** might be potentially considered covered by the parent compound. However, the JMPR report indicates that this metabolite exceeded 10% of the administered dose in either excreta or plasma in ADME studies. Considering that the term excreta might refer to both urine and faeces, EFSA cannot evaluate if this metabolite was exceeding 10% in plasma or urine and to exclude that this metabolite is excreted in faeces. Therefore, uncertainty is identified if this metabolite can be considered fully covered by the parent compound. Regarding **metabolites P-aniline isobutyryl** (metabolite L), **P-acid** (metabolite H) **and P-NH-5-CH2OH**, no toxicological information available in the JMPR report. Therefore, EFSA cannot comment on the toxicological properties of these metabolites.				

5.45.3. Residue definitions

Table 219: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Pyflubumide (only fruits and leafy crops)	No specific residue definition is set in the EU; the default residue definition as pyflubumide is applicable	Not appropriate
	Animal products	No information available		Not appropriate
RD RA	Plant products	Sum of pyflubumide and 3′-isobutyl-1,3,5-trimethyl-4′-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl] pyrazole-4-carboxanilide (P-NH), expressed as pyflubumide.		Not appropriate
	Animal products	No information available		Not appropriate
Conclusion, comments	The plant residue definitions derived by JMPR are based on metabolism studies in fruits crops (apples and aubergines) and leafy crops (spinach) via foliar applications. Parent was the major compound through all the studies (accounting, up to 92% TRRs in fruits apples, up to 91% TRRs in spinach and 90–98% in eggplant fruits). Besides the parent, pyflubumide-NH was found in apples (up to 18% TRRs at 28 DAT and 16%TRRs at 51 DAT); in spinach pyflubumide-NH and P-acid accounted for max. 3.2% TRR (21 DAT). In the three crops investigated, the other identified metabolites were found in insignificant amount in the edible parts. Based on this data JMPR proposed the RD for enforcement in plant as pyflubumide. For RA, considering the toxicity of P-NH is covered by the parent, JMPR proposed the residue definitions as reported above. These residue definitions cover only fruit and leafy crops. The use of pyflubumide in apples is expected to lead to a significant dietary burden for livestock, triggering the assessment of residues in animal products. Hence, metabolism studies for livestock would be required. Hydrolysis studies under standard conditions were provided for pyflubumide residues; under pasteurisation conditions, pyflubumide remains stable, whereas under baking/brewing/boiling and sterilisation conditions, parent degraded up to 71% of applied radioactivity (AR). Under baking/brewing/boiling**, P-NH** (metabolite H) and **P-aniline isobutyryl** (metabolite L) is formed up to 19% and 10% of the AR, respectively. Under the sterilisation condition **P-NH** is also formed up to 12% of AR. A toxicological assessment of **P-aniline-isobutyryl** (metabolite L) should be made available to decide on the toxicological relevance of the degradation products expected in processed products. **In EU, pyflubumide was never evaluated and the default applicable residue definitions could underestimate the risk assessment to the European consumer (see RA).**			

5.45.4. Codex MRL proposals

Table 220: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL Default MRLs apply	Comment
Apple	**1** (ft)	*	cGAP: Japan: 1x10 g/hL, PHI 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The number of trials is sufficient to support the Codex MRL proposal. However, the use in apples would trigger a dietary burden calculation for livestock and an assessment of residues in animal products, which were not reported in the JMPR report. **Conclusion:** The proposed Codex MRL is not acceptable

Commodity	Codex MRL proposal	EU MRL Default MRLs apply	Comment
			because an acute risk consumer was identified. Follow-up action: None
Tea, Green, Black (black, fermented and dried)	**80** (ft)	0.01*	cGAP: Japan: 1x10 g/hL, PHI 7 days Number of trials: 6 (matching GAP), 2 (with application of 5g/hL) Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal was derived by combining the 6 GAP compliant trials with the two underdosed trials which were scaled up with a factor of 2. **Conclusion:** The proposed Codex MRL is not acceptable because an acute risk consumer was identified. Follow-up action: None
General comments	Default MRL of 0.01 mg/kg according to Art. 18(1)(b) Reg 396/2005 for all the commodities.		

*: Indicates that the MRL is proposed at the limit of quantification.

5.45.5. Consumer risk assessment

Table 221: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The calculations are affected by additional, non-standard uncertainties, related to missing information on livestock assessment and toxicological information on the metabolite P-NH-isobutyryl. The risk assessment was performed with the JMPR ARfD. The calculations are indicative, because underestimate the contribution of the toxicity of P-NH-isobutyryl metabolite.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1, by using the default EU-MRLs and including the STMR values derived by JMPR for the evaluated crops with higher the proposed Codex MRL than the EU MRL. The calculations are affected by additional, non-standard uncertainties, related to missing information on livestock assessment and toxicological information on the metabolite P-NH-isobutyryl. The risk assessment was performed with the EU ADI. The calculations are indicative, because underestimate the contribution of the toxicity of P-NH-isobutyryl metabolite.	**Specific comments:** JMPR concluded that the estimated acute dietary exposure to residues of pyflubumide for the consumption of apple and tea may present a public health concern.
Results: The calculated short-term exposure exceeded the ARfD for both crops under assessment. Apples: 741% of ARfD; Tea leaves: 258% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 82% of the ADI. Among the crops under consideration, tea leaves were identified as the main contributor, accounting for up to 27% of the ADI.	**Results:** Long-term exposure: Max 20% of the JMPR ADI. Short-term exposure: Also for JMPR an acute risk was identified for both crops; apples 160% of ARfD and tea (dried leaf) 230% ARfD

5.46. Pyridate (315) T

5.46.1. Background information

Table 222: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/1115[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2014m)
MRL review performed	Yes, see comments	(EFSA, 2012e)
MRL applications/assessments	Yes, see comments	(EFSA, 2012g) (celery leaves)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded/not finalised, see comments	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2015/1115 of 9 July 2015 renewing the approval of the active substance pyridate 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 182, 10.7.2015, p. 22–25.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.46.2. Toxicological reference values

Table 223: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
ADI	0.2 mg/kg bw per day	JMPR (2019)	0.036 mg/kg bw per day	(EFSA, 2014m) (3-generation study with uncertainty factor 100)	No
ARfD	2 mg/kg bw	JMPR (2019)	0.4 mg/kg bw	(EFSA, 2014m) (developmental study in rats with uncertainty factor 400)	No
Conclusion/ comment	The ADI and ARfD set by JMPR and at EU level are not comparable. For deriving the ADI, JMPR selected as point of departure the NOAEL of 20 mg/kg bw per day from the 2-year study in rats whereas the EU peer review selected the NOAEL of 3.6 mg/kg bw per day from the multi-generation study. The difference is likely because a different NOAEL for parental toxicity was set by JMPR and EU; adversity regarding the critical effect (increase relative weight) was set at different level by JMPR and EU. JMPR set a higher NOAEL of 26 mg/kg bw per day than in the EU, i.e. 3.6 mg/kg bw per day. For setting the ARfD, JMPR selected as point of departure the NOAEL of 177 from the acute neurotoxicity study based on clinical signs and mortality at 500 mg/kg bw whereas in the EU the maternal NOAEL of 165 mg/kg bw per day from the developmental rat toxicity study based on mortalities observed at 400 mg/kg bw per day. Although the NOAEL value is the same range, in the EU evaluation, an additional UF of 4 was applied because of the severity of effect (i.e. mortality). An additional UF was not considered justified by JMPR because human exposure is unlikely to result in saturation of renal excretion. In the EU, available information including toxicity studies with the metabolites pyridafol, CL 9673-N-glucoside (pyridafol-N-glucoside) and pyridafol-O-methyl (CL 9869) indicated similar toxicological properties to pyridate. Consumer health-based reference values of pyridate were considered applicable to these metabolites. JMPR considered pyridafol, pyridafol-N-glucoside covered by parent too.				

5.46.3. Residue definitions

Table 224: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Not assessed	Reg. 396/2005, peer review (EFSA, 2014m) and MRL review (EFSA 2012e): Pyridate (sum of pyridate, its hydrolysis product CL 9673 (6-chloro-4-hydroxy-3-phenylpyridazin) and hydrolysable conjugates of CL 9673 expressed as pyridate)	Not appropriate
	Animal products	Not assessed	Reg. 396/2005, peer review (EFSA, 2014m) and MRL review (EFSA, 2012e): Pyridate (sum of pyridate, its hydrolysis product CL 9673 (6-chloro-4-hydroxy-3-phenylpyridazin) and hydrolysable conjugates of CL 9673 expressed as pyridate) The residue is not fat soluble	Not appropriate
RD RA	Plant products	Not assessed	Peer review (EFSA, 2014m) and MRL review Art. 12 (EFSA, 2012e) Pyridate (sum of pyridate, its hydrolysis product CL 9673 (6-chloro-4-hydroxy-3-phenylpyridazin) and hydrolysable conjugates of CL 9673, expressed as pyridate)	Not appropriate
	Animal products	Not assessed	Peer review (EFSA, 2014m): CL 9673 (Pyridafol), expressed as Pyridate MRL review Art. 12 (EFSA, 2012e): Sum of pyridate, its hydrolysis product 6-chloro-4-hydroxy-3-phenylpyridazin and hydrolysable conjugates of 6-chloro-4-hydroxy-3-phenylpyridazin, expressed as pyridate	Not appropriate
Conclusion, comments	–			

5.46.4. Codex MRL proposals

Not relevant, no MRL proposals were derived by JMPR.

5.46.5. Consumer risk assessment

Not relevant, no MRL proposals were derived by JMPR.

5.47. Pyrifluquinazon (316) R/T

5.47.1. Background information

Table 225: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	
RMS	no RMS assigned	
Approval status	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
MRL applications/assessments	No	
Classification of a.s. – cut-off criteria	No	

		Comments, references
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.47.2. Toxicological reference values

Table 226: Comparison of toxicological reference values (TRV derived by JMPR and at EU level)

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.005 mg/kg bw per day	JMPR (2019)	–	–	Not appropriate
ARfD	1 mg/kg bw	JMPR (2019)	–	–	Not appropriate
Conclusion/ comment	The ADI and ARfD derived by JMPR applies also to IV-01 and IV-203. The JMPR could not conclude on the toxicological relevance of metabolites IV-02 (found in radish roots), IV-03 (found in goat milk and tissues, and in chicken liver), IV-04 (predominant residue in milk), IV-15 (found in goat kidney and liver, in eggs and chicken liver), IV-17 (goat fat) and IV-208 (milk, muscle, fat, liver, kidney, eggs). In view of the absence of repeated dose toxicity studies, no conclusion could be drawn on the toxicity of these metabolites. For IV-03, IV-04 and IV-15, JMPR used the TTC of 0.0025 μg/kg bw per day (genotoxicity); the estimated exposure was above the threshold for compounds that are potential DNA-reactive mutagens and/or carcinogens. For IV-02, IV-17 and IV-208 the TTC for Cramer class II substances was used.				

5.47.3. Residue definitions

Table 227: 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 pyrifluquinazon and 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) expressed as pyrifluquinazon	No EU residue definitions derived	Not appropriate
	Animal products	Tissues: Sum of 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) and 1,2,3,4-tetrahydro-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl] quinazolin-2,4-dione (IV-203) and their conjugates (expressed as pyrifluquinazon). Milk: 1,2,3,4-tetrahydro-3-[3-(1-oxy-pyridylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-04). The residue is not fat soluble	–	Not appropriate
RD RA	Plant products	Sum of pyrifluquinazon and 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) expressed as pyrifluquinazon	–	Not appropriate
	Animal products	A conclusion could not be reached	–	Not appropriate
Conclusion, comments	Because JMPR could not conclude on the toxicological relevance of metabolites IV-03, IV-04 and IV-15, no conclusion on a residue definition for dietary risk assessment could be reached. The JMPR approach, not to derive residue definitions for risk assessment as long as the toxicological relevance of metabolites is not clarified, is supported.			

5.47.4. Codex MRL proposals

Not relevant, no Codex MRL proposals were derived.

5.47.5. Consumer risk assessment

Not relevant, no Codex MRL proposals were derived.

5.48. Triflumuron (317) R/T

5.48.1. Background information

Table 228: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	
RMS	IT	
Approval status	Not approved	expiry of approval: 31/03/2021, no application to renew approval
EFSA conclusion available	Yes, see comments	(EFSA, 2011a)
MRL review performed	Yes, see comments	(EFSA, 2017e)
MRL applications/assessments	Yes, see comments	(EFSA, 2014d) (peaches, plums, oranges and mandarins)
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]) has not been performed yet.

(a): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

5.48.2. Toxicological reference values

Table 229: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments	Value	Comments	
Triflumuron					
ADI	0.008 mg/kg bw per day	JMPR (2019) (based on 2-year rat study, with safety factor of 100) See	0.014 mg/kg bw per day	(EFSA, 2011a) (based on 1-year dog study supported by 2-year rat study, with uncertainty factor of 100) confirmed in (European Commission, 2011a)	No
ARfD	Unnecessary	JMPR (2019)	Not necessary	(EFSA, 2011a) confirmed in (European Commission, 2011a)	Yes
Metabolites M02 and M03					
ADI	Same ADI as for parent		M02: Same ADI as for parent M03: not relevant, not included in RD.		No
ARfD	Unnecessary		M02: Not necessary M03: not relevant, not included in RD		Yes

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Metabolites M01 and M04					
ADI	No conclusion	No toxicity information available	M01: Same value as for parent M04: not assessed in the peer review		Not appropriate
ARfD	No conclusion	No toxicity information available	M01: Not necessary M04: not assessed in the peer review		Not appropriate
Metabolites M07 and M08 (expressed as M07)					
ADI	0.02 mg/kg bw per day	JMPR (2019) (based on single oral gavage dose in rats, with safety factor 25)	Same value as for parent		No
ARfD	0.02 mg/kg bw per day	JMPR (2019) (based on single oral gavage dose in rats, with safety factor 25)	**M07:** 0.005 mg/kg bw per day M08: not necessary	(EFSA, 2011a) confirmed in (European Commission, 2011a) (based on 6-day single dose toxicity study in rat, with uncertainty factor of 100)	No
Conclusion/ comment	During the EU evaluation (EFSA, 2011a), it was considered that both species (rats and dogs) were equally sensitive to **triflumuron**, and the ADI was based on the 1-year dog study supported by the 2-year rat study (a lower NOAEL than JMPR's was derived for the 1-year dog study, i.e. 1.42 mg/kg bw per day i.o. 3.2 mg/kg bw per day). The JMPR assessment (JMPR, 2019) established an ADI for triflumuron on the basis of the 2-year rat study (same NOAEL as in the EU evaluation). During the EU evaluation (EFSA, 2011a), it was agreed that the ADI of triflumuron was applicable to the metabolites **M01, M02, M07 and M08.** An ARfD was considered necessary and was derived only for the metabolite M07 based on a 6-day single dose toxicity with rats (with a standard uncertainty factor of 100). The JMPR assessment (JMPR, 2019) considered that the ADI of triflumuron was also applicable to the metabolites M02 and M03, and derived an ADI (and ARfD) applicable to M07 and M08 on the basis of apparently the same single dose toxicity study in rats (with M07) and applying a reduced safety factor of 25. JMPR also reported that M01 and M04 were not detected in rat metabolism; since no toxicological data were available, the genotoxic TTC value was used for dietary exposure assessment. It is noted that available new data were probably provided to JMPR (and were not considered by the EU peer review), and that the EU assessment might have to be updated according to current knowledge. Risk managers to discuss under which framework the additional toxicological data should be assessed in the EU.				

5.48.3. Residue definitions

Table 230: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Triflumuron	Reg. 396/2005: Triflumuron Peer review (EFSA, 2011a): Triflumuron MRL review Art. 12 (EFSA, 2017e): Triflumuron (for fruit crops only)	Yes
	Animal products	Triflumuron The residue is fat soluble	Reg. 396/2005: Triflumuron Peer review (EFSA, 2011a): Triflumuron MRL review Art. 12 (EFSA, 2017e): Triflumuron The residue is fat soluble	Yes
RD RA	Plant products	A conclusion cannot be reached	Peer review (EFSA, 2011a): Fruit crops: Triflumuron Oilseed and tuber crops: Sum of triflumuron, M07 and M08 expressed as triflumuron (provisional)	Not appropriate

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			MRL review Art. 12 (EFSA, 2017e): Triflumuron (for fruit crops only)	
	Animal products	A conclusion cannot be reached	Peer review (EFSA, 2011a): Triflumuron (provisional) MRL review Art. 12 (EFSA, 2017e): Triflumuron	Not appropriate
Conclusion, comments	JMPR assessed metabolism studies in apples, tomatoes, soyabeans and potatoes and metabolism studies in lactating goats and laying hens. Metabolite M01 was found in soya bean (seed and forage), in tissues and milk from goats, in eggs and in kidney from hens as well as in confined rotational crop studies. Metabolite M04 was found in kidney of lactating goats and of laying hens. As no toxicity information was available for M01 and M04, JMPR concluded that the genotoxic TTC value is appropriate for M01 and M04 for dietary exposure assessment. The estimated exposure for M01 and M04 exceeded the TTC for both metabolites.			

5.48.4. Codex MRL proposals

Residue data were submitted to JMPR to support a use in soyabeans (Colombian GAP), but since no residue definitions for risk assessment could be derived, the JMPR did not derive MRL proposals.

In the EU, a number of MRLs are established for fruit crops (apples, pears: 0.5 mg/kg, apricots: 1 mg/kg, peaches: 0.4 mg/kg, plums: 0.1 mg/kg).

Considering the recent toxicological assessment of JMPR, risk managers should discuss the possible re-evaluation of the active substance in the EU.

5.48.5. Consumer risk assessment

Not relevant, since no Codex MRL proposal was derived.

5.49. Valifenalate (318) R/T

5.49.1. Background information

Table 231: Background information

		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	New compound evaluation	
RMS	HU	
Approval status	Approved	Commission Implementing Regulation (EU) No 144/2014[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2013i)
MRL review performed	Yes, see comments	(EFSA, 2021i)[(c)]
MRL applications/ assessments	Yes, see comments	(EFSA, 2018l) (various crops) (EFSA, 2009e) (tomatoes and aubergines)
Classification of a.s. – cut-off criteria	Not assessed/not concluded	
Endocrine effects of a.s.	Not assessed/not concluded	Not assessed: ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) No 144/2014 of 14 February 2014 approving the active substance valifenalate, 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 45, 15.2.2014, p. 7–11.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

(c): The assessment performed in the recently published reasoned opinion could not be taken into account for the assessment in this report.

5.49.2. Toxicological reference values

Table 232: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.2 mg/kg bw per day	JMPR meeting September 2019	0.07 mg/kg bw per day	(EFSA, 2013i) (1-year dog study and 100 UF) confirmed in (European Commission, 2013b)	No
ARfD	Unnecessary	JMPR meeting September 2019	Not necessary	(EFSA, 2013i) confirmed in (European Commission, 2013b)	Yes
Conclusion/ comment	ADI from JMPR was derived from the 78-week mouse study supported by the 90-day mouse study, while ADI in EU was derived from the 1-year dog study. The ADI derived by JMPR applies also to valifenalate acid and valifenalate acid (IR 5839) glucosyl ester, expressed as valifenalate.				

5.49.3. Residue definitions

Table 233: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Valifenalate	Reg. 396/2005: Valifenalate Peer review (EFSA, 2013i): Valifenalate	Yes
	Animal products	Valifenalate The residue is not fat soluble	Reg. 396/2005: Valifenalate Peer review (EFSA, 2013i) Valifenalate and its metabolite IR5839 (valifenalate acid, R2) The residue is not fat soluble	Yes, compared with the RD in Reg. 396/2005
RD RA	Plant products	Valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), (free and conjugated) expressed as valifenalate	Peer review (EFSA, 2013i): Valifenalate	No
	Animal products	Valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), expressed as valifenalate	Peer review (EFSA, 2013i): Valifenalate and its metabolite IR5839 (valifenalate acid, R2)	Yes
Conclusion, comments	JMPR assessed metabolism studies in fruits (grapes), roots (potatoes) and leafy (lettuce) following foliar treatment. Valifenalate was the major residues in all investigated crops accounting between 66 and 99% of TRRs. For plants, JMPR proposed the enforcement residue definition as valifenalate. For the risk assessment, valifenalate acid was also included in the RD. In the EU, based on the same metabolism studies, the residue definition for enforcement and risk assessment was derived as valifenalate. The RDs for enforcement (plant and animal products) derived by JMPR are comparable with the EU residue definitions implemented in Reg. 396/2005. The RD for risk assessment (animal products) is also comparable. However, the residue definition for RA derived by JMPR for plants is wider than the EU RD. Hence the input values for RA are likely to be more conservative.			

5.49.4. Codex MRL proposals

Table 234: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Eggplants	0.4	0.8	cGAP: France, 3 × 150 g a.i./ha, RTI 7 days, PHI 3 daysNumber of trials: 9 (tomatoes) Sufficiently supported by data: Yes Specific comments/observations: Nine GAP compliant residue trials conducted in tomatoes were submitted, which were used to derive the MRL proposal by extrapolation. The existing EU MRL is higher and is based on indoor use on tomatoes. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Grapes	**0.3**	0.2 (table and wine grapes)	cGAP: Italy, 3 × 120 g a.i./ha, RTI 10–14 days, PHI 28 days for wine grapes, 70 days for table grapes. Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The setting of separate MRLs for table and wine grapes might be considered, since the PHI differ significantly. However, it is acknowledged that JMPR has a different policy on the setting MRLs for grapes (usually the setting of separate MRLs for table and wine grapes is not the usual JMPR practice). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: To check in JMPR evaluation whether the residue trials assessed were compliant with the GAP for table or for wine grapes.
Onion, bulb	0.5	0.5	cGAP: Bulgaria, 3 × 150 g a.i./ha, RTI 7 days, PHI 3 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: The existing EU MRL is based on the same GAP. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Shallot	0.5	0.5	cGAP: Bulgaria, 3 × 150 g a.i./ha, RTI 7 days, PHI 3 days Number of trials: 12 trials in onions Sufficiently supported by data: Yes Specific comments/observations: Extrapolation from onions. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Tomato	0.4	0.8	cGAP: France, 3 × 150 g a.i./ha, RTI 7 days, PHI 3 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: Nine GAP compliant residue trials conducted in tomatoes were submitted. The existing EU MRL is higher and is based on indoor use on tomatoes. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Edible offal (mammalian)	0.01*	0.01*	Grape and tomato pomace are potential feed items in Australia for livestock. Since valifenalate is not registered in Australia, JMPR proposed a default CXL

Commodity	Codex MRL proposal	EU MRL	Comment
			of 0.01 mg/kg. The proposal is acceptable.
Eggs	0.01*	0.01*	The crops under consideration are not feed for poultry. The CXL proposal is acceptable.
Milks	0.01*	0.01*	See edible offal (mammalian)
Meat (from mammals other than marine mammals)	0.01*	0.01*	See edible offal (mammalian)
Mammalian fats (except milk fats)	0.01*	0.01*	See edible offal (mammalian)
Poultry edible offal	0.01*	0.01*	See eggs
Poultry fat	0.01*	0.01*	See eggs
Poultry meat	0.01*	0.01*	See eggs.
General comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.49.5. Consumer risk assessment

Table 235: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant since no ARfD was allocated.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2018l) were updated, including the STMR values for grapes.	**Specific comments:** –
Results: **Not relevant**	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 2% of the ADI. Among the crops under consideration, wine grapes were identified as the main contributor, accounting for up to 0.28% of the ADI.	**Results:** Long-term exposure: Max 0% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD).

5.50. Acetamiprid (246), carbendazim (072) – Codex MRL proposals for spices (seeds)

5.50.1. Background information

Table 236: Background information

Acetamiprid		Comments, references
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Other evaluation, see comment	Review of monitoring data to derive MRL proposal for spices
RMS	NL	
Approval status	Approved	Commission Implementing Regulation (EU) 2018/113[(a)]
EFSA conclusion available	Yes, see comments	(EFSA, 2016p)
MRL review performed	Yes, see comments	(EFSA, 2011j)
MRL applications/assessments	Yes, see comments	(EFSA, 2018h) (Art.43 assessment and modification of the existing MRLs in table olives, olives for oil production, barley and oats)

Acetamiprid		Comments, references
		(EFSA, 2016a) (various crops) (EFSA, 2015t) (leafy brassicas) (EFSA, 2014n) (bananas) (EFSA, 2013s) (apricots and tree nuts) (EFSA, 2012m) (purslane, legume vegetables and pulses) (EFSA, 2011g) (flowering brassica and figs) (EFSA, 2010l) (various commodities) (EFSA, 2010i) (land cress and red mustard) (EFSA, 2009f) (beet leaves) (EFSA, 2009c) (cress, spinach and herbs) Ongoing (additional data requested): modification of the existing MRLs in poppy seeds and in various crops
Classification of a.s. – cut-off criteria	No	
Endocrine effects of a.s.	Not assessed, see comments	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet
Carbendazim		**Comments, references**
JMPR assessment	JMPR meeting September 2019	
Type of JMPR evaluation	Other evaluation, see comment	Review of monitoring data to derive MRL proposal for spices
RMS	DE	
Approval status	Not approved	Non-approval due classification Reg. 1272/2008[(c)] (see cut-off criteria Max. period of grace: 31/05/2016
EFSA conclusion available	Yes, see comments	(EFSA, 2010g)
MRL review performed	Yes, see comments	(EFSA, 2014q)
MRL applications/assessments	Yes, see comments	(EFSA, 2012d) Ongoing: Art. 43 assessment
Classification of a.s. – cut-off criteria	Yes, see comments	Mutagen cat. 1B Toxic for reproduction cat. 1B
Endocrine effects of a.s.	Not assessed, see comments	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]) has not been performed yet

(a): Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 renewing the approval of the active substance acetamiprid 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 20, 25.1.2018, p. 7–10.

(b): Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

(c): Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, 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 Commission Implementing Regulation (EU) No 540/2011. OJ L 114, 30.4.2019, p. 15–17.

5.50.2. Toxicological reference values

Table 237: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments**	**Value**	**Comments**	
Acetamiprid					
ADI	0.07 mg/kg bw per day	JMPR (2011)	0.025 mg/kg bw per day	Reg. (EU) 2018/113[(b)]	No
ARfD	0.1 mg/kg bw	JMPR (2011)	0.025 mg/kg bw	Reg. (EU) 2018/113[(b)]	No
Carbendazim					
ADI	0.03 mg/kg bw per day	JMPR (1995)	0.02 mg/kg bw per day	Commission Directive 2006/135/EC[(a)]	No
ARfD	0.1 mg/kg bw for women of child-bearing age) 0.5 mg/kg bw (for the general population)	JMPR (1995)	0.02 mg/kg bw	Commission Directive 2006/135/EC[(a)]	No

(a): Commission Directive 2006/135/EC of 11 December 2006 amending Council Directive 91/414/EEC to include carbendazim as active substance. OJ L 349, 12.12.2006, p. 37–41.
(b): Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 renewing the approval of the active substance acetamiprid 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 20, 25.1.2018, p. 7–10.

5.50.3. Residue definitions

Table 238: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Acetamiprid				
RD enf	Plant products	Acetamiprid	Reg. 396/2005: Acetamiprid	Yes
RD RA	Plant products	Sum of acetamiprid and its desmethyl (IM-2-1) metabolite, expressed as acetamiprid	sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid Reg. 396/2005: Sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid	Yes
Carbendazim				
RD enf	Plant products	Sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim	Reg. 396/2005: Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim)	No
RD RA	Plant products	Sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim	Art. 12 (EFSA, 2014q): carbendazim	No
Conclusion, comments	–			

5.50.4. Codex MRL proposals

Table 239: Comparison of Codex MRL proposals derived by JMPR with EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Acetamiprid			
Spices, seeds, Subgroup of	2	0.05*	Number of monitoring results: 357 samples of cumin (123 samples with quantifiable residues) Sufficiently supported by data: Yes Specific comments/observations: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Carbendazim			
Spices, seeds, Subgroup of	5	0.1*	Number of monitoring results: 357 samples of cumin (172 samples with quantifiable residues) Sufficiently supported by data: Yes Specific comments/observations: The samples were analysed in compliance with the Codex residue definition. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Comments	–		

*: Indicates that the MRL is proposed at the limit of quantification.

5.50.5. Consumer risk assessment

Table 240: Summary of the consumer risk assessment

Acute exposure assessment		Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: A short-term dietary risk assessment was performed using PRIMo rev. 3.1 for spices, seeds only. EFSA used the STMR values, since it is likely that the spices are bulked and blended before they are consumed by European consumers. The risk assessment was performed with the EU ARfD values for acetamiprid and carbendazim, respectively.		**RA assumptions:** EFSA calculated a focussed long-term dietary risk assessment for spices seeds only using PRIMo rev. 3.1 for spices, seeds only. The risk assessment was performed with the EU ADI values derived for acetamiprid and carbendazim, respectively.	**Specific comments:** –
Acetamiprid			
Results: No short-term consumer health risk was identified for the crops under assessment.		**Results:** No long-term consumer health risk was identified. The contribution of spices to the chronic exposure accounted for 0.1% of the ADI.	**Results:** Long-term exposure: Max 0% of the JMPR ADI. Short-term exposure: IESTI 0% of ARfD
1.76%	Fennel seed		
0.23%	Black caraway/black cumin		
0.23%	Nutmeg		
0.23%	Fenugreek		
0.23%	Coriander seed		
0.23%	Anise/aniseed		

<table>
<tr><th colspan="2">Acute exposure assessment</th><th>Chronic exposure assessment</th><th>Comments on JMPR exposure assessment</th></tr>
<tr><td colspan="4">Carbendazim</td></tr>
<tr><td colspan="2">Results:
No short-term consumer health risk was identified for the crops under assessment.</td><td rowspan="7">Results:
No long-term consumer health risk was identified.
The contribution to the overall chronic exposure accounted for 0.1% of the ADI.</td><td rowspan="7">Results:
Long-term exposure: Max 0% of the JMPR ADI.
Short-term exposure: IESTI 0% of ARfD</td></tr>
<tr><td>2.02%</td><td>Fennel seed</td></tr>
<tr><td>0.26%</td><td>Black caraway/black cumin</td></tr>
<tr><td>0.26%</td><td>Nutmeg</td></tr>
<tr><td>0.26%</td><td>Fenugreek</td></tr>
<tr><td>0.26%</td><td>Coriander seed</td></tr>
<tr><td>0.26%</td><td>Anise/aniseed</td></tr>
</table>

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Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
a.s.	active substance
bw	body weight
BBCH	growth stages of mono- and dicotyledonous plants
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DALA	days after last application
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DNT	developmental neurotoxicity
dw	dry weight
EMS	evaluating Member State
EU	European union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GM	genetically modified
ha	hectare
hL	hectolitre
HR	highest residue
IEDI	international estimated daily intake

IESTI	International estimated of short-term intake
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LD_{50}	lethal dose, median
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
ppm	parts per million (10-6)
P_{ow}	partition *coefficient between* n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RAR	renewal assessment report
RD	residue definition
RD-RA	residue definition for risk assessment
RD-ENF	residue definition for enforcement practice
RMS	rapporteur Member State
RTI	re-treatment interval
SEU	Southern European Union
STMR	supervised trials median residue
TDMs	triazole-derivative metabolites
TTC	threshold of toxicological concern
TRR	total radioactive residues
TRV	toxicological reference values
WHO	World Health Organization
UF	uncertainty factor

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Acetamiprid

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw per day):	**0.025**	ARfD (mg/kg bw):	**0.025**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.1%	DE child	0.03	0.0%	Nutmeg	0.0%	Fennel seed	0.0%	Cumin seed		
0.0%	GEMS/Food G11	0.01	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G06	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G07	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G07	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G08	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G10	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	FR toddler 2 3 yr	0.00	0.0%	Other spices (seeds)	0.0%	Coriander seed	0.0%	Coriander seed		
0.0%	DE women 14-50 yr	0.00	0.0%	Nutmeg	0.0%	Black caraway/black cumin	0.0%	Coriander seed		
0.0%	DE general	0.00	0.0%	Nutmeg	0.0%	Black caraway/black cumin	0.0%	Coriander seed		
0.0%	FR child 3 15 yr	0.00	0.0%	Other spices (seeds)		FRUIT AND TREE NUTS				
0.0%	FR adult	0.00	0.0%	Other spices (seeds)	0.0%	Anise/aniseed	0.0%	Coriander seed		
0.0%	FR infant	0.00	0.0%	Other spices (seeds)		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Acetamiprid is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Fennel seed	2/0.57	0.44	0.2%	Black caraway/black cumin	2/0.57	0.06
0.05%	Coriander seed	2/0.57	0.01	0.2%	Nutmeg	2/0.57	0.06
0.05%	Anise/aniseed	2/0.57	0.01	0.2%	Fenugreek	2/0.57	0.06
0.02%	Nutmeg	2/0.57	0.01	0.2%	Coriander seed	2/0.57	0.06
0.01%	Fenugreek	2/0.57	0.00	0.2%	Fennel seed	2/0.57	0.06
0.01%	Dill seed	2/0.57	0.00	0.2%	Anise/aniseed	2/0.57	0.06
0.01%	Cumin seed	2/0.57	0.00	0.00%	Dill seed	2/0.57	0.00
				0.00%	Cumin seed	2/0.57	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
				0.1%	Cumin seed / processed (not	2 / 0.57	0.02

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Acetamiprid is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Acetochlor

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.0036	ARfD (mg/kg bw):	1.5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
35%	NL toddler	1.27	17%	Milk: Cattle	3%	Apples	2%	Maize/corn	34%	0.9%
26%	GEMS/Food G11	0.94	15%	Soyabeans	2%	Milk: Cattle	1%	Potatoes	11%	15%
23%	GEMS/Food G10	0.83	14%	Soyabeans	2%	Milk: Cattle	1%	Wheat	9%	14%
19%	NL child	0.69	7%	Milk: Cattle	2%	Sugar beet roots	2%	Apples	18%	1.0%
18%	GEMS/Food G08	0.66	8%	Soyabeans	2%	Milk: Cattle	1%	Wheat	10%	8%
18%	DE child	0.64	5%	Milk: Cattle	3%	Apples	1%	Wheat	18%	0.2%
18%	GEMS/Food G07	0.63	7%	Soyabeans	2%	Milk: Cattle	1%	Wheat	10%	8%
17%	GEMS/Food G15	0.63	7%	Soyabeans	2%	Milk: Cattle	1%	Wheat	10%	7%
17%	UK infant	0.61	11%	Milk: Cattle	0.9%	Potatoes	0.7%	Wheat	17%	0.2%
16%	FR toddler 2 3 yr	0.57	8%	Milk: Cattle	0.9%	Apples	0.9%	Wheat	16%	0.3%
16%	FR child 3 15 yr	0.56	6%	Milk: Cattle	1%	Wheat	1%	Sugar beet roots	15%	0.2%
15%	GEMS/Food G06	0.55	5%	Soyabeans	2%	Wheat	1.0%	Tomatoes	10%	5%
12%	UK toddler	0.45	6%	Milk: Cattle	1%	Wheat	1.0%	Potatoes	12%	0.0%
11%	DK child	0.41	4%	Milk: Cattle	2%	Rye	1%	Wheat	11%	0.1%
10%	RO general	0.38	3%	Milk: Cattle	1%	Wheat	1%	Potatoes	10%	
10%	DE women 14-50 yr	0.38	3%	Milk: Cattle	1%	Sugar beet roots	0.7%	Apples	10%	0.2%
10%	ES child	0.38	3%	Milk: Cattle	1%	Wheat	0.7%	Cocoa beans	10%	0.1%
10%	SE general	0.37	3%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Potatoes	10%	
10%	DE general	0.37	3%	Milk: Cattle	1%	Sugar beet roots	0.7%	Apples	10%	0.2%
10%	FI adult	0.35	8%	Coffee beans	0.3%	Potatoes	0.2%	Rye	10%	0.1%
9%	IE adult	0.34	1%	Milk: Cattle	1.0%	Sweet potatoes	0.6%	Wheat	9%	0.2%
9%	NL general	0.32	2%	Milk: Cattle	0.8%	Sugar beet roots	0.7%	Potatoes	8%	0.5%
8%	FR infant	0.29	5%	Milk: Cattle	0.5%	Potatoes	0.5%	Apples	8%	0.0%
7%	PT general	0.25	1%	Potatoes	1%	Soyabeans	1%	Wheat	6%	1%
6%	FR adult	0.22	1%	Milk: Cattle	0.6%	Wine grapes	0.6%	Wheat	6%	0.1%
6%	ES adult	0.21	1%	Milk: Cattle	0.7%	Wheat	0.4%	Oranges	6%	0.0%
5%	FI 3 yr	0.18	1%	Potatoes	0.4%	Bananas	0.3%	Wheat	5%	0.0%
5%	IT toddler	0.17	2%	Wheat	0.4%	Other cereals	0.4%	Tomatoes	5%	0.0%
5%	DK adult	0.16	1%	Milk: Cattle	0.4%	Potatoes	0.3%	Wheat	5%	0.0%
5%	LT adult	0.16	1%	Milk: Cattle	0.9%	Potatoes	0.5%	Apples	4%	0.0%
4%	UK vegetarian	0.15	0.9%	Milk: Cattle	0.6%	Wheat	0.4%	Potatoes	4%	0.0%
4%	FI 6 yr	0.14	1%	Potatoes	0.3%	Cocoa beans	0.3%	Wheat	4%	0.0%
4%	UK adult	0.14	0.8%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	0.0%
3%	IT adult	0.12	1%	Wheat	0.3%	Tomatoes	0.2%	Apples	3%	0.0%
3%	PL general	0.10	1.0%	Potatoes	0.6%	Apples	0.2%	Tomatoes	3%	0.0%
2%	IE child	0.08	1.0%	Milk: Cattle	0.3%	Wheat	0.2%	Potatoes	2%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Acetochlor is unlikely to present a public health concern.

Acute risk assessment/children | **Acute risk assessment/adults/general population**

Details - acute risk assessment/children | Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.02%	Soyabeans	0.01/0.15	0.35
0.02%	Bovine: Liver	0.01/0.04	0.34
0.02%	Bovine: Edible offals (other	0.01/0.04	0.30
0.01%	Bovine: Kidney	0.01/0.04	0.16
0.01%	Swine: Edible offals (other	0.01/0.04	0.13
0.00%	Swine: Kidney	0.01/0.04	0.05
0.00%	Swine: Liver	0.01/0.04	0.05

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.06%	Soyabeans	0.01/0.15	0.83
0.01%	Bovine: Liver	0.01/0.04	0.17
0.01%	Bovine: Edible offals (other	0.01/0.04	0.14
0.01%	Swine: Other products	0.01/0.04	0.14
0.01%	Sheep: Liver	0.01/0.04	0.12
0.01%	Swine: Edible offals (other	0.01/0.04	0.11
0.01%	Swine: Kidney	0.01/0.04	0.09
0.01%	Bovine: Kidney	0.01/0.04	0.09
0.01%	Bovine: Other products	0.01/0.04	0.08
0.00%	Swine: Liver	0.01/0.04	0.06
0.00%	Sheep: Edible offals (other	0.01/0.04	0.03
0.00%	Sheep: Kidney	0.01/0.04	0.00

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Soyabeans / soya drink	0.01/0.15	0.63
0.0%	Soyabeans / boiled	0.01/0.06	0.22

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Acetochlor is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Afidopyropen

LOQs (mg/kg) range from:	0.001	to:	5.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.08	ARfD (mg/kg bw):	0.2
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2019	Year of evaluation:	2019

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
5%	NL toddler	3.77	1%	Milk: Cattle	0.8%	Spinaches	0.3%	Apples	0.5%	4%
3%	SE general	2.55	1.0%	Bovine: Muscle/meat	0.6%	Chinese cabbages/pe-tsai	0.4%	Lettuces	0.2%	3%
3%	NL child	2.15	0.6%	Milk: Cattle	0.3%	Spinaches	0.2%	Swine: Muscle/meat	0.3%	2%
3%	GEMS/Food G10	2.07	0.5%	Chinese cabbages/pe-tsai	0.4%	Lettuces	0.2%	Bovine: Muscle/meat	0.2%	2%
2%	DE child	1.96	0.5%	Milk: Cattle	0.3%	Apples	0.3%	Oranges	0.2%	2%
2%	FR child 3 15 yr	1.78	0.6%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.3%	Swine: Muscle/meat	0.2%	2%
2%	IE adult	1.74	0.6%	Other leafy brassica	0.2%	Rhubarbs	0.1%	Spinaches	0.2%	2%
2%	FR toddler 2 3 yr	1.72	0.7%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.3%	Swine: Muscle/meat	0.2%	2%
2%	ES child	1.70	0.5%	Lettuces	0.3%	Bovine: Muscle/meat	0.3%	Milk: Cattle	0.1%	2%
2%	DK child	1.69	0.5%	Swine: Muscle/meat	0.3%	Cucumbers	0.3%	Milk: Cattle	0.2%	2%
2%	GEMS/Food G11	1.59	0.3%	Swine: Muscle/meat	0.2%	Milk: Cattle	0.2%	Celeries	0.2%	2%
2%	GEMS/Food G07	1.51	0.3%	Lettuces	0.3%	Swine: Muscle/meat	0.2%	Bovine: Muscle/meat	0.2%	2%
2%	GEMS/Food G08	1.51	0.4%	Swine: Muscle/meat	0.2%	Lettuces	0.1%	Milk: Cattle	0.2%	2%
2%	UK infant	1.43	1.0%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.1%	Oranges	0.2%	2%
2%	NL general	1.34	0.2%	Swine: Muscle/meat	0.2%	Milk: Cattle	0.2%	Kales	0.2%	2%
2%	GEMS/Food G06	1.33	0.1%	Tomatoes	0.1%	Cucumbers	0.1%	Lettuces	0.3%	1%
2%	ES adult	1.29	0.6%	Lettuces	0.2%	Bovine: Muscle/meat	0.2%	Swine: Muscle/meat	0.1%	2%
2%	GEMS/Food G15	1.28	0.3%	Swine: Muscle/meat	0.2%	Milk: Cattle	0.1%	Lettuces	0.2%	1%
1%	UK toddler	1.16	0.5%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.1%	Oranges	0.2%	1%
1%	DE general	1.14	0.3%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Lettuces	0.2%	1%
1%	DE women 14-50 yr	1.13	0.3%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Oranges	0.2%	1%
1%	FR infant	1.02	0.4%	Milk: Cattle	0.3%	Spinaches	0.1%	Swine: Muscle/meat	0.1%	1%
1%	RO general	0.93	0.3%	Milk: Cattle	0.3%	Swine: Muscle/meat	0.1%	Tomatoes	0.2%	1%
1%	IT adult	0.92	0.4%	Lettuces	0.1%	Spinaches	0.1%	Other leafy brassica	0.1%	1%
1%	PT general	0.86	0.6%	Kales	0.1%	Lettuces	0.1%	Potatoes	0.2%	0.9%
1%	IT toddler	0.81	0.3%	Lettuces	0.1%	Wheat	0.1%	Chards/beet leaves	0.1%	0.9%
0.9%	DK adult	0.72	0.2%	Swine: Muscle/meat	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	0.8%
0.9%	FR adult	0.71	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat	0.1%	Milk: Cattle	0.1%	0.8%
0.8%	LT adult	0.60	0.2%	Swine: Muscle/meat	0.1%	Milk: Cattle	0.1%	Cucumbers	0.1%	0.7%
0.7%	FI 3 yr	0.56	0.2%	Cucumbers	0.1%	Spinaches	0.1%	Chinese cabbages/pe-tsai	0.2%	0.6%
0.6%	FI 6 yr	0.51	0.2%	Cucumbers	0.1%	Chinese cabbages/pe-tsai	0.1%	Lettuces	0.1%	0.6%
0.6%	UK adult	0.50	0.1%	Bovine: Muscle/meat	0.1%	Lettuces	0.1%	Milk: Cattle	0.1%	0.6%
0.6%	UK vegetarian	0.50	0.2%	Lettuces	0.1%	Milk: Cattle	0.1%	Oranges	0.1%	0.5%
0.5%	FI adult	0.43	0.2%	Lettuces	0.1%	Cucumbers	0.1%	Coffee beans	0.1%	0.4%
0.3%	PL general	0.27	0.1%	Chinese cabbages/pe-tsai	0.1%	Apples	0.0%	Potatoes	0.1%	0.3%
0.3%	IE child	0.22	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Swine: Fat tissue	0.0%	0.2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Afidopyropen is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
106%	Kales	5/4.8	211	61%	Chinese cabbages/pe-tsai	5/4.8	122
77%	Chinese cabbages/pe-tsai	5/4.8	154	46%	Kales	5/4.8	92
52%	Escaroles/broad-leaved endives	2/2.6	104	26%	Escaroles/broad-leaved	2/2.6	52
49%	Lettuces	2/2.6	99	25%	Chards/beet leaves	2/2.6	49
41%	Celeries	3/2.2	82	21%	Florence fennels	3/2.2	41
41%	Rhubarbs	3/2.2	82	18%	Celeries	3/2.2	35
29%	Spinaches	2/2.6	59	16%	Lettuces	2/2.6	32
20%	Chards/beet leaves	2/2.6	41	13%	Red mustards	5/4.8	25
20%	Cucumbers	0.7/0.6	39	11%	Cardoons	3/2.2	23
18%	Florence fennels	3/2.2	36	10%	Rhubarbs	3/2.2	20
10%	Cauliflowers	0.4/0.34	20	8%	Cucumbers	0.7/0.6	17
7%	Broccoli	0.4/0.34	14	5%	Spinaches	2/2.6	10
6%	Roman rocket/rucola	5/4.8	13	4%	Broccoli	0.4/0.34	8.1
6%	Oranges	0.15/0.09	11	4%	Cauliflowers	0.4/0.34	7.9
4%	Lamb's lettuce/corn salads	2/2.6	7.3	3%	Parsley	5/4.8	5.7

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
86%	Escaroles/broad-leaved endives/boiled	2/2.6	172	37%	Celeries/boiled	3/2.2	74
66%	Kales/boiled	5/4.8	132	27%	Escaroles/broad-leaved	2/2.6	53
50%	Florence fennels/boiled	3/2.2	100	21%	Florence fennels/boiled	3/2.2	43
41%	Rhubarbs/sauce/puree	3/2.2	82	16%	Chards/beet leaves/boiled	2/2.6	33
40%	Chards/beet leaves/boiled	2/2.6	81	16%	Rhubarbs/sauce/puree	3/2.2	32
18%	Spinaches/frozen; boiled	2/2.6	36	13%	Cardoons/boiled	3/2.2	27
13%	Broccoli/boiled	0.4/0.34	27	11%	Spinaches/frozen; boiled	2/2.6	22
12%	Cauliflowers/boiled	0.4/0.34	24	7%	Cauliflowers/boiled	0.4/0.34	14
2%	Pumpkins/boiled	0.05/0.05	4.3	5%	Purslanes/boiled	2/2.6	11
1%	Oranges/juice	0.15/0.05	2.8	4%	Broccoli/boiled	0.4/0.34	8.2
0.9%	Courgettes/boiled	0.07/0.05	1.8	1%	Pumpkins/boiled	0.05/0.05	2.7
0.6%	Apples/juice	0.03/0.02	1.1	0.6%	Courgettes/boiled	0.07/0.05	1.1
0.5%	Potatoes/fried	0.01/0.01	0.93	0.4%	Oranges/juice	0.15/0.05	0.81
0.3%	Pears/juice	0.03/0.02	0.68	0.3%	Apples/juice	0.03/0.02	0.70
0.3%	Potatoes/dried (flakes)	0.01/0.05	0.59	0.3%	Grapefruits/juice	0.15/0.05	0.58

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw per day):	0.2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
22%	NL toddler	43.33	5%	Oranges	5%	Potatoes	4%	Sugar beet roots		22%
19%	DE child	38.93	10%	Oranges	3%	Potatoes	1%	Mandarins		19%
19%	NL child	37.29	6%	Sugar beet roots	4%	Potatoes	3%	Oranges		19%
16%	FR child 3 15 yr	31.21	8%	Oranges	2%	Sugar beet roots	2%	Potatoes		16%
13%	UK toddler	26.98	5%	Oranges	4%	Potatoes	2%	Sugar beet roots		13%
13%	IE adult	25.32	3%	Potatoes	2%	Oranges	2%	Grapefruits		13%
13%	GEMS/Food G07	25.24	4%	Potatoes	3%	Oranges	0.5%	Wine grapes		13%
12%	GEMS/Food G06	24.92	2%	Oranges	2%	Potatoes	1%	Sugar beet roots		12%
12%	FR toddler 2 3 yr	24.69	3%	Oranges	2%	Potatoes	2%	Sugar beet roots		12%
12%	DE women 14-50 yr	24.36	5%	Oranges	3%	Sugar beet roots	1%	Potatoes		12%
12%	GEMS/Food G11	23.69	4%	Potatoes	2%	Oranges	0.9%	Lemons		12%
12%	SE general	23.46	5%	Potatoes	2%	Oranges	1%	Mandarins		12%
12%	GEMS/Food G10	23.35	3%	Potatoes	3%	Oranges	0.6%	Onions		12%
11%	GEMS/Food G08	22.20	4%	Potatoes	1%	Oranges	0.6%	Lemons		11%
11%	DE general	22.06	4%	Oranges	3%	Sugar beet roots	1%	Potatoes		11%
11%	PT general	21.63	6%	Potatoes	1%	Oranges	0.9%	Wine grapes		11%
11%	GEMS/Food G15	21.15	4%	Potatoes	2%	Oranges	0.6%	Onions		11%
10%	ES child	20.60	5%	Oranges	2%	Potatoes	0.7%	Lettuces		10%
10%	NL general	20.38	3%	Potatoes	2%	Oranges	2%	Sugar beet roots		10%
10%	RO general	20.34	4%	Potatoes	0.9%	Sugar beet roots	0.9%	Head cabbages		10%
10%	UK infant	19.69	4%	Potatoes	3%	Oranges	1.0%	Sugar beet roots		10%
9%	FI 3 yr	17.89	5%	Potatoes	1.0%	Mandarins	0.4%	Onions		9%
7%	FI 6 yr	14.79	4%	Potatoes	0.8%	Mandarins	0.4%	Oranges		7%
7%	ES adult	14.37	3%	Oranges	1%	Potatoes	0.9%	Lettuces		7%
6%	FR infant	12.91	2%	Potatoes	0.9%	Sugar beet roots	0.6%	Oranges		6%
6%	UK vegetarian	12.48	2%	Oranges	2%	Potatoes	0.4%	Sugar beet roots		6%
6%	PL general	11.41	4%	Potatoes	0.4%	Onions	0.2%	Head cabbages		6%
6%	DK child	11.20	3%	Potatoes	0.4%	Oranges	0.3%	Onions		6%
5%	FR adult	10.75	1%	Oranges	0.8%	Potatoes	0.8%	Wine grapes		5%
5%	UK adult	10.29	2%	Potatoes	1%	Oranges	0.4%	Wine grapes		5%
5%	IT toddler	10.20	1%	Oranges	1%	Potatoes	0.5%	Mandarins		5%
5%	LT adult	9.40	4%	Potatoes	0.2%	Head cabbages	0.2%	Oranges		5%
5%	IT adult	9.09	0.9%	Oranges	0.7%	Potatoes	0.6%	Lettuces		5%
4%	FI adult	7.78	1%	Potatoes	1.0%	Oranges	0.3%	Mandarins		4%
4%	DK adult	7.16	1%	Potatoes	0.3%	Wine grapes	0.3%	Oranges		4%
1%	IE child	2.86	0.7%	Potatoes	0.2%	Oranges	0.1%	Rice		1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of azoxystrobin is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Benzovindiflupyr

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.05	ARfD (mg/kg bw):	0.1
Source of ADI:	European	Source of ARfD:	European Commision
Year of evaluation:	2015	Year of evaluation:	2015

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
5%	NL toddler	2.58	2%	Milk: Cattle	1%	Apples	0.5%	Pears		5%
3%	DE child	1.55	1%	Apples	0.8%	Milk: Cattle	0.2%	Tomatoes		3%
2%	NL child	1.21	1.0%	Milk: Cattle	0.7%	Apples	0.2%	Wheat		2%
2%	UK infant	1.13	2%	Milk: Cattle	0.2%	Apples	0.1%	Wheat		2%
2%	FR toddler 2 3 yr	1.03	1%	Milk: Cattle	0.4%	Apples	0.1%	Wheat		2%
2%	FR child 3 15 yr	0.93	0.9%	Milk: Cattle	0.2%	Apples	0.2%	Wheat		2%
2%	GEMS/Food G06	0.92	0.6%	Tomatoes	0.3%	Wheat	0.2%	Sugar canes		2%
2%	GEMS/Food G11	0.92	0.3%	Milk: Cattle	0.3%	Barley	0.3%	Sugar canes		2%
2%	GEMS/Food G15	0.92	0.3%	Barley	0.3%	Milk: Cattle	0.2%	Tomatoes		2%
2%	GEMS/Food G08	0.91	0.3%	Barley	0.2%	Milk: Cattle	0.2%	Sugar canes		2%
2%	DK child	0.89	0.5%	Milk: Cattle	0.3%	Apples	0.2%	Wheat		2%
2%	GEMS/Food G07	0.86	0.3%	Milk: Cattle	0.2%	Barley	0.2%	Sugar canes		2%
2%	RO general	0.83	0.5%	Milk: Cattle	0.3%	Tomatoes	0.2%	Wheat		2%
2%	GEMS/Food G10	0.80	0.2%	Tomatoes	0.2%	Barley	0.2%	Milk: Cattle		2%
2%	UK toddler	0.78	0.8%	Milk: Cattle	0.2%	Apples	0.2%	Wheat		2%
1%	DE general	0.74	0.5%	Milk: Cattle	0.3%	Apples	0.2%	Barley		1%
1%	DE women 14-50 yr	0.70	0.5%	Milk: Cattle	0.3%	Apples	0.1%	Tomatoes		1%
1%	ES child	0.67	0.5%	Milk: Cattle	0.2%	Wheat	0.2%	Tomatoes		1%
1%	SE general	0.66	0.5%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.1%	Tomatoes		1%
1%	NL general	0.53	0.3%	Milk: Cattle	0.2%	Apples	0.1%	Barley		1%
1%	FR infant	0.53	0.7%	Milk: Cattle	0.2%	Apples	0.0%	Potatoes		1%
1.0%	IE adult	0.49	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Apples		1.0%
1.0%	ES adult	0.48	0.2%	Milk: Cattle	0.2%	Barley	0.1%	Tomatoes		1.0%
0.8%	PT general	0.42	0.2%	Tomatoes	0.2%	Wheat	0.1%	Wine grapes		0.8%
0.8%	LT adult	0.40	0.2%	Apples	0.2%	Milk: Cattle	0.1%	Tomatoes		0.8%
0.8%	FR adult	0.38	0.2%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat		0.8%
0.7%	IT toddler	0.37	0.3%	Wheat	0.3%	Tomatoes	0.1%	Apples		0.7%
0.7%	DK adult	0.36	0.2%	Milk: Cattle	0.1%	Apples	0.1%	Tomatoes		0.7%
0.7%	FI 3 yr	0.36	0.2%	Oat	0.1%	Apples	0.1%	Tomatoes		0.7%
0.6%	UK vegetarian	0.28	0.1%	Milk: Cattle	0.1%	Tomatoes	0.1%	Wheat		0.6%
0.6%	IT adult	0.28	0.2%	Tomatoes	0.2%	Wheat	0.1%	Apples		0.6%
0.5%	PL general	0.27	0.2%	Apples	0.2%	Tomatoes	0.1%	Potatoes		0.5%
0.5%	FI 6 yr	0.26	0.1%	Oat	0.1%	Potatoes	0.1%	Tomatoes		0.5%
0.5%	UK adult	0.25	0.1%	Milk: Cattle	0.1%	Tomatoes	0.1%	Wheat		0.5%
0.5%	FI adult	0.25	0.2%	Coffee beans	0.1%	Tomatoes	0.1%	Apples		0.5%
0.3%	IE child	0.15	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Apples		0.3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Benzovindiflupyr is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
59%	Table grapes	1/0.81	59
36%	Tomatoes	0.9/0.62	36
24%	Pears	0.2/0.17	24
18%	Apples	0.2/0.17	18
16%	Aubergines/egg plants	0.9/0.62	16
10%	Cucumbers	0.08/0.16	10
8%	Kaki/Japanese persimmons	0.2/0.17	7.9
8%	Wine grapes	1/0.81	7.5
7%	Courgettes	0.08/0.16	7.4
4%	Quinces	0.2/0.17	4.2
4%	Sweet peppers/bell peppers	1/0.06	3.7
3%	Potatoes	0.02/0.02	3.1
2%	Milk: Cattle	0.01/0.02	2.5
2%	Medlar	0.2/0.17	2.4
1%	Barley	1.5/0.19	1.1
1%	Bovine: Liver	0.1/0.13	1.0
0.9%	Bovine: Edible offals (other than liver and kidney)	0.1/0.13	0.93
0.6%	Yams	0.02/0.02	0.62
0.5%	Milk: Goat	0.01/0.02	0.48
0.5%	Bovine: Kidney	0.1/0.13	0.48
0.4%	Gherkins	0.08/0.16	0.45
0.4%	Sweet corn	0.01/0.01	0.43
0.4%	Swine: Edible offals (other than liver and kidney)	0.1/0.13	0.38
0.3%	Onions	0.02/0.02	0.34
0.3%	Poultry: Muscle/meat	0.01/0.02	0.34
0.3%	Wheat	0.1/0.02	0.29
0.2%	Eggs: Chicken	0.01/0.02	0.25
0.2%	Swine: Muscle/meat	0.01/0.02	0.24
0.2%	Oat	1.5/0.19	0.21
0.2%	Beans	0.2/0.01	0.20
0.2%	Swine: Kidney	0.1/0.13	0.16
0.2%	Cassava roots/manioc	0.02/0.02	0.16
0.2%	Swine: Liver	0.1/0.13	0.16
0.1%	Bovine: Muscle/meat	0.01/0.02	0.14
0.1%	Other farmed animals: Muscle/meat	0.01/0.02	0.14
0.1%	Equine: Muscle/meat	0.01/0.02	0.12
0.1%	Sheep: Muscle/meat	0.01/0.02	0.11
0.1%	Sweet potatoes	0.02/0.02	0.11
0.08%	Bovine: Fat tissue	0.03/0.04	0.08
0.07%	Lentils	0.2/0.01	0.07
0.07%	Peas	0.2/0.01	0.07
0.07%	Milk: Sheep	0.01/0.02	0.07
0.07%	Maize/corn	0.02/0.01	0.07
0.06%	Swine: Fat tissue	0.03/0.04	0.06
0.06%	Rye	0.1/0.01	0.06
0.05%	Garlic	0.02/0.02	0.05
0.05%	Sugar canes	0.4/0.25	0.05
0.03%	Rapeseeds/canola seeds	0.2/0.02	0.03
0.03%	Peanuts/groundnuts	0.04/0.01	0.03
0.02%	Soyabeans	0.08/0.01	0.02
0.02%	Poultry: Liver	0.01/0.02	0.02
0.02%	Linseeds	0.15/0.02	0.02
0.02%	Mustard seeds	0.15/0.02	0.02
0.01%	Ginger	0.15/0.15	0.01
0.01%	Coffee beans	0.15/0.02	0.01
0.005%	Shallots	0.02/0.02	0.00
0.00%	Turmeric/curcuma	0.15/0.15	0.00
0.00%	Poultry: Fat tissue	0.01/0.02	0.00

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
27%	Table grapes	1/0.81	27
19%	Wine grapes	1/0.81	19
17%	Aubergines/egg plants	0.9/0.62	17
10%	Tomatoes	0.9/0.62	9.8
5%	Pears	0.2/0.17	5.2
5%	Apples	0.2/0.17	4.8
4%	Cucumbers	0.08/0.16	4.4
4%	Kaki/Japanese persimmons	0.2/0.17	3.7
4%	Courgettes	0.08/0.16	3.7
3%	Quinces	0.2/0.17	2.6
1%	Medlar	0.2/0.17	1.2
1%	Sweet peppers/bell peppers	1/0.06	1.0
1.0%	Gherkins	0.08/0.16	0.97
0.9%	Barley	1.5/0.19	0.92
0.8%	Milk: Cattle	0.01/0.02	0.77
0.6%	Potatoes	0.02/0.02	0.60
0.6%	Yams	0.02/0.02	0.57
0.5%	Bovine: Liver	0.1/0.13	0.51
0.4%	Bovine: Edible offals (other than liver and kidney)	0.1/0.13	0.42
0.4%	Sweet potatoes	0.02/0.02	0.42
0.4%	Milk: Goat	0.01/0.02	0.37
0.4%	Sheep: Liver	0.1/0.13	0.36
0.3%	Swine: Edible offals (other than liver and kidney)	0.1/0.13	0.33
0.3%	Milk: Sheep	0.01/0.02	0.30
0.3%	Swine: Kidney	0.1/0.13	0.28
0.3%	Bovine: Kidney	0.1/0.13	0.27
0.2%	Poultry: Muscle	0.01/0.02	0.23
0.2%	Onions	0.02/0.02	0.22
0.2%	Jerusalem artichokes	0.02/0.02	0.19
0.2%	Swine: Liver	0.1/0.13	0.18
0.2%	Wheat	0.1/0.02	0.17
0.2%	Sweet corn	0.01/0.01	0.16
0.1%	Oat	1.5/0.19	0.12
0.1%	Bovine: Muscle	0.01/0.02	0.11
0.1%	Other farmed animals: Muscle/meat	0.01/0.02	0.11
0.10%	Swine: Muscle/meat	0.01/0.02	0.10
0.10%	Equine: Muscle/meat	0.01/0.02	0.10
0.09%	Sheep: Muscle/meat	0.01/0.02	0.09
0.09%	Poultry: Liver	0.01/0.02	0.09
0.09%	Sheep: Edible offals (other than liver and kidney)	0.1/0.13	0.09
0.09%	Eggs: Chicken	0.01/0.02	0.09
0.08%	Swine: Fat tissue	0.03/0.04	0.08
0.07%	Beans	0.2/0.01	0.07
0.07%	Lentils	0.2/0.01	0.07
0.07%	Swine: Other products	0.01/0.02	0.07
0.06%	Cassava roots/manioc	0.02/0.02	0.06
0.06%	Soyabeans	0.08/0.01	0.06
0.05%	Rye	0.1/0.01	0.05
0.04%	Bovine: Other products	0.01/0.02	0.04
0.04%	Shallots	0.02/0.02	0.04
0.04%	Bovine: Fat tissue	0.03/0.04	0.04
0.04%	Peas	0.2/0.01	0.04
0.03%	Goat: Muscle	0.01/0.02	0.03
0.03%	Eggs: Quail	0.01/0.02	0.03
0.03%	Poultry: Kidney	0.01/0.02	0.03
0.02%	Peanuts/groundnuts	0.04/0.01	0.02
0.02%	Maize/corn	0.02/0.01	0.02
0.02%	Turmeric/curcuma	0.15/0.15	0.02
0.01%	Poppy seeds	0.15/0.02	0.01
0.01%	Poppy seeds	0.15/0.02	0.01
0.01%	Sheep: Kidney	0.1/0.13	0.01
0.01%	Rapeseeds/canola seeds	0.2/0.02	0.01
0.01%	Coffee beans	0.15/0.02	0.01
0.01%	Eggs: Goose	0.01/0.02	0.01
0.01%	Garlic	0.02/0.02	0.01
0.01%	Linseeds	0.15/0.02	0.01
0.01%	Poultry: Fat tissue	0.01/0.02	0.01

Expand/collapse list	
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)	

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Courgettes/boiled	0.08/0.16	5.7
4%	Gherkins/pickled	0.08/0.16	3.7
3%	Apples/juice	0.2/0.06	3.1
2%	Pears/juice	0.2/0.06	1.9
2%	Potatoes/fried	0.02/0.02	1.9
2%	Tomatoes/juice	0.9/0.09	1.7
2%	Lentils/boiled	0.2/0.2	1.6
1%	Peas/canned	0.2/0.08	1.4
1%	Wine grapes/juice	1/0.03	1.3
1%	Sweet potatoes/boiled	0.02/0.02	1.0
0.8%	Tomatoes/sauce/puree	0.9/0.09	0.85
0.7%	Oat/boiled	1.5/0.19	0.69
0.7%	Barley/cooked	1.5/0.19	0.69
0.6%	Potatoes/dried (flakes)	0.02/0.05	0.59
0.6%	Oat/milling (flakes)	1.5/0.19	0.57
0.5%	Jerusalem artichokes/boiled	0.02/0.02	0.51
0.3%	Barley/milling (flour)	1.5/0.19	0.34
0.2%	Shallots/boiled	0.02/0.02	0.24
0.2%	Wheat/milling (flour)	0.1/0.02	0.24
0.2%	Maize/oil	0.02/0.25	0.23
0.2%	Ginger/jam	0.15/0.08	0.23
0.2%	Quinces/jam	0.2/0.06	0.18
0.1%	Wheat/milling (wholemeal)-baking	0.1/0.02	0.11
0.0%	Soyabeans/soya drink	0.08/0.01	0.04
0.0%	Rye/boiled	0.1/0.01	0.04
0.0%	Peanuts/peanut butter	0.04/0.01	0.04
0.0%	Rye/milling (wholemeal)-baking	0.1/0.01	0.04
0.0%	Coffee beans/extraction	0.15/0	0.03
0.03%	Sugar canes/sugar	0.4/0	0.03
0.0%	Maize/processed (not specified)	0.02/0.01	0.02
0.0%	Soyabeans/boiled	0.08/0	0.01
0.0%	Rapeseeds/oils	0.2/0.05	0.01
0.0%	Arrowroots/starch	0.02/0.01	0.01

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wine grapes/wine	1/0.81	7.7
5%	Table grapes/raisins	1/3.81	4.7
4%	Courgettes/boiled	0.08/0.16	3.7
2%	Apples/juice	0.2/0.06	1.9
1%	Beans/canned	0.2/0.2	1.4
1%	Barley/beer	1.5/0.04	1.4
0.7%	Tomatoes/sauce/puree	0.9/0.09	0.73
0.6%	Wine grapes/juice	1/0.03	0.60
0.5%	Peas/canned	0.2/0.08	0.53
0.4%	Cassava roots/boiled	0.02/0.02	0.38
0.3%	Sweet potatoes/boiled	0.02/0.02	0.31
0.3%	Oat/boiled	1.5/0.19	0.29
0.2%	Jerusalem artichokes/boiled	0.02/0.02	0.16
0.1%	Onions/boiled	0.02/0.02	0.14
0.1%	Maize/oil	0.02/0.25	0.13
0.1%	Okra, lady's fingers/boiled	1/0.06	0.10
0.09%	Ginger/jam	0.15/0.08	0.09
0.09%	Shallots/boiled	0.02/0.02	0.09
0.09%	Wheat/bread/pizza	0.1/0.02	0.09
0.08%	Potatoes/chips	0.02/0.01	0.08
0.08%	Wheat/pasta	0.1/0.02	0.08
0.07%	Quinces/jam	0.2/0.06	0.07
0.07%	Coffee beans/extraction	0.15/0	0.07
0.07%	Wheat/bread (wholemeal)	0.1/0.02	0.07
0.06%	Potatoes/dried (flakes)	0.02/0.05	0.06
0.02%	Sugar canes/sugar	0.4/0	0.02
0.003%	Arrowroots/starch	0.02/0.01	0.00
0.002%	Turmeric (Curcuma)/boiled	0.15/0.15	0.00

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Benzovindiflupyr is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Bifenthrin (F)

LOQs (mg/kg) range from:	0.01	to:	30.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.015	ARfD (mg/kg bw):	0.03
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute riskt assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
41%	NL toddler	6.12	21%	Milk: Cattle	7%	Wheat	2%	Maize/corn		41%
26%	UK infant	3.90	14%	Milk: Cattle	4%	Wheat	2%	Tea (dried leaves of Camellia sinensi		26%
25%	FR child 3 15 yr	3.76	8%	Milk: Cattle	8%	Wheat	2%	Bovine: Muscle/meat		25%
24%	NL child	3.64	9%	Milk: Cattle	7%	Wheat	1%	Swine: Muscle/meat		24%
22%	DE child	3.33	7%	Wheat	7%	Milk: Cattle	2%	Strawberries		22%
22%	FR toddler 2 3 yr	3.30	10%	Milk: Cattle	5%	Wheat	1%	Bovine: Muscle/meat		22%
21%	GEMS/Food G06	3.19	12%	Wheat	2%	Tea (dried leaves of Camellia sinensis)	1%	Tomatoes		21%
21%	UK toddler	3.15	7%	Milk: Cattle	7%	Wheat	1%	Bovine: Muscle/meat		21%
20%	GEMS/Food G15	3.04	8%	Wheat	2%	Milk: Cattle	2%	Swine: Muscle/meat		20%
20%	GEMS/Food G07	3.01	7%	Wheat	2%	Milk: Cattle	2%	Tea (dried leaves of Camellia sinensi		20%
20%	RO general	2.99	8%	Wheat	4%	Milk: Cattle	1%	Swine: Muscle/meat		20%
20%	GEMS/Food G11	2.94	6%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat		20%
19%	GEMS/Food G08	2.90	7%	Wheat	2%	Swine: Muscle/meat	2%	Milk: Cattle		19%
19%	SE general	2.89	5%	Wheat	5%	Bovine: Muscle/meat	4%	Milk: Cattle		19%
19%	DK child	2.83	7%	Wheat	4%	Milk: Cattle	3%	Swine: Muscle/meat		19%
19%	ES child	2.79	7%	Wheat	4%	Milk: Cattle	2%	Bovine: Muscle/meat		19%
18%	GEMS/Food G10	2.74	7%	Wheat	2%	Milk: Cattle	1%	Soyabeans		18%
18%	IE adult	2.65	5%	Tea (dried leaves of Camellia sinensis)	4%	Wheat	2%	Milk: Cattle		18%
15%	FR adult	2.18	5%	Tea (dried leaves of Camellia sinensis)	4%	Wheat	2%	Milk: Cattle		15%
14%	DE women 14-50 yr	2.10	4%	Milk: Cattle	4%	Wheat	1%	Tea (dried leaves of Camellia sinensi		14%
14%	DE general	2.08	4%	Milk: Cattle	3%	Wheat	1%	Swine: Muscle/meat		14%
13%	IT toddler	1.94	11%	Wheat	0.6%	Tomatoes	0.4%	Strawberries		13%
13%	NL general	1.91	3%	Wheat	3%	Milk: Cattle	1%	Tea (dried leaves of Camellia sinensi		13%
11%	PT general	1.65	7%	Wheat	2%	Potatoes	1.0%	Wine grapes		11%
10%	FR infant	1.57	6%	Milk: Cattle	1%	Wheat	0.6%	Potatoes		10%
10%	ES adult	1.50	4%	Wheat	2%	Milk: Cattle	0.9%	Bovine: Muscle/meat		10%
9%	DK adult	1.33	2%	Wheat	2%	Milk: Cattle	1%	Swine: Muscle/meat		9%
9%	UK adult	1.32	3%	Wheat	2%	Tea (dried leaves of Camellia sinensis)	1%	Milk: Cattle		9%
9%	UK vegetarian	1.32	3%	Wheat	2%	Tea (dried leaves of Camellia sinensis)	1%	Milk: Cattle		9%
8%	IT adult	1.24	7%	Wheat	0.5%	Tomatoes	0.2%	Potatoes		8%
7%	LT adult	1.08	2%	Wheat	1%	Milk: Cattle	1%	Swine: Muscle/meat		7%
6%	FI 3 yr	0.95	2%	Wheat	2%	Potatoes	1%	Strawberries		6%
5%	FI 6 yr	0.76	2%	Wheat	1%	Potatoes	0.9%	Strawberries		5%
5%	IE child	0.71	2%	Wheat	1%	Milk: Cattle	0.5%	Swine: Fat tissue		5%
2%	PL general	0.37	1%	Potatoes	0.4%	Tomatoes	0.3%	Head cabbages		2%
2%	FI adult	0.36	0.5%	Wheat	0.4%	Strawberries	0.4%	Potatoes		2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Bifenthrin (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
125%	Strawberries	3/2.3	38	72%	Strawberries	3/2.3	21
61%	Sweet peppers/bell peppers	0.5/0.31	18	49%	Blueberries	3/1.6	15
37%	Cauliflowers	0.4/0.19	11	27%	Head cabbages	0.4/0.19	8.0
34%	Table grapes	0.3/0.14	10	17%	Sweet peppers/bell peppers	0.5/0.31	5.1
33%	Kohlrabies	0.4/0.19	9.9	16%	Table grapes	0.3/0.14	4.7
32%	Blueberries	3/1.6	9.5	15%	Broccoli	0.4/0.19	4.5
29%	Tomatoes	0.3/0.15	8.7	15%	Cauliflowers	0.4/0.19	4.4
28%	Head cabbages	0.4/0.19	8.4	14%	Blackberries	1/0.51	4.2
27%	Tea (dried leaves of Camellia sinensis)	30/5.2	8.0	13%	Swine: Fat tissue	3/1.9	3.9
26%	Broccoli	0.4/0.19	7.9	11%	Wine grapes	0.3/0.14	3.3
26%	Potatoes	0.05/0.05	7.7	9%	Raspberries (red and yellow)	1/0.51	2.8
22%	Oranges	0.05/0.05	6.6	9%	Aubergines/egg plants	0.3/0.1	2.7
22%	Milk: Cattle	0.2/0.05	6.6	9%	Kohlrabies	0.4/0.19	2.7
19%	Swine: Muscle/meat	0.2/0.46	5.6	9%	Bovine: Muscle	0.2/0.46	2.6
18%	Blackberries	1/0.51	5.5	9%	Tea (dried leaves of Camellia sinensis)	30/5.2	2.6

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
50%	Broccoli/boiled	0.4/0.19	15	26%	Cauliflowers/boiled	0.4/0.19	7.9
44%	Cauliflowers/boiled	0.4/0.19	13	15%	Broccoli/boiled	0.4/0.19	4.6
16%	Potatoes/fried	0.05/0.05	4.7	13%	Kohlrabies/boiled	0.4/0.19	4.0
11%	Raspberries/juice	1/0.29	3.4	6%	Beetroots/boiled	0.05/0.05	1.9
10%	Wheat/milling (flour)	0.5/0.25	3.0	6%	Peas (with pods)/boiled	0.9/0.5	1.7
10%	Potatoes/dried (flakes)	0.05/0.23	3.0	4%	Wine grapes/wine	0.3/0.14	1.3
9%	Oranges/juice	0.05/0.05	2.6	4%	Wine grapes/juice	0.3/0.06	1.2
9%	Wine grapes/juice	0.3/0.06	2.6	4%	Head cabbages/canned	0.4/0.12	1.1
8%	Turnips/boiled	0.05/0.05	2.5	4%	Wheat/bread/pizza	0.5/0.25	1.1
8%	Parsnips/boiled	0.05/0.05	2.5	4%	Parsnips/boiled	0.05/0.05	1.1
8%	Sweet potatoes/boiled	0.05/0.05	2.5	4%	Tea (dried leaves of Camellia sinensis)/	30/0.05	1.1
7%	Beetroots/boiled	0.05/0.05	2.2	3%	Turnips/boiled	0.05/0.05	0.95
6%	Brussels sprouts/boiled	0.4/0.19	1.9	3%	Wheat/pasta	0.5/0.25	0.95
6%	Tea (dried leaves of Camellia sinensis)/infusion	30/0.05	1.8	3%	Cassava roots/boiled	0.05/0.05	0.95
6%	Carrots/juice	0.05/0.05	1.8	3%	Celeriacs/boiled	0.05/0.05	0.91

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
75%	NL toddler	30.17	11%	Apples	10%	Spinaches	6%	Witloofs/Belgian endives		75%
50%	DE child	20.03	13%	Apples	5%	Table grapes	3%	Spinaches		50%
40%	NL child	15.98	6%	Apples	4%	Table grapes	4%	Spinaches		40%
37%	IE adult	14.78	4%	Wine grapes	3%	Sweet potatoes	2%	Tea (dried leaves of Camellia sinensi		37%
36%	GEMS/Food G08	14.40	4%	Wine grapes	3%	Potatoes	3%	Onions		36%
35%	GEMS/Food G06	14.19	4%	Onions	4%	Table grapes	4%	Tomatoes		35%
35%	GEMS/Food G10	13.95	5%	Lettuces	3%	Onions	2%	Potatoes		35%
34%	GEMS/Food G07	13.79	5%	Wine grapes	3%	Lettuces	3%	Potatoes		34%
33%	GEMS/Food G11	13.21	4%	Wine grapes	3%	Potatoes	2%	Barley		33%
33%	GEMS/Food G15	13.20	4%	Wine grapes	3%	Onions	3%	Potatoes		33%
30%	SE general	12.00	6%	Lettuces	3%	Potatoes	2%	Onions		30%
29%	RO general	11.73	6%	Wine grapes	4%	Onions	4%	Head cabbages		29%
27%	FR child 3 15 yr	10.74	2%	Wheat	2%	Apples	2%	Other lettuce and other salad plants		27%
27%	PT general	10.71	9%	Wine grapes	4%	Potatoes	2%	Onions		27%
26%	NL general	10.41	3%	Witloofs/Belgian endives	2%	Spinaches	2%	Wine grapes		26%
25%	FR adult	10.20	8%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	2%	Other lettuce and other salad plants		25%
24%	FR toddler 2 3 yr	9.70	3%	Apples	2%	Spinaches	2%	Leeks		24%
23%	DK child	9.26	3%	Cucumbers	2%	Apples	2%	Rye		23%
23%	DE women 14-50 yr	9.08	3%	Wine grapes	3%	Apples	2%	Lettuces		23%
23%	DE general	9.06	3%	Wine grapes	3%	Apples	1%	Barley		23%
22%	FI 3 yr	8.64	4%	Potatoes	2%	Onions	2%	Cucumbers		22%
21%	IT adult	8.46	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		21%
21%	ES adult	8.44	7%	Lettuces	1%	Wine grapes	1%	Barley		21%
20%	IT toddler	8.08	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plants		20%
20%	ES child	8.03	6%	Lettuces	2%	Wheat	1%	Potatoes		20%
19%	UK toddler	7.56	3%	Potatoes	2%	Apples	2%	Wheat		19%
19%	UK infant	7.44	2%	Potatoes	2%	Milk: Cattle	2%	Apples		19%
18%	FR infant	7.25	4%	Spinaches	2%	Apples	2%	Leeks		18%
17%	FI 6 yr	6.71	3%	Potatoes	2%	Onions	1%	Strawberries		17%
16%	UK vegetarian	6.27	3%	Wine grapes	2%	Lettuces	1%	Onions		16%
14%	PL general	5.57	3%	Potatoes	2%	Apples	2%	Onions		14%
14%	UK adult	5.56	4%	Wine grapes	2%	Lettuces	1%	Potatoes		14%
13%	DK adult	5.38	3%	Wine grapes	1%	Lettuces	1%	Apples		13%
12%	FI adult	4.64	2%	Lettuces	1%	Wine grapes	0.9%	Potatoes		12%
11%	LT adult	4.28	2%	Potatoes	2%	Apples	1%	Head cabbages		11%
4%	IE child	1.57	0.5%	Wheat	0.5%	Potatoes	0.3%	Apples		4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Boscalid is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Buprofezin (F)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
13%	NL toddler	1.26	6%	Milk: Cattle	1%	Apples	0.7%	Maize/corn	12%	0.3%
7%	NL child	0.68	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples	7%	0.3%
6%	DE child	0.65	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	6%	0.1%
6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	6%	
6%	FR toddler 2 3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat	6%	0.0%
6%	FR child 3 15 yr	0.56	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots	6%	0.1%
4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes	4%	0.0%
4%	GEMS/Food G11	0.43	0.8%	Milk: Cattle	0.4%	Potatoes	0.4%	Soyabeans	4%	0.1%
4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat	4%	0.0%
4%	GEMS/Food G07	0.39	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes	4%	0.1%
4%	GEMS/Food G06	0.39	0.7%	Wheat	0.4%	Tomatoes	0.2%	Milk: Cattle	4%	0.1%
4%	GEMS/Food G08	0.39	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes	4%	0.1%
4%	GEMS/Food G15	0.39	0.7%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	0.1%
4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	4%	0.0%
4%	ES child	0.38	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans	4%	0.0%
4%	GEMS/Food G10	0.38	0.5%	Milk: Cattle	0.4%	Wheat	0.3%	Soyabeans	4%	0.1%
4%	DE women 14-50 yr	0.38	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples	4%	0.0%
4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes	4%	
4%	DE general	0.37	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples	4%	0.0%
4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye	4%	0.0%
3%	IE adult	0.35	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat	3%	0.2%
3%	NL general	0.31	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes	3%	0.2%
3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples	3%	0.0%
2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat	2%	0.0%
2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes	2%	
2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	2%	0.0%
2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat	2%	0.0%
2%	IT toddler	0.17	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes	2%	0.0%
2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	0.0%
2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples	2%	0.0%
1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.0%
1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat	1%	0.0%
1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	0.0%
1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples	1%	0.0%
1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes	1.0%	0.0%
0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.8%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Buprofezin (F) is unlikely to present a public health concern.

Acute risk assessment /children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Coconuts	0.01/0.05	0.72	0.09%	Coconuts	0.01/0.05	0.43
0.06%	Pistachios	0.01/0.05	0.29	0.05%	Chestnuts	0.01/0.05	0.23
0.04%	Chestnuts	0.01/0.05	0.21	0.03%	Pistachios	0.01/0.05	0.13
0.03%	Walnuts	0.01/0.05	0.17	0.02%	Pecans	0.01/0.05	0.11
0.03%	Hazelnuts/cobnuts	0.01/0.05	0.16	0.02%	Walnuts	0.01/0.05	0.11
0.03%	Almonds	0.01/0.05	0.14	0.02%	Macadamia	0.01/0.05	0.11
0.03%	Pecans	0.01/0.05	0.14	0.02%	Cashew nuts	0.01/0.05	0.09
0.03%	Cashew nuts	0.01/0.05	0.13	0.01%	Almonds	0.01/0.05	0.07
0.01%	Brazil nuts	0.01/0.05	0.04	0.01%	Hazelnuts/cobnuts	0.01/0.05	0.06
0.01%	Macadamia	0.01/0.05	0.03	0.01%	Pine nut kernels	0.01/0.05	0.05
0.00%	Pine nut kernels	0.01/0.05	0.02	0.01%	Brazil nuts	0.01/0.05	0.03

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Coconuts/drink	0.01/0.05	0.43	0.0%	Coconuts/drink	0.01/0.05	0.18

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Buprofezin (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Carbendazim

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.02	ARfD (mg/kg bw):	0.02
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.1%	DE child	0.03	0.0%	Nutmeg	0.0%	Fennel seed	0.0%	Cumin seed		
0.0%	GEMS/Food G11	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G06	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G07	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G07	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G08	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	GEMS/Food G10	0.00	0.0%	Anise/aniseed	0.0%	Nutmeg				
0.0%	FR toddler 2 3 yr	0.00	0.0%	Other spices (seeds)	0.0%	Coriander seed	0.0%	Coriander seed		
0.0%	DE women 14-50 yr	0.00	0.0%	Nutmeg	0.0%	Black caraway/black cumin	0.0%	Coriander seed		
0.0%	DE general	0.00	0.0%	Nutmeg	0.0%	Black caraway/black cumin	0.0%	Coriander seed		
0.0%	FR child 3 15 yr	0.00	0.0%	Other spices (seeds)		FRUIT AND TREE NUTS				
0.0%	FR adult	0.00	0.0%	Other spices (seeds)	0.0%	Anise/aniseed	0.0%	Coriander seed		
0.0%	FR infant	0.00	0.0%	Other spices (seeds)		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Carbendazim is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acuterisk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Fennel seed	5/0.53	0.40
0.05%	Coriander seed	5/0.53	0.01
0.05%	Anise/aniseed	5/0.53	0.01
0.03%	Nutmeg	5/0.53	0.01
0.01%	Fenugreek	5/0.53	0.00
0.01%	Dill seed	5/0.53	0.00
0.01%	Cumin seed	5/0.53	0.00

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Black caraway/black cumin	5/0.53	0.05
0.3%	Nutmeg	5/0.53	0.05
0.3%	Fenugreek	5/0.53	0.05
0.3%	Coriander seed	5/0.53	0.05
0.3%	Fennel seed	5/0.53	0.05
0.3%	Anise/aniseed	5/0.53	0.05
0.00%	Dill seed	5/0.53	0.00
0.00%	Cumin seed	5/0.53	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Cumin seed/processed (not	5/0.53	0.02

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Carbendazim is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

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EFSA PRIMo revision 3.1; 2019/03/19

Chlorantraniliprole (DPX E-2Y45) (F)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	1.56	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.8%	NL toddler	13.07	0.3%	Spinaches	0.1%	Witloofs/Belgian endives	0.1%	Escaroles/broad-leaved endives	0.0%	0.8%
0.4%	SE general	6.68	0.1%	Lettuces	0.1%	Chinese cabbages/pe-tsai	0.0%	Spinaches	0.0%	0.4%
0.4%	DE child	6.64	0.1%	Spinaches	0.1%	Apples	0.1%	Oranges	0.0%	0.4%
0.4%	GEMS/Food G10	6.41	0.1%	Lettuces	0.1%	Chinese cabbages/pe-tsai	0.0%	Cress and other sprouts and shoots	0.0%	0.4%
0.4%	NL child	6.32	0.1%	Spinaches	0.0%	Escaroles/broad-leaved endives	0.0%	Apples	0.0%	0.4%
0.3%	NL general	4.97	0.1%	Witloofs/Belgian endives	0.1%	Spinaches	0.0%	Escaroles/broad-leaved endives	0.0%	0.3%
0.3%	GEMS/Food G08	4.93	0.1%	Lettuces	0.0%	Lamb's lettuce/corn salads	0.0%	Watercress	0.0%	0.3%
0.3%	ES adult	4.92	0.2%	Lettuces	0.0%	Chards/beet leaves	0.0%	Spinaches	0.0%	0.3%
0.3%	GEMS/Food G07	4.84	0.1%	Lettuces	0.0%	Celeries	0.0%	Wine grapes	0.0%	0.3%
0.3%	GEMS/Food G11	4.78	0.0%	Celeries	0.0%	Spinaches	0.0%	Lamb's lettuce/corn salads	0.0%	0.3%
0.3%	ES child	4.71	0.1%	Lettuces	0.0%	Oranges	0.0%	Spinaches	0.0%	0.3%
0.3%	GEMS/Food G06	4.50	0.0%	Lettuces	0.0%	Spinaches	0.0%	Kales	0.0%	0.3%
0.3%	IE adult	4.43	0.0%	Spinaches	0.0%	Rhubarbs	0.0%	Lettuces	0.0%	0.3%
0.3%	IT adult	4.18	0.1%	Lettuces	0.0%	Spinaches	0.0%	Chards/beet leaves	0.0%	0.3%
0.2%	FR toddler 2 3 yr	3.72	0.1%	Spinaches	0.0%	Milk: Cattle	0.0%	Witloofs/Belgian endives	0.0%	0.2%
0.2%	FR child 3 15 yr	3.58	0.0%	Oranges	0.0%	Spinaches	0.0%	Witloofs/Belgian endives	0.0%	0.2%
0.2%	GEMS/Food G15	3.50	0.0%	Lettuces	0.0%	Head cabbages	0.0%	Wine grapes	0.0%	0.2%
0.2%	IT toddler	3.41	0.1%	Lettuces	0.0%	Chards/beet leaves	0.0%	Spinaches	0.0%	0.2%
0.2%	PT general	3.32	0.1%	Kales	0.0%	Lettuces	0.0%	Wine grapes	0.0%	0.2%
0.2%	DE women 14-50 yr	3.03	0.0%	Lettuces	0.0%	Oranges	0.0%	Spinaches	0.0%	0.2%
0.2%	FR infant	2.93	0.1%	Spinaches	0.0%	Milk: Cattle	0.0%	Chards/beet leaves	0.0%	0.2%
0.2%	DE general	2.85	0.0%	Lettuces	0.0%	Oranges	0.0%	Spinaches	0.0%	0.2%
0.2%	FR adult	2.42	0.0%	Witloofs/Belgian endives	0.0%	Wine grapes	0.0%	Spinaches	0.0%	0.2%
0.2%	RO general	2.36	0.0%	Head cabbages	0.0%	Wine grapes	0.0%	Milk: Cattle	0.0%	0.2%
0.1%	DK child	2.20	0.1%	Lettuces	0.0%	Milk: Cattle	0.0%	Apples	0.0%	0.1%
0.1%	UK vegetarian	2.12	0.1%	Lettuces	0.0%	Spinaches	0.0%	Oranges	0.0%	0.1%
0.1%	UK toddler	2.10	0.0%	Oranges	0.0%	Milk: Cattle	0.0%	Spinaches	0.0%	0.1%
0.1%	UK infant	1.94	0.0%	Milk: Cattle	0.0%	Oranges	0.0%	Eggs: Chicken	0.0%	0.1%
0.1%	FI 6 yr	1.75	0.0%	Lettuces	0.0%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	0.1%
0.1%	UK adult	1.68	0.0%	Lettuces	0.0%	Wine grapes	0.0%	Oranges	0.0%	0.1%
0.1%	FI 3 yr	1.68	0.0%	Spinaches	0.0%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.0%	0.1%
0.1%	FI adult	1.61	0.1%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.0%	Oranges	0.0%	0.1%
0.1%	DK adult	1.48	0.0%	Lettuces	0.0%	Wine grapes	0.0%	Milk: Cattle	0.0%	0.1%
0.1%	LT adult	1.10	0.0%	Lettuces	0.0%	Head cabbages	0.0%	Apples	0.0%	0.1%
0.1%	PL general	1.03	0.0%	Head cabbages	0.0%	Apples	0.0%	Chinese cabbages/pe-tsai	0.0%	0.1%
0.0%	IE child	0.41	0.0%	Milk: Cattle	0.0%	Lettuces	0.0%	Rice	0.0%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Chlorantraniliprole (DPX E-2Y45) (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

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EFSA PRIMo revision 3.1; 2019/03/19

Chlorothalonil (R)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.015	ARfD (mg/kg bw):	0.05
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.8%	SE general	0.12	0.5%	Papayas	0.2%	Cranberries	0.1%	Bananas		0.8%
0.7%	NL toddler	0.11	0.4%	Papayas	0.4%	Bananas	0.0%	Peanuts/groundnuts		0.7%
0.7%	GEMS/Food G10	0.11	0.4%	Cranberries	0.3%	Papayas	0.0%	Bananas		0.7%
0.6%	GEMS/Food G06	0.09	0.5%	Papayas	0.0%	Cranberries	0.0%	Bananas		0.6%
0.5%	NL child	0.07	0.3%	Papayas	0.1%	Bananas	0.1%	Cranberries		0.5%
0.4%	DE child	0.06	0.3%	Papayas	0.1%	Bananas	0.0%	Peanuts/groundnuts		0.4%
0.4%	GEMS/Food G11	0.05	0.3%	Papayas	0.0%	Cranberries	0.0%	Bananas		0.4%
0.2%	GEMS/Food G07	0.03	0.2%	Papayas	0.0%	Cranberries	0.0%	Bananas		0.2%
0.2%	GEMS/Food G15	0.02	0.1%	Papayas	0.0%	Cranberries	0.0%	Bananas		0.2%
0.2%	GEMS/Food G08	0.02	0.1%	Papayas	0.0%	Cranberries	0.0%	Bananas		0.2%
0.1%	DK child	0.02	0.1%	Bananas	0.1%	Papayas				0.1%
0.1%	DE women 14-50 yr	0.02	0.1%	Papayas	0.0%	Bananas	0.0%	Peanuts/groundnuts		0.1%
0.1%	UK infant	0.01	0.1%	Bananas	0.0%	Peanuts/groundnuts				0.1%
0.1%	DE general	0.01	0.1%	Papayas	0.0%	Bananas	0.0%	Peanuts/groundnuts		0.1%
0.1%	FI 3 yr	0.01	0.1%	Bananas	0.0%	Peanuts/groundnuts				0.1%
0.1%	UK toddler	0.01	0.1%	Bananas	0.0%	Peanuts/groundnuts				0.1%
0.1%	ES child	0.01	0.1%	Bananas	0.0%	Peanuts/groundnuts				0.1%
0.1%	DK adult	0.01	0.0%	Bananas	0.0%	Papayas				0.1%
0.1%	IE adult	0.01	0.1%	Bananas	0.0%	Peanuts/groundnuts				0.1%
0.1%	ES adult	0.01	0.0%	Papayas	0.0%	Bananas	0.0%	Peanuts/groundnuts		0.1%
0.1%	FI 6 yr	0.01	0.1%	Bananas	0.0%	Peanuts/groundnuts				0.1%
0.0%	FR child 3 15 yr	0.01	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	FR toddler 2 3 yr	0.01	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	IT toddler	0.01	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	UK vegetarian	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	NL general	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	UK adult	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	PT general	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	FI adult	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	RO general	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	FR infant	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	IT adult	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	IE child	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	PL general	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	FR adult	0.00	0.0%	Bananas	0.0%	Peanuts/groundnuts				0.0%
0.0%	LT adult	0.00	0.0%	Bananas		FRUIT AND TREE NUTS				0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Chlorothalonil (R) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
433%	Papayas	15/5.1	216	142%	Papayas	15/5.1	71
69%	Cranberries	15/7.7	35	17%	Cranberries	15/7.7	8.7
4%	Bananas	0.02/0.02	1.9	0.8%	Bananas	0.02/0.02	0.42
0.06%	Peanuts/groundnuts	0.01/0.01	0.03	0.05%	Peanuts/groundnuts	0.01/0.01	0.02

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
35%	Cranberries/juice	15/3	17	5%	Cranberries/dried	15/3	2.3
0.1%	Peanuts/peanut butter	0.01/0.01	0.04				

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

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EFSA PRIMo revision 3.1; 2019/03/19

SDS-3701

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw per day):	0.008	ARfD (mg/kg bw):	0.03
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2009	Year of evaluation:	0.03

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.0%	GEMS/Food G10	0.00020	0.0%	Cranberries						0.0%
0.0%	SE general	0.0001	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%
0.0%	NL child	0.0001	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G11	0.0000	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.0000	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.0000	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.0000	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.0000	0.0%	Cranberries		FRUIT AND TREE NUTS				0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of SDS-3701 is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Cranberries	0/0.02	0.09	0.07%	Cranberries	0/0.02	0.02
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Cranberries/juice	0/0.01	0.06	0.0%	Cranberries/dried	0/0.01	0.01
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of SDS-3701 is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

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EFSA PRIMo revision 3.1; 2019/03/19

Clethodim

LOQs (mg/kg) range from:	0.05	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.16	ARfD (mg/kg bw):	Not necessary
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
20%	NL toddler	32.01	4%	Spinaches	4%	Cauliflowers	3%	Broccoli	2%	20%
8%	GEMS/Food G11	12.36	3%	Soyabeans	0.6%	Cauliflowers	0.5%	Spinaches	0.2%	8%
8%	NL child	12.26	1%	Spinaches	0.9%	Cauliflowers	0.8%	Milk: Cattle	0.8%	8%
8%	GEMS/Food G10	12.14	2%	Soyabeans	1%	Rice	0.8%	Tomatoes	0.2%	8%
8%	IE adult	12.14	1%	Broccoli	1%	Brussels sprouts	1.0%	Cauliflowers	0.1%	8%
7%	UK infant	11.57	2%	Cauliflowers	1%	Milk: Cattle	1%	Brussels sprouts	1%	7%
7%	GEMS/Food G06	11.37	2%	Tomatoes	2%	Rice	0.8%	Soyabeans	0.1%	7%
7%	FR toddler 2 3 yr	10.92	1%	Cauliflowers	0.9%	Spinaches	0.9%	Milk: Cattle	0.9%	7%
6%	DE child	10.00	1%	Spinaches	0.7%	Broccoli	0.7%	Broccoli	0.7%	6%
6%	GEMS/Food G08	9.93	1%	Soyabeans	0.7%	Tomatoes	0.7%	Head cabbages	0.2%	6%
6%	FR child 3 15 yr	9.76	1%	Cauliflowers	0.7%	Milk: Cattle	0.6%	Spinaches	0.8%	6%
6%	GEMS/Food G15	9.75	1%	Soyabeans	1%	Head cabbages	0.7%	Tomatoes	0.2%	6%
6%	GEMS/Food G07	9.61	1%	Soyabeans	0.6%	Tomatoes	0.5%	Cauliflowers	0.2%	6%
6%	SE general	9.55	0.9%	Head cabbages	0.6%	Bovine: Muscle/meat	0.5%	Potatoes	0.4%	6%
6%	NL general	9.32	1%	Cauliflowers	0.9%	Spinaches	0.8%	Witloofs/Belgian endives	0.3%	6%
6%	FR infant	8.82	2%	Spinaches	2%	Cauliflowers	0.8%	Broccoli	0.5%	6%
5%	RO general	8.69	2%	Head cabbages	1%	Tomatoes	0.4%	Potatoes	0.4%	5%
5%	UK toddler	8.43	0.7%	Rice	0.7%	Cauliflowers	0.6%	Milk: Cattle	0.7%	5%
4%	DE general	6.22	0.9%	Cauliflowers	0.4%	Tomatoes	0.4%	Milk: Cattle	0.4%	4%
4%	DE women 14-50 yr	6.21	0.9%	Cauliflowers	0.4%	Tomatoes	0.4%	Milk: Cattle	0.4%	4%
4%	FI 3 yr	6.18	0.7%	Rice	0.6%	Potatoes	0.5%	Broccoli		4%
4%	PT general	6.12	0.9%	Rice	0.6%	Potatoes	0.5%	Tomatoes		4%
4%	ES child	5.81	0.6%	Tomatoes	0.6%	Rice	0.5%	Spinaches	0.4%	4%
4%	FR adult	5.71	0.8%	Cauliflowers	0.5%	Witloofs/Belgian endives	0.4%	Wine grapes	0.2%	4%
3%	UK vegetarian	5.54	0.7%	Cauliflowers	0.5%	Broccoli	0.5%	Rice	0.1%	3%
3%	UK adult	4.63	0.4%	Broccoli	0.4%	Rice	0.4%	Cauliflowers	0.1%	3%
3%	ES adult	4.36	0.5%	Tomatoes	0.4%	Spinaches	0.3%	Cauliflowers	0.2%	3%
3%	DK child	4.31	0.4%	Milk: Cattle	0.3%	Rice	0.3%	Tomatoes	0.4%	3%
3%	FI 6 yr	4.11	0.5%	Rice	0.5%	Potatoes	0.3%	Spinaches		3%
2%	PL general	3.86	0.5%	Cauliflowers	0.5%	Head cabbages	0.5%	Tomatoes		2%
2%	IT adult	3.79	0.7%	Tomatoes	0.6%	Spinaches	0.3%	Cauliflowers		2%
2%	DK adult	3.56	0.3%	Tomatoes	0.2%	Cauliflowers	0.2%	Peas (without pods)	0.2%	2%
2%	IT toddler	3.55	0.8%	Tomatoes	0.3%	Spinaches	0.2%	Cauliflowers		2%
2%	LT adult	3.33	0.6%	Head cabbages	0.4%	Potatoes	0.4%	Tomatoes	0.1%	2%
2%	FI adult	2.48	0.3%	Tomatoes	0.2%	Cauliflowers	0.2%	Rice		2%
1%	IE child	2.37	0.4%	Broccoli	0.4%	Rice	0.2%	Beans (without pods)	0.1%	1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Clethodim is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Conclusion:

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Cyclaniliprole (F)

LOQs (mg/kg) range from:	0.01	to:	50.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.0043	ARfD (mg/kg bw):	Unnecessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2016	Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
125%	NL toddler	5.37	40%	Spinaches	14%	Apples	14%	Escaroles/broad-leaved endives	8%	117%
88%	IE adult	3.78	38%	Tea (dried leaves of Camellia sinensis)	15%	Other leafy brassica	7%	Spinaches	4%	84%
71%	DE child	3.04	17%	Apples	11%	Spinaches	8%	Oranges	4%	67%
69%	NL child	2.96	14%	Spinaches	8%	Apples	5%	Escaroles/broad-leaved endives	6%	63%
67%	GEMS/Food G10	2.90	18%	Lettuces	13%	Chinese cabbages/pe-tsai	9%	Tea (dried leaves of Camellia sinensis)	5%	63%
64%	SE general	2.73	23%	Lettuces	16%	Chinese cabbages/pe-tsai	4%	Kales	3%	61%
62%	FR adult	2.66	41%	Tea (dried leaves of Camellia sinensis)	6%	Wine grapes	3%	Spinaches	2%	60%
55%	GEMS/Food G06	2.35	15%	Tea (dried leaves of Camellia sinensis)	6%	Lettuces	3%	Table grapes	5%	50%
54%	GEMS/Food G07	2.31	14%	Tea (dried leaves of Camellia sinensis)	13%	Lettuces	4%	Wine grapes	5%	49%
51%	NL general	2.21	10%	Tea (dried leaves of Camellia sinensis)	8%	Spinaches	6%	Escaroles/broad-leaved endives	3%	48%
51%	ES adult	2.17	30%	Lettuces	4%	Chards/beet leaves	4%	Spinaches	2%	49%
49%	ES child	2.11	23%	Lettuces	5%	Spinaches	4%	Chards/beet leaves	3%	46%
49%	GEMS/Food G11	2.10	11%	Tea (dried leaves of Camellia sinensis)	5%	Spinaches	5%	Lamb's lettuce/corn salads	5%	43%
46%	GEMS/Food G08	1.97	11%	Lettuces	8%	Tea (dried leaves of Camellia sinensis)	4%	Lamb's lettuce/corn salads	5%	41%
45%	IT adult	1.92	21%	Lettuces	5%	Spinaches	4%	Other spinach and similar	2%	43%
42%	DE women 14-50 yr	1.79	9%	Tea (dried leaves of Camellia sinensis)	6%	Lettuces	4%	Oranges	3%	38%
39%	FR child 3 15 yr	1.69	7%	Tea (dried leaves of Camellia sinensis)	7%	Oranges	6%	Spinaches	4%	35%
39%	DE general	1.69	9%	Tea (dried leaves of Camellia sinensis)	5%	Lettuces	3%	Apples	3%	36%
37%	PT general	1.60	15%	Kales	7%	Wine grapes	6%	Lettuces	3%	34%
37%	IT toddler	1.60	16%	Lettuces	3%	Chards/beet leaves	3%	Spinaches	3%	35%
35%	UK infant	1.50	17%	Tea (dried leaves of Camellia sinensis)	4%	Milk: Cattle	3%	Oranges	3%	31%
35%	UK vegetarian	1.50	14%	Tea (dried leaves of Camellia sinensis)	8%	Lettuces	2%	Wine grapes	2%	33%
34%	FR toddler 2 3 yr	1.46	9%	Spinaches	4%	Apples	3%	Oranges	3%	30%
33%	UK adult	1.40	16%	Tea (dried leaves of Camellia sinensis)	7%	Lettuces	3%	Wine grapes	1%	31%
31%	GEMS/Food G15	1.35	6%	Lettuces	4%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	4%	27%
30%	UK toddler	1.27	8%	Tea (dried leaves of Camellia sinensis)	4%	Oranges	2%	Apples	3%	26%
28%	FR infant	1.19	15%	Spinaches	2%	Apples	2%	Cauliflowers	2%	26%
25%	DK child	1.05	8%	Lettuces	3%	Apples	1%	Swine: Muscle/meat	4%	21%
23%	FI adult	0.98	8%	Lettuces	6%	Coffee beans	1%	Chinese cabbages/pe-tsai	7%	15%
19%	FI 3 yr	0.83	4%	Spinaches	2%	Lettuces	2%	Chinese cabbages/pe-tsai	3%	16%
19%	DK adult	0.82	5%	Lettuces	3%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	1%	18%
19%	RO general	0.82	5%	Wine grapes	2%	Apples	1%	Tomatoes	3%	16%
19%	FI 6 yr	0.81	5%	Lettuces	3%	Spinaches	3%	Chinese cabbages/pe-tsai	2%	16%
11%	PL general	0.47	3%	Apples	2%	Chinese cabbages/pe-tsai	0.9%	Table grapes	1%	10%
11%	LT adult	0.47	4%	Lettuces	2%	Apples	0.7%	Potatoes	1%	9%
4%	IE child	0.19	0.6%	Tea (dried leaves of Camellia sinensis)	0.4%	Apples	0.4%	Lettuces	0.7%	4%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 124.9 % of the ADI.
For 1 diet(s) the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 13

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 8

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10789%	Escaroles/broad-leaved endives/boiled	7/7	464	3327%	Escaroles/broad-leaved endives/boiled	7/7	143
6414%	Kales/boiled	10/10	276	2037%	Chards/beet leaves/boiled	7/7	88
5066%	Chards/beet leaves/boiled	7/7	218	1347%	Spinaches/frozen; boiled	7/7	58
2264%	Spinaches/frozen; boiled	7/7	97	775%	Cauliflowers/boiled	0.8/0.8	33
1466%	Broccoli/boiled	0.8/0.8	63	671%	Purslanes/boiled	7/7	29
1295%	Cauliflowers/boiled	0.8/0.8	56	448%	Broccoli/boiled	0.8/0.8	19
206%	Pumpkins/boiled	0.1/0.1	8.9	132%	Wine grapes/wine	0.6/0.6	5.7
183%	Currants (red, black and white)/juice	1.5/0.28	7.9	128%	Pumpkins/boiled	0.1/0.1	5.5
181%	Peaches/canned	0.3/0.3	7.8	82%	Currants (red, black and white)/juice	1.5/0.28	3.5
122%	Wine grapes/juice	0.6/0.12	5.2	80%	Table grapes/raisins	0.6/2.82	3.5
107%	Oranges/juice	0.4/0.09	4.6	59%	Tea (dried leaves of Camellia sinensis)/infusion	50/0.13	2.5
102%	Tea (dried leaves of Camellia sinensis)/infusion	50/0.13	4.4	59%	Elderberries/juice	1.5/0.28	2.5
102%	Elderberries/juice	1.5/0.28	4.4	58%	Wine grapes/juice	0.6/0.12	2.5
73%	Raspberries/juice	0.8/0.27	3.2	57%	Peaches/canned	0.3/0.3	2.5
72%	Apples/juice	0.2/0.06	3.1	44%	Apples/juice	0.2/0.06	1.9

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Cyclaniliprole (F) is unlikely to present a public health risk.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Cypermethrin (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.005	ARfD (mg/kg bw):	0.005
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Cypermethrin (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Ginseng root	0.15/0.1	0.02	1%	Ginseng root	0.15/0.1	0.06

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Cypermethrin (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Cyprodinil

LOQs (mg/kg) range from:	0.02	to:	5.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.03	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	France
Year of evaluation:	2005	Year of evaluation:	2018

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
56%	NL toddler	16.83	17%	Apples	7%	Spinaches	7%	Pears	0.3%	56%
43%	DE child	12.83	20%	Apples	3%	Table grapes	2%	Spinaches	0.3%	43%
29%	GEMS/Food G11	8.61	8%	Celeries	2%	Apples	2%	Wine grapes	0.3%	29%
28%	NL child	8.52	9%	Apples	3%	Spinaches	2%	Table grapes	0.3%	28%
24%	GEMS/Food G07	7.29	4%	Celeries	3%	Wine grapes	2%	Lettuces	0.3%	24%
23%	GEMS/Food G08	6.79	2%	Wine grapes	2%	Barley	2%	Lettuces	0.3%	23%
20%	GEMS/Food G10	6.14	3%	Lettuces	2%	Wheat	2%	Celeries	0.2%	20%
20%	IE adult	6.12	4%	Celeries	3%	Wine grapes	1%	Spinaches	0.2%	20%
20%	GEMS/Food G15	5.97	2%	Celeries	2%	Wine grapes	2%	Wheat	0.3%	20%
20%	GEMS/Food G06	5.85	3%	Wheat	2%	Table grapes	2%	Tomatoes	0.2%	20%
18%	DK child	5.41	4%	Apples	2%	Rye	2%	Carrots	0.2%	18%
17%	FR child 3 15 yr	5.21	3%	Apples	2%	Wheat	2%	Milk: Cattle	0.2%	17%
17%	FR toddler 2 3 yr	5.11	5%	Apples	2%	Milk: Cattle	2%	Spinaches	0.2%	17%
17%	IT adult	5.00	4%	Lettuces	2%	Wheat	2%	Other lettuce and other salad plants	0.0%	17%
16%	IT toddler	4.84	3%	Lettuces	3%	Wheat	1%	Apples	0.1%	16%
16%	ES adult	4.75	6%	Lettuces	1%	Apples	1%	Barley	0.1%	16%
16%	SE general	4.71	4%	Lettuces	2%	Apples	1%	Wheat	0.3%	16%
15%	DE women 14-50 yr	4.63	4%	Apples	2%	Wine grapes	1%	Lettuces	0.1%	15%
15%	DE general	4.55	4%	Apples	2%	Wine grapes	1%	Barley	0.1%	15%
15%	ES child	4.53	4%	Lettuces	2%	Wheat	2%	Apples	0.2%	15%
15%	PT general	4.50	6%	Wine grapes	2%	Wheat	2%	Apples	0.4%	15%
14%	RO general	4.34	4%	Wine grapes	2%	Apples	2%	Wheat	0.3%	14%
14%	FR adult	4.26	5%	Wine grapes	2%	Other lettuce and other salad plants	1%	Apples	0.1%	14%
14%	NL general	4.13	2%	Apples	2%	Spinaches	1%	Wine grapes	0.2%	14%
13%	UK infant	3.99	3%	Milk: Cattle	3%	Apples	2%	Carrots	0.3%	13%
13%	FR infant	3.98	3%	Spinaches	3%	Apples	2%	Carrots	0.1%	13%
12%	UK toddler	3.72	3%	Apples	2%	Wheat	1%	Milk: Cattle	0.3%	12%
11%	FI 3 yr	3.40	2%	Apples	1%	Oat	1%	Carrots	0.3%	11%
9%	UK vegetarian	2.81	2%	Wine grapes	1%	Lettuces	1.0%	Celeries	0.1%	9%
9%	DK adult	2.75	2%	Wine grapes	2%	Apples	0.9%	Lettuces	0.1%	9%
9%	FI 6 yr	2.63	0.9%	Strawberries	0.9%	Apples	0.9%	Carrots	0.3%	9%
8%	PL general	2.33	3%	Apples	0.7%	Table grapes	0.5%	Tomatoes	0.2%	8%
8%	UK adult	2.32	2%	Wine grapes	1%	Lettuces	0.7%	Wheat	0.1%	8%
7%	LT adult	2.17	3%	Apples	0.7%	Lettuces	0.5%	Rye	0.2%	7%
7%	FI adult	1.96	1%	Lettuces	0.9%	Apples	0.7%	Wine grapes	0.1%	7%
3%	IE child	0.78	0.5%	Apples	0.5%	Wheat	0.3%	Carrots	0.1%	3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Cyprodinil is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results of IESTI calculation for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Dicamba

LOQs (mg/kg) range from:	0.05	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
14%	NL toddler	43.49	10%	Milk: Cattle	3%	Wheat	0.4%	Barley	0.6%	0.0%
9%	UK infant	26.60	6%	Milk: Cattle	2%	Wheat	0.2%	Bovine: Muscle/meat	0.2%	0.0%
8%	NL child	23.34	4%	Milk: Cattle	3%	Wheat	0.2%	Apples	0.5%	0.0%
8%	FR child 3 15 yr	23.07	4%	Milk: Cattle	3%	Wheat	0.2%	Bovine: Muscle/meat	0.3%	0.0%
8%	FR toddler 2 3 yr	23.00	5%	Milk: Cattle	2%	Wheat	0.2%	Bovine: Muscle/meat	0.3%	0.0%
8%	DE child	22.84	3%	Milk: Cattle	3%	Wheat	0.4%	Apples	0.4%	0.0%
7%	GEMS/Food G15	21.37	3%	Wheat	2%	Barley	1%	Milk: Cattle	0.3%	0.0%
7%	GEMS/Food G08	21.11	3%	Wheat	2%	Barley	0.9%	Milk: Cattle	0.3%	0.1%
7%	GEMS/Food G11	20.66	2%	Wheat	2%	Barley	1%	Milk: Cattle	0.3%	0.1%
7%	GEMS/Food G06	20.41	5%	Wheat	0.6%	Sugar canes	0.4%	Milk: Cattle	0.3%	0.1%
7%	UK toddler	20.12	3%	Milk: Cattle	3%	Wheat	0.2%	Bovine: Muscle/meat	0.3%	0.0%
7%	GEMS/Food G07	20.01	3%	Wheat	1%	Barley	1%	Milk: Cattle	0.3%	0.1%
7%	DK child	19.84	3%	Wheat	2%	Milk: Cattle	0.9%	Rye	0.2%	0.0%
6%	GEMS/Food G10	18.59	3%	Wheat	1%	Barley	0.9%	Milk: Cattle	0.3%	0.1%
6%	RO general	17.20	3%	Wheat	2%	Milk: Cattle	0.1%	Potatoes	0.3%	0.0%
6%	ES child	17.03	3%	Wheat	2%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.2%	0.0%
5%	SE general	16.26	2%	Wheat	2%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.3%	
5%	DE general	15.91	2%	Milk: Cattle	1%	Wheat	1%	Barley	0.2%	0.0%
5%	IT toddler	14.44	4%	Wheat	0.2%	Other cereals	0.0%	Apples	0.1%	0.0%
5%	DE women 14-50 yr	14.35	2%	Milk: Cattle	1%	Wheat	0.4%	Barley	0.3%	0.0%
4%	ES adult	11.85	2%	Wheat	1%	Barley	0.8%	Milk: Cattle	0.2%	0.0%
4%	NL general	11.63	1%	Milk: Cattle	1%	Wheat	0.7%	Barley	0.2%	0.0%
4%	FR infant	10.88	3%	Milk: Cattle	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.2%	0.0%
3%	IE adult	9.61	2%	Wheat	0.7%	Milk: Cattle	0.2%	Asparagus	0.4%	0.0%
3%	PT general	9.22	3%	Wheat	0.1%	Potatoes	0.1%	Rice	0.2%	0.0%
3%	IT adult	9.14	3%	Wheat	0.1%	Other cereals	0.0%	Apples	0.1%	0.0%
3%	FR adult	7.89	1%	Wheat	0.7%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.2%	0.0%
2%	UK vegetarian	6.54	1%	Wheat	0.5%	Milk: Cattle	0.0%	Barley	0.1%	0.0%
2%	DK adult	6.05	0.9%	Milk: Cattle	0.7%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	
2%	UK adult	5.93	1%	Wheat	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	0.0%
2%	LT adult	5.92	0.7%	Wheat	0.7%	Milk: Cattle	0.2%	Rye	0.1%	0.0%
1%	IE child	4.43	0.8%	Wheat	0.6%	Milk: Cattle	0.0%	Rice	0.0%	0.0%
1%	FI 3 yr	4.38	0.8%	Wheat	0.2%	Barley	0.1%	Rye	0.2%	0.0%
1%	FI 6 yr	3.52	0.6%	Wheat	0.1%	Barley	0.1%	Rye	0.2%	0.0%
0.6%	FI adult	1.84	0.2%	Wheat	0.1%	Rye	0.1%	Coffee beans	0.2%	0.0%
0.2%	PL general	0.63	0.1%	Apples	0.1%	Potatoes	0.0%	Tomatoes	0.1%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Dicamba is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Maize/corn	0.5/0.02	0.13	0.10%	Soyabeans	10/0.05	0.29
0.04%	Soyabeans	10/0.05	0.12	0.01%	Maize/corn	0.5/0.02	0.04

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Maize/oil	0.5/0.5	0.47	0.1%	Maize/oil	0.5/0.5	0.25
0.1%	Soyabeans/soya drink	10/0.05	0.22				
0.0%	Soyabeans/boiled	10/0.02	0.08				
0.0%	Maize/processed (not specified)	0.5/0.02	0.04				

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Dicamba is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Dimethoate

LOQs (mg/kg) range from:	0.01	to:	5.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.002	ARfD (mg/kg bw):	0.02
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
8%	DE child	0.15	2%	Wheat	0.7%	Vanilla pods	0.4%	Rye		8%
5%	GEMS/Food G06	0.10	4%	Wheat	0.9%	Olives for oil production	0.2%	Tamarind		5%
5%	DK child	0.10	3%	Rye	2%	Wheat				5%
5%	GEMS/Food G08	0.10	2%	Wheat	2%	Olives for oil production	0.3%	Rye		5%
4%	ES child	0.08	2%	Wheat	2%	Olives for oil production	0.0%	Table olives		4%
4%	GEMS/Food G10	0.07	2%	Wheat	0.9%	Olives for oil production	0.4%	Ginger		4%
4%	GEMS/Food G11	0.07	2%	Wheat	0.6%	Olives for oil production	0.4%	Peppercorn (black, green and white)		4%
3%	GEMS/Food G07	0.07	2%	Wheat	0.7%	Olives for oil production	0.2%	Peppercorn (black, green and white)		3%
3%	GEMS/Food G15	0.07	2%	Wheat	0.5%	Olives for oil production	0.1%	Peppercorn (black, green and white)		3%
3%	IT toddler	0.07	3%	Wheat	0.0%	Table olives				3%
3%	PT general	0.05	2%	Wheat	0.6%	Olives for oil production	0.1%	Rye		3%
3%	FR child 3 15 yr	0.05	2%	Wheat	0.3%	Olives for oil production	0.0%	Other spices (seeds)		3%
3%	RO general	0.05	3%	Wheat	0.0%	Table olives				3%
2%	NL toddler	0.05	2%	Wheat	0.2%	Rye	0.1%	Olives for oil production		2%
2%	NL child	0.05	2%	Wheat	0.1%	Olives for oil production	0.1%	Rye		2%
2%	ES adult	0.05	1%	Wheat	1%	Olives for oil production	0.0%	Table olives		2%
2%	IT adult	0.04	2%	Wheat	0.0%	Table olives				2%
2%	UK toddler	0.04	2%	Wheat	0.0%	Rye				2%
2%	FR toddler 2 3 yr	0.04	2%	Wheat	0.1%	Olives for oil production	0.0%	Other spices (roots)		2%
2%	DE women 14-50 yr	0.04	1%	Wheat	0.2%	Rye	0.2%	Olives for oil production		2%
2%	SE general	0.04	2%	Wheat	0.1%	Rye	0.1%	Table olives		2%
2%	DE general	0.03	0.9%	Wheat	0.3%	Rye	0.2%	Olives for oil production		2%
2%	IE adult	0.03	1%	Wheat	0.3%	Horseradish, root spices	0.1%	Rye		2%
1%	FR adult	0.03	1%	Wheat	0.2%	Olives for oil production	0.0%	Peppercorn (black, green and white)		1%
1%	UK infant	0.03	1%	Wheat		FRUIT AND TREE NUTS				1%
1%	NL general	0.02	1.0%	Wheat	0.1%	Olives for oil production	0.0%	Rye		1%
1%	LT adult	0.02	0.5%	Rye	0.5%	Wheat				1%
1%	UK vegetarian	0.02	1%	Wheat	0.0%	Rye	0.0%	Table olives		1%
1.0%	FI 3 yr	0.02	0.6%	Wheat	0.3%	Rye	0.0%	Olives for oil production		1.0%
0.8%	UK adult	0.02	0.8%	Wheat	0.0%	Rye	0.0%	Table olives		0.8%
0.8%	DK adult	0.02	0.6%	Wheat	0.3%	Rye				0.8%
0.8%	FI 6 yr	0.02	0.5%	Wheat	0.3%	Rye	0.0%	Olives for oil production		0.8%
0.6%	IE child	0.01	0.6%	Wheat	0.0%	Ginger	0.0%	Turmeric/curcuma		0.6%
0.5%	FI adult	0.01	0.4%	Rye	0.2%	Wheat	0.0%	Table olives		0.5%
0.4%	FR infant	0.01	0.4%	Wheat	0.0%	Olives for oil production	0.0%	Other spices (seeds)		0.4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Dimethoate is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
51%	Table olives	3/3	10	15%	Table olives	3/3	3.0
19%	Fennel seed	5/5	3.9	3%	Black caraway/black cumin	5/5	0.50
2%	Vanilla pods	0.5/0.5	0.31	3%	Black caraway/black cumin	5/5	0.50
0.7%	Wheat	0.05/0.01	0.14	3%	Black caraway/black cumin	5/5	0.50
0.5%	Anise/aniseed	5/5	0.10	3%	Anise/aniseed	5/5	0.50
0.5%	Anise/aniseed	5/5	0.10	3%	Anise/aniseed	5/5	0.50
0.3%	Olives for oil production	3/0.05	0.06	3%	Anise/aniseed	5/5	0.50
0.3%	Rye	0.02/0.01	0.06	0.4%	Wheat	0.05/0.01	0.08
0.3%	Juniper berry	0.5/0.5	0.05	0.3%	Cardamom	0.5/0.5	0.05
0.3%	Nutmeg	5/5	0.05	0.3%	Cardamom	0.5/0.5	0.05
0.1%	Cumin seed	5/5	0.03	0.2%	Rye	0.02/0.01	0.05
0.1%	Cumin seed	5/5	0.03	0.2%	Olives for oil production	3/0.05	0.04
0.1%	Cumin seed	5/5	0.03	0.1%	Tamarind	0.5/0.5	0.02
0.1%	Peppercorn (black, green and white)	0.5/0.5	0.02	0.08%	Peppercorn (black, green and white)	0.5/0.5	0.02
0.06%	Allspice/pimento	0.5/0.5	0.01	0.05%	Caraway	0.5/0.5	0.01

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Ginger/jam	0.1/0.68	2.1	4%	Ginger/jam	0.1/0.68	0.85
0.6%	Wheat/milling (flour)	0.05/0.01	0.12	0.2%	Wheat/bread/pizza	0.05/0.01	0.04
0.5%	Olives for oil production/oils	3/0.1	0.09	0.2%	Wheat/pasta	0.05/0.01	0.04
0.3%	Wheat/milling (wholemeal)-baking	0.05/0.01	0.06	0.2%	Wheat/bread (wholemeal)	0.05/0.01	0.03
0.2%	Rye/boiled	0.02/0.01	0.04	0.1%	Table olives/canned	3/0.02	0.03
0.2%	Rye/milling (wholemeal)-baking	0.02/0.01	0.04	0.1%	Cumin seed/processed (not specified)	5/0.68	0.02
0.1%	Table olives/canned	3/0.02	0.02	0.01%	Turmeric (Curcuma)/boiled	0.1/0.1	0.00

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Dimethoate is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Fenazaquin

Status of the active substance:	0.01	Code no.	0.01
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:	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
17 88

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)
87.8	DE child	24.1	Apples	12.9	Oranges	9.8	Strawberries	
72.0	WHO Cluster diet B	30.8	Tomatoes	5.0	Peppers	4.2	Peaches	
64.1	NL child	12.7	Apples	10.6	Oranges	6.8	Bananas	
57.1	IE adult	10.5	Tea (dried leaves and stalks,	5.7	Peaches	5.0	Strawberries	
55.4	FR toddler	12.5	Strawberries	7.9	Milk and cream,	7.7	Tomatoes	
41.6	UK Toddler	6.7	Oranges	5.9	Tomatoes	4.6	Sugar beet (root)	
41.0	UK Infant	7.7	Milk and cream,	5.8	Bananas	4.6	Tea (dried leaves and stalks,	
37.8	ES child	9.8	Tomatoes	7.4	Oranges	4.0	Bananas	
37.7	SE general population 90th percentile	7.7	Tomatoes	7.2	Bananas	3.3	Strawberries	
36.8	DK child	6.5	Cucumbers	5.3	Tomatoes	4.6	Apples	
36.1	FR infant	9.8	Strawberries	5.1	Milk and cream,	5.0	Apples	
34.1	IT kids/toddler	14.3	Tomatoes	3.5	Peaches	2.4	Strawberries	
33.3	WHO regional European diet	11.0	Tomatoes	3.0	Tea (dried leaves and stalks,	2.1	Peaches	
29.1	WHO cluster diet D	10.1	Tomatoes	2.8	Tea (dried leaves and stalks,	1.3	Apples	
28.1	IT adult	11.6	Tomatoes	3.8	Peaches	1.6	Apples	
28.0	WHO cluster diet E	5.3	Tomatoes	2.6	Tea (dried leaves and stalks,	1.7	Strawberries	
27.7	PT General population	9.0	Tomatoes	3.6	Peaches	2.1	Apples	
27.0	ES adult	7.8	Tomatoes	4.4	Oranges	2.1	Peaches	
24.4	WHO Cluster diet F	6.8	Tomatoes	3.0	Oranges	2.3	Bananas	
24.2	UK vegetarian	6.2	Tomatoes	3.9	Tea (dried leaves and stalks,	2.9	Oranges	
23.3	NL general	5.1	Oranges	4.3	Tomatoes	2.4	Apples	
20.9	FR all population	4.3	Tomatoes	3.2	Wine grapes	1.8	Strawberries	
19.9	PL general population	8.8	Tomatoes	4.1	Apples	1.0	Plums	
19.3	UK Adult	4.4	Tomatoes	4.3	Tea (dried leaves and stalks,	1.9	Oranges	
17.6	DK adult	4.1	Tomatoes	1.6	Apples	1.5	Bananas	
17.0	FI adult	4.3	Tomatoes	3.3	Oranges	1.5	Strawberries	
16.6	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)
2.484	Milk and milk products:	0.02/-	2.484	Milk and milk	0.02/-	0.345	Milk and milk	0.02/-	0.345	Milk and milk products: Cattle	0.02/-
0.5	Milk and milk products:	0.02/-	0.5	Milk and milk	0.02/-	0.1	Milk and milk	0.02/-	0.1	Milk and milk products: Goat	0.02/-
0.3	Bovine: Meat	0.02/-	0.3	Bovine: Meat	0.02/-	0.1	Bovine: Meat	0.02/-	0.1	Bovine: Meat	0.02/-
0.3	Meat, preparations of	0.02/-	0.3	Meat, preparations	0.02/-	0.1	Swine: Meat	0.02/-	0.1	Swine: Meat	0.02/-
0.2	Sheep: Meat	0.02/-	0.2	Sheep: Meat	0.02/-	0.1	Sheep: Meat	0.02/-	0.1	Sheep: Meat	0.02/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---		**No of commodities for which ARfD/ADI is exceeded:**		---	
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
24.8	Orange juice	0.5/-		5.0	Orange juice	0.5/-	
9.0	Peach juice	0.5/-		1.0	Peach preserved with syrup	0.5/-	
8.7	Tomato juice	0.5/-		1.0	Tomato (preserved-	0.5/-	
6.6	Grape juice	0.2/-		0.8	Wine	0.2/-	
5.1	Apple juice	0.1/-		0.7	Apple juice	0.1/-	

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

Conclusion:

For 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flonicamid

LOQs (mg/kg) range from:	0.02	to:	6.0

Toxicological reference values

ADI (mg/kg bw per day):	0.025	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA, EC	Source of ARfD:	EFSA, EC
Year of evaluation:	2010	Year of evaluation:	2010

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
31%	NL toddler	7.81	12%	Milk: Cattle	6%	Wheat	3%	Beans (with pods)		31%
21%	DK child	5.31	8%	Rye	6%	Wheat	3%	Milk: Cattle		21%
21%	DE child	5.24	6%	Wheat	4%	Milk: Cattle	3%	Apples		21%
19%	FR child 3 15 yr	4.80	6%	Wheat	5%	Milk: Cattle	2%	Beans (with pods)		19%
19%	NL child	4.78	6%	Wheat	5%	Milk: Cattle	1%	Apples		19%
18%	FR toddler 2 3 yr	4.44	6%	Milk: Cattle	4%	Wheat	3%	Beans (with pods)		18%
18%	UK infant	4.39	8%	Milk: Cattle	4%	Wheat	1%	Peas (without pods)		18%
17%	GEMS/Food G06	4.30	10%	Wheat	2%	Tomatoes	0.5%	Milk: Cattle		17%
16%	UK toddler	4.00	5%	Wheat	4%	Milk: Cattle	1%	Beans		16%
15%	RO general	3.70	7%	Wheat	2%	Milk: Cattle	0.9%	Potatoes		15%
14%	ES child	3.59	6%	Wheat	2%	Milk: Cattle	1.0%	Oranges		14%
14%	GEMS/Food G15	3.48	6%	Wheat	1%	Milk: Cattle	0.9%	Potatoes		14%
13%	GEMS/Food G08	3.36	6%	Wheat	1%	Milk: Cattle	0.9%	Potatoes		13%
13%	SE general	3.34	4%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat		13%
13%	GEMS/Food G07	3.33	6%	Wheat	1%	Milk: Cattle	0.9%	Potatoes		13%
13%	GEMS/Food G10	3.14	5%	Wheat	1%	Milk: Cattle	0.7%	Potatoes		13%
12%	GEMS/Food G11	3.12	5%	Wheat	2%	Milk: Cattle	0.9%	Potatoes		12%
12%	IT toddler	3.04	9%	Wheat	0.6%	Tomatoes	0.3%	Beans (with pods)		12%
11%	IE adult	2.80	3%	Wheat	0.9%	Milk: Cattle	0.6%	Beans (with pods)		11%
11%	DE women 14-50 yr	2.74	3%	Wheat	2%	Milk: Cattle	0.9%	Oranges		11%
11%	DE general	2.69	3%	Wheat	2%	Milk: Cattle	0.8%	Rye		11%
10%	PT general	2.44	5%	Wheat	1%	Potatoes	0.6%	Beans (without pods)		10%
9%	NL general	2.27	3%	Wheat	2%	Milk: Cattle	0.8%	Beans (with pods)		9%
9%	FR infant	2.15	3%	Milk: Cattle	2%	Beans (with pods)	1%	Wheat		9%
9%	ES adult	2.13	3%	Wheat	1.0%	Milk: Cattle	0.8%	Beans (with pods)		9%
8%	IT adult	2.11	6%	Wheat	0.5%	Beans (with pods)	0.5%	Tomatoes		8%
7%	FR adult	1.84	3%	Wheat	0.9%	Milk: Cattle	0.8%	Beans (with pods)		7%
7%	FI 3 yr	1.68	2%	Wheat	1%	Potatoes	0.9%	Rye		7%
7%	LT adult	1.67	2%	Rye	1%	Wheat	0.8%	Milk: Cattle		7%
7%	UK vegetarian	1.63	3%	Wheat	0.7%	Milk: Cattle	0.6%	Beans		7%
6%	DK adult	1.42	2%	Wheat	1%	Milk: Cattle	0.7%	Rye		6%
5%	FI 6 yr	1.37	1%	Wheat	0.9%	Potatoes	0.9%	Rye		5%
5%	UK adult	1.35	2%	Wheat	0.6%	Milk: Cattle	0.3%	Beans		5%
3%	IE child	0.80	2%	Wheat	0.7%	Milk: Cattle	0.2%	Beans (without pods)		3%
3%	FI adult	0.79	1.0%	Rye	0.4%	Wheat	0.3%	Potatoes		3%
3%	PL general	0.67	0.8%	Potatoes	0.5%	Apples	0.4%	Tomatoes		3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flonicamid is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 3

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
127%	Oranges	0.4/0.24	32	63%	Peas (without pods)	5/2.94	16
114%	Peaches	0.4/0.3	29	46%	Beans (without pods)	5/2.94	12
105%	Pears	0.3/0.19	26	43%	Beans (with pods)	3/1.41	11
97%	Lemons	1.5/0.71	24	39%	Head cabbages	0.5/0.23	9.7
96%	Peas (without pods)	5/2.94	24	38%	Cucumbers	0.6/0.34	9.5
93%	Beans (without pods)	5/2.94	23	37%	Aubergines/egg plants	0.5/0.34	9.2
89%	Cucumbers	0.6/0.34	22	32%	Courgettes	0.6/0.34	7.9
85%	Melons	0.4/0.14	21	29%	Oranges	0.4/0.24	7.4
82%	Apples	0.3/0.19	20	28%	Peas (with pods)	3/2.03	6.9
79%	Tomatoes	0.5/0.34	20	25%	Lemons	1.5/0.71	6.4
68%	Watermelons	0.4/0.14	17	23%	Pears	0.3/0.19	5.8
68%	Potatoes	0.2/0.11	17	23%	Watermelons	0.4/0.14	5.7
66%	Peas (with pods)	3/2.03	17	22%	Peaches	0.4/0.3	5.6
64%	Beans (with pods)	3/1.41	16	22%	Melons	0.4/0.14	5.5
63%	Courgettes	0.6/0.34	16	22%	Tomatoes	0.5/0.34	5.4

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 3

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
71%	Beans (with pods)/boiled	3/1.41	18	61%	Beans (without pods)/boiled	5/2.94	15
50%	Pumpkins/boiled	0.4/0.14	12	37%	Peas (without pods)/boiled	5/2.94	9.2
48%	Courgettes/boiled	0.6/0.34	12	31%	Courgettes/boiled	0.6/0.34	7.8
41%	Potatoes/fried	0.2/0.11	10	31%	Pumpkins/boiled	0.4/0.14	7.7
31%	Gherkins/pickled	0.6/0.34	7.8	28%	Peas (with pods)/boiled	3/2.03	6.9
31%	Peaches/canned	0.4/0.3	7.8	23%	Beetroots/boiled	0.3/0.15	5.8
30%	Turnips/boiled	0.3/0.15	7.6	13%	Parsnips/boiled	0.3/0.15	3.2
30%	Parsnips/boiled	0.3/0.15	7.6	12%	Currants (red, black and white)/juice	0.8/0.23	2.9
27%	Beetroots/boiled	0.3/0.15	6.7	11%	Turnips/boiled	0.3/0.15	2.9
26%	Currants (red, black and white)/juice	0.8/0.23	6.6	11%	Beans/canned	2/0.39	2.8
24%	Oranges/juice	0.4/0.12	6.1	11%	Celeriacs/boiled	0.3/0.15	2.7
18%	Peas (without pods)/canned	5/0.55	4.4	10%	Peaches/canned	0.4/0.3	2.5
17%	Wheat/milling (flour)	2/0.35	4.2	8%	Apples/juice	0.3/0.06	2.0
17%	Raspberries/juice	1/0.36	4.2	7%	Oranges/juice	0.4/0.12	1.7
15%	Salsifies/boiled	0.3/0.15	3.9	6%	Wheat/bread/pizza	2/0.35	1.5

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 3 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fluazifop-p-butyl

LOQs (mg/kg) range from:	0.01	to:	0.08
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.017
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 2

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
142%	GEMS/Food G11	14.20	139%	Soyabeans	0.7%	Strawberries	0.4%	Potatoes		142%
132%	GEMS/Food G10	13.19	122%	Soyabeans	6%	Rapeseeds/canola seeds	0.8%	Strawberries		132%
84%	GEMS/Food G08	8.44	74%	Soyabeans	8%	Rapeseeds/canola seeds	0.6%	Strawberries		84%
83%	GEMS/Food G07	8.27	66%	Soyabeans	13%	Rapeseeds/canola seeds	0.8%	Peas (with pods)		83%
73%	GEMS/Food G15	7.29	65%	Soyabeans	5%	Rapeseeds/canola seeds	0.4%	Peas (with pods)		73%
52%	GEMS/Food G06	5.15	46%	Soyabeans	1%	Sugar beet roots	0.8%	Rapeseeds/canola seeds		52%
41%	NL toddler	4.10	22%	Rapeseeds/canola seeds	6%	Soyabeans	5%	Sugar beet roots		41%
32%	NL child	3.16	11%	Rapeseeds/canola seeds	8%	Sugar beet roots	8%	Soyabeans		32%
16%	NL general	1.62	6%	Rapeseeds/canola seeds	5%	Soyabeans	3%	Sugar beet roots		16%
14%	PT general	1.39	11%	Soyabeans	0.5%	Potatoes	0.4%	Peas (without pods)		14%
10%	FR child 3 15 yr	1.04	4%	Sugar beet roots	2%	Strawberries	1%	Soyabeans		10%
10%	FR toddler 2 3 yr	0.98	3%	Sugar beet roots	2%	Beans (with pods)	2%	Soyabeans		10%
9%	IE adult	0.88	3%	Linseeds	1%	Strawberries	0.6%	Peas		9%
8%	DE women 14-50 yr	0.81	5%	Sugar beet roots	1%	Soyabeans	0.8%	Strawberries		8%
8%	UK toddler	0.80	3%	Sugar beet roots	2%	Beans	1%	Strawberries		8%
8%	DE child	0.78	3%	Strawberries	2%	Soyabeans	0.5%	Carrots		8%
8%	DE general	0.77	4%	Sugar beet roots	1%	Soyabeans	0.7%	Strawberries		8%
7%	UK infant	0.67	1%	Strawberries	1%	Sugar beet roots	1%	Peas (without pods)		7%
6%	FI 3 yr	0.65	2%	Strawberries	2%	Rapeseeds/canola seeds	0.5%	Potatoes		6%
6%	FR infant	0.56	1%	Sugar beet roots	1%	Beans (with pods)	1%	Strawberries		6%
5%	FI 6 yr	0.51	2%	Strawberries	1%	Rapeseeds/canola seeds	0.4%	Potatoes		5%
4%	FR adult	0.43	0.8%	Strawberries	0.8%	Sugar beet roots	0.6%	Soyabeans		4%
4%	RO general	0.41	1%	Sugar beet roots	0.5%	Onions	0.4%	Potatoes		4%
4%	SE general	0.36	1%	Strawberries	0.4%	Carrots	0.4%	Potatoes		4%
3%	ES child	0.33	0.6%	Beans (with pods)	0.5%	Lentils	0.5%	Strawberries		3%
3%	UK vegetarian	0.30	0.8%	Beans	0.5%	Sugar beet roots	0.5%	Strawberries		3%
3%	FI adult	0.27	1.0%	Strawberries	0.8%	Soyabeans	0.2%	Carrots		3%
3%	IT toddler	0.25	0.8%	Strawberries	0.3%	Beans (with pods)	0.2%	Peas (without pods)		3%
2%	ES adult	0.25	0.6%	Beans (with pods)	0.4%	Strawberries	0.2%	Lentils		2%
2%	DK child	0.24	1.0%	Strawberries	0.7%	Carrots	0.2%	Potatoes		2%
2%	UK adult	0.22	0.6%	Sugar beet roots	0.5%	Beans	0.3%	Strawberries		2%
2%	IT adult	0.19	0.4%	Beans (with pods)	0.4%	Strawberries	0.2%	Peas (without pods)		2%
1%	DK adult	0.14	0.5%	Strawberries	0.3%	Peas (without pods)	0.2%	Carrots		1%
1%	PL general	0.13	0.3%	Potatoes	0.2%	Onions	0.2%	Carrots		1%
0.9%	LT adult	0.09	0.3%	Potatoes	0.3%	Strawberries	0.1%	Carrots		0.9%
0.4%	IE child	0.04	0.2%	Strawberries	0.1%	Carrots	0.1%	Potatoes		0.4%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 142 % of the ADI.
For 2 diet(s) the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
144%	Strawberries	3/1.5	25	121%	Soyabeans	15/3.75	21
103%	Tomatoes	0.06/0.3	17	96%	Aubergines/egg plants	1/0.6	16
97%	Beetroots	0.5/0.29	17	82%	Strawberries	3/1.5	14
90%	Potatoes	0.15/0.1	15	58%	Swedes/rutabagas	0.5/0.29	9.9
90%	Carrots	0.4/0.24	15	40%	Globe artichokes	0.9/0.53	6.9
88%	Swedes/rutabagas	0.5/0.29	15	39%	Beetroots	0.5/0.29	6.7
88%	Aubergines/egg plants	1/0.6	15	38%	Beans (with pods)	1.5/0.84	6.5
62%	Parsnips	0.5/0.29	10	28%	Tomatoes	0.06/0.3	4.8
61%	Turnips	0.5/0.29	10	28%	Carrots	0.4/0.24	4.7
56%	Beans (with pods)	1.5/0.84	9.6	26%	Peas (without pods)	1.5/0.84	4.5
55%	Celeriacs/turnip rooted	0.5/0.17	9.4	24%	Parsnips	0.5/0.29	4.1
55%	Globe artichokes	0.9/0.53	9.3	20%	Peas (with pods)	2/1	3.4
53%	Salsifies	0.5/0.29	9.0	19%	Turnips	0.5/0.29	3.2
51%	Soyabeans	15/3.75	8.7	18%	Salsifies	0.5/0.29	3.1
48%	Peas (with pods)	2/1	8.2	18%	Radishes	0.5/0.29	3.0

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 3

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
92%	Soyabeans/soya drink	15/3.75	16	66%	Beetroots/boiled	0.5/0.29	11
87%	Turnips/boiled	0.5/0.29	15	36%	Parsnips/boiled	0.5/0.29	6.2
87%	Parsnips/boiled	0.5/0.29	15	33%	Turnips/boiled	0.5/0.29	5.5
76%	Beetroots/boiled	0.5/0.29	13	26%	Celeries/boiled	0.3/0.13	4.4
65%	Sugar beets (root)/sugar	0.5/1.2	11	26%	Sugar beets (root)/sugar	0.5/1.2	4.4
62%	Beans (with pods)/boiled	1.5/0.84	11	20%	Peas (with pods)/boiled	2/1	3.4
55%	Potatoes/fried	0.15/0.1	9.3	18%	Celeriacs/boiled	0.5/0.17	3.1
44%	Salsifies/boiled	0.5/0.29	7.5	15%	Peas (without pods)/boiled	1.5/0.84	2.6
44%	Jerusalem artichokes/boiled	0.5/0.29	7.4	15%	Florence fennels/boiled	0.3/0.13	2.5
35%	Florence fennels/boiled	0.3/0.13	5.9	14%	Salsifies/boiled	0.5/0.29	2.4
32%	Soyabeans/boiled	15/1.5	5.4	14%	Jerusalem artichokes/	0.5/0.29	2.4
29%	Rhubarbs/sauce/puree	0.3/0.13	4.8	11%	Rhubarbs/sauce/puree	0.3/0.13	1.9
18%	Shallots/boiled	0.3/0.19	3.1	11%	Onions/boiled	0.3/0.19	1.8
11%	Peas (without pods)/canned	1.5/0.23	1.8	9%	Cardoons/boiled	0.3/0.13	1.6
11%	Carrots/juice	0.4/0.05	1.8	9%	Beans/canned	4/0.22	1.6

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 3 commodities.

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

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EFSA PRIMo revision 3.1; 2019/03/19

Fluensulfone			
LOQs (mg/kg) range from:	0.025	to:	0.03
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.3
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	NL toddler	0.15	0.7%	Maize/corn	0.4%	Wheat	0.2%	Oranges		2%
1%	GEMS/Food G06	0.14	0.7%	Wheat	0.2%	Sugar canes	0.2%	Rice		1%
1.0%	DE child	0.10	0.4%	Wheat	0.4%	Oranges	0.0%	Mandarins		1.0%
1.0%	GEMS/Food G10	0.10	0.4%	Wheat	0.1%	Sugar canes	0.1%	Rice		1.0%
0.9%	FR child 3 15 yr	0.09	0.5%	Wheat	0.3%	Oranges	0.0%	Rice		0.9%
0.9%	GEMS/Food G07	0.09	0.4%	Wheat	0.2%	Sugar canes	0.1%	Oranges		0.9%
0.9%	GEMS/Food G15	0.09	0.5%	Wheat	0.1%	Sugar canes	0.1%	Barley		0.9%
0.9%	GEMS/Food G11	0.09	0.4%	Wheat	0.2%	Sugar canes	0.1%	Barley		0.9%
0.9%	GEMS/Food G08	0.09	0.4%	Wheat	0.2%	Sugar canes	0.1%	Barley		0.9%
0.8%	IT toddler	0.08	0.7%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.8%
0.8%	ES child	0.08	0.4%	Wheat	0.2%	Oranges	0.0%	Rice		0.8%
0.7%	NL child	0.07	0.4%	Wheat	0.1%	Oranges	0.1%	Mandarins		0.7%
0.7%	UK toddler	0.07	0.4%	Wheat	0.2%	Oranges	0.1%	Rice		0.7%
0.7%	RO general	0.07	0.5%	Wheat	0.1%	Maize/corn	0.0%	Oranges		0.7%
0.6%	FR toddler 2 3 yr	0.06	0.3%	Wheat	0.1%	Oranges	0.1%	Mandarins		0.6%
0.6%	PT general	0.06	0.4%	Wheat	0.1%	Rice	0.1%	Oranges		0.6%
0.6%	UK infant	0.06	0.3%	Wheat	0.1%	Oranges	0.1%	Maize/corn		0.6%
0.6%	IE adult	0.06	0.2%	Wheat	0.1%	Oranges	0.1%	Grapefruits		0.6%
0.5%	DK child	0.05	0.4%	Wheat	0.0%	Rice	0.0%	Oranges		0.5%
0.5%	SE general	0.05	0.3%	Wheat	0.1%	Oranges	0.0%	Mandarins		0.5%
0.5%	IT adult	0.05	0.4%	Wheat	0.0%	Oranges	0.0%	Rice		0.5%
0.5%	DE women 14-50 yr	0.05	0.2%	Wheat	0.2%	Oranges	0.0%	Lemons		0.5%
0.5%	ES adult	0.05	0.2%	Wheat	0.1%	Oranges	0.0%	Barley		0.5%
0.5%	DE general	0.05	0.2%	Wheat	0.2%	Oranges	0.1%	Barley		0.5%
0.4%	NL general	0.04	0.2%	Wheat	0.1%	Oranges	0.0%	Barley		0.4%
0.4%	UK vegetarian	0.04	0.2%	Wheat	0.1%	Oranges	0.0%	Rice		0.4%
0.3%	FR adult	0.03	0.2%	Wheat	0.1%	Oranges	0.0%	Rice		0.3%
0.3%	UK adult	0.03	0.2%	Wheat	0.1%	Oranges	0.0%	Rice		0.3%
0.2%	FI 3 yr	0.02	0.1%	Wheat	0.1%	Rice	0.0%	Mandarins		0.2%
0.2%	FI 6 yr	0.02	0.1%	Wheat	0.0%	Rice	0.0%	Mandarins		0.2%
0.2%	IE child	0.02	0.1%	Wheat	0.0%	Rice	0.0%	Oranges		0.2%
0.1%	DK adult	0.01	0.1%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.1%
0.1%	LT adult	0.01	0.1%	Wheat	0.0%	Rice	0.0%	Oranges		0.1%
0.1%	FR infant	0.01	0.1%	Wheat	0.0%	Oranges	0.0%	Mandarins		0.1%
0.1%	FI adult	0.01	0.0%	Oranges	0.0%	Wheat	0.0%	Mandarins		0.1%
0.0%	PL general	0.00	0.0%	Lemons	0.0%	Mandarins	0.0%	Walnuts		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluensulfone is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Oranges	0.2/0.06	8.4	0.8%	Sweet corn	0.15/0.15	2.4
2%	Sweet corn	0.15/0.15	6.5	0.6%	Oranges	0.2/0.06	1.9
2%	Grapefruits	0.2/0.06	4.9	0.4%	Mandarins	0.2/0.06	1.1
1%	Mandarins	0.2/0.06	3.7	0.4%	Grapefruits	0.2/0.06	1.1
0.7%	Lemons	0.2/0.06	2.2	0.2%	Lemons	0.2/0.06	0.56
0.4%	Limes	0.2/0.06	1.3	0.1%	Limes	0.2/0.06	0.44
0.05%	Wheat	0.08/0.01	0.14	0.03%	Coconuts	0.03/0.01	0.09
0.05%	Coconuts	0.03/0.01	0.14	0.03%	Rice	0.04/0.01	0.09
0.04%	Rice	0.04/0.01	0.13	0.03%	Wheat	0.08/0.01	0.08
0.02%	Maize/corn	0.15/0.01	0.07	0.02%	Barley	0.08/0.01	0.05
0.02%	Pistachios	0.03/0.01	0.06	0.02%	Chestnuts	0.03/0.01	0.05
0.02%	Barley	0.08/0.01	0.06	0.01%	Pistachios	0.03/0.01	0.03
0.01%	Chestnuts	0.03/0.01	0.04	0.01%	Pecans	0.03/0.01	0.02
0.01%	Walnuts	0.03/0.01	0.03	0.01%	Walnuts	0.03/0.01	0.02
0.01%	Hazelnuts/cobnuts	0.03/0.01	0.03	0.01%	Maize/corn	0.15/0.01	0.02

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Wine grapes/juice	0.7/0.7	31	5%	Wine grapes/juice	0.7/0.7	15
4%	Apples/juice	0.2/0.2	11	2%	Apples/juice	0.2/0.2	6.7
2%	Pears/juice	0.2/0.2	6.5	2%	Wine grapes/wine	0.7/0.7	6.6
0.8%	Peaches/canned	0.09/0.09	2.3	1%	Table grapes/raisins	0.7/3.29	4.0
0.5%	Peaches/juice	0.09/0.09	1.5	0.2%	Peaches/canned	0.09/0.09	0.74
0.3%	Plums/juice	0.09/0.09	0.85	0.08%	Quinces/jam	0.2/0.2	0.25
0.2%	Quinces/jam	0.2/0.2	0.61	0.08%	Coffee beans/extraction	0.05/0.01	0.24
0.2%	Oranges/juice	0.2/0.01	0.53	0.05%	Oranges/juice	0.2/0.01	0.15
0.1%	Maize/oil	0.15/0.25	0.23	0.04%	Maize/oil	0.15/0.25	0.13
0.0%	Wheat/milling (flour)	0.08/0.01	0.12	0.04%	Grapefruits/juice	0.2/0.01	0.11
0.0%	Coffee beans/extraction	0.05/0.01	0.09	0.02%	Barley/beer	0.08/0	0.07
0.0%	Sugar canes/sugar	0.06/0.01	0.09	0.02%	Sugar canes/sugar	0.06/0.01	0.06
0.0%	Coconuts/drink	0.03/0.01	0.09	0.01%	Wheat/bread/pizza	0.08/0.01	0.04
0.0%	Rice/milling (polishing)	0.04/0	0.06	0.01%	Rice/milling (polishing)	0.04/0	0.04
0.0%	Wheat/milling (wholemeal)-baking	0.08/0.01	0.06	0.01%	Wheat/pasta	0.08/0.01	0.04

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fluensulfone is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/08/18

Flupyradifurone and DFA, expressed as flupyradifurone

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	**0.064**	ARfD (mg/kg bw):	**0.15**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2015**	Year of evaluation:	**2015**

Input values

Details – chronic risk

Supplementary results –

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
50%	NL toddler	32.02	20%	Milk: Cattle	6%	Wheat	4%	Apples		0.4%
29%	GEMS/Food G06	18.49	11%	Wheat	4%	Tomatoes	1%	Watermelons		0.1%
28%	DE child	17.98	6%	Milk: Cattle	6%	Wheat	4%	Apples		0.2%
28%	UK infant	17.71	13%	Milk: Cattle	4%	Wheat	3%	Beans		0.1%
27%	FR child 3 15 yr	17.33	8%	Milk: Cattle	7%	Wheat	1%	Bovine: Muscle/meat		0.1%
26%	NL child	16.87	8%	Milk: Cattle	6%	Wheat	2%	Apples		0.4%
25%	UK toddler	16.06	7%	Milk: Cattle	6%	Wheat	5%	Beans		0.3%
25%	FR toddler 2 3 yr	15.86	10%	Milk: Cattle	4%	Wheat	1%	Beans (with pods)		0.1%
24%	DK child	15.11	6%	Wheat	4%	Milk: Cattle	4%	Rye		0.0%
23%	RO general	14.71	7%	Wheat	4%	Milk: Cattle	2%	Tomatoes		
23%	GEMS/Food G15	14.64	7%	Wheat	2%	Milk: Cattle	1%	Tomatoes		0.2%
23%	ES child	14.51	6%	Wheat	4%	Milk: Cattle	1%	Lentils		0.1%
22%	GEMS/Food G07	14.13	6%	Wheat	2%	Milk: Cattle	1%	Wine grapes		0.1%
22%	GEMS/Food G08	13.98	6%	Wheat	2%	Milk: Cattle	2%	Barley		0.2%
22%	GEMS/Food G10	13.96	6%	Wheat	2%	Milk: Cattle	2%	Tomatoes		0.1%
22%	GEMS/Food G11	13.86	5%	Wheat	3%	Milk: Cattle	1%	Potatoes		0.2%
21%	SE general	13.45	5%	Wheat	4%	Milk: Cattle	4%	Bovine: Muscle/meat		0.1%
21%	IE adult	13.43	3%	Wheat	2%	Peas	1%	Milk: Cattle		0.4%
17%	IT toddler	10.86	10%	Wheat	2%	Tomatoes	1%	Other cereals		0.0%
16%	PT general	10.51	6%	Wheat	2%	Wine grapes	2%	Potatoes		
15%	DE women 14-50 yr	9.55	4%	Milk: Cattle	3%	Wheat	0.9%	Tomatoes		0.3%
15%	DE general	9.53	4%	Milk: Cattle	3%	Wheat	0.9%	Barley		0.3%
15%	ES adult	9.28	3%	Wheat	2%	Milk: Cattle	1.0%	Lettuces		0.0%
14%	NL general	8.82	3%	Wheat	3%	Milk: Cattle	0.8%	Potatoes		0.2%
13%	FR adult	8.50	3%	Wheat	2%	Wine grapes	1%	Milk: Cattle		0.2%
13%	FR infant	8.21	6%	Milk: Cattle	1%	Wheat	0.9%	Beans (with pods)		0.0%
13%	IT adult	8.03	6%	Wheat	1%	Tomatoes	0.7%	Lettuces		0.0%
11%	UK vegetarian	7.33	3%	Wheat	2%	Beans	1%	Milk: Cattle		0.1%
10%	FI 3 yr	6.48	2%	Wheat	2%	Potatoes	1%	Cucumbers		0.5%
10%	UK adult	6.21	2%	Wheat	1%	Beans	1%	Wine grapes		0.1%
9%	DK adult	5.82	2%	Milk: Cattle	2%	Wheat	0.9%	Wine grapes		0.0%
9%	FI 6 yr	5.53	1%	Wheat	1%	Potatoes	0.8%	Cucumbers		0.3%
9%	LT adult	5.47	2%	Wheat	1%	Milk: Cattle	1%	Potatoes		0.0%
7%	FI adult	4.61	3%	Coffee beans	0.6%	Tomatoes	0.5%	Rye		3%
5%	PL general	3.14	1%	Potatoes	1%	Tomatoes	0.7%	Apples		0.0%
4%	IE child	2.76	2%	Wheat	1%	Milk: Cattle	0.2%	Potatoes		0.0%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Flupyradifurone and DFA, expressed as flupyradifurone is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
31%	Blackberries	0/4.3	46
26%	Raspberries (red and yellow)	0/4.3	40
12%	Avocados	0/0.36	18
5%	Dewberries	0/4.3	7.6
0.2%	Cocoa beans	0/0.11	0.35
0.2%	HOPS (dried)	0/8.1	0.34

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Blackberries	0/4.3	35
15%	Raspberries (red and yellow)	0/4.3	23
4%	Dewberries	0/4.3	6.2
4%	Avocados	0/0.36	5.4
1.0%	HOPS (dried)	0/8.1	1.5
0.1%	Cocoa beans	0/0.11	0.19

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
11%	Raspberries/juice	0/1.4	16
0.4%	Coffee beans/extraction	0/0.06	0.55
0.1%	Cocoa (fermented beans)/processed (not specified)	0/0	0.08

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Coffee beans/extraction	0/0.06	1.4
0.3%	Hops/beer	0/0.01	0.51
0.03%	Cocoa (fermented beans)/processed (not specified)	0/0	0.05

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Flupyradifurone and DFA, expressed as flupyradifurone is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluxapyroxad

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
61%	NL toddler	12.25	15%	Apples	6%	Pears	4%	Oranges	0.2%	6%
46%	DE child	9.17	17%	Apples	8%	Oranges	3%	Table grapes	0.2%	9%
38%	NL child	7.53	8%	Apples	5%	Sugar beet roots	3%	Oil palm fruits	0.1%	4%
30%	GEMS/Food G06	5.99	7%	Rice	4%	Wheat	2%	Table grapes	0.1%	3%
28%	FR child 3 15 yr	5.66	7%	Oranges	3%	Wheat	2%	Apples	0.2%	7%
28%	GEMS/Food G11	5.57	3%	Sugar canes	2%	Wine grapes	2%	Celeries	0.1%	3%
27%	GEMS/Food G07	5.37	3%	Wine grapes	3%	Oranges	2%	Wheat	0.1%	4%
26%	GEMS/Food G10	5.16	5%	Rice	2%	Wheat	2%	Oranges	0.1%	3%
24%	FR toddler 2 3 yr	4.85	4%	Apples	3%	Oranges	3%	Rice	0.1%	4%
24%	GEMS/Food G08	4.81	2%	Wine grapes	2%	Barley	2%	Wheat	0.1%	2%
24%	IE adult	4.70	3%	Wine grapes	2%	Oranges	2%	Rhubarbs	0.2%	4%
23%	GEMS/Food G15	4.52	3%	Wheat	2%	Wine grapes	2%	Barley	0.1%	2%
21%	PT general	4.17	6%	Wine grapes	3%	Rice	2%	Potatoes	0.0%	1%
20%	DE women 14-50 yr	4.01	4%	Oranges	4%	Apples	3%	Sugar beet roots	0.1%	4%
20%	UK toddler	4.01	4%	Oranges	2%	Rice	2%	Apples	0.0%	5%
19%	DE general	3.86	3%	Apples	3%	Oranges	3%	Sugar beet roots	0.1%	4%
19%	NL general	3.77	2%	Apples	2%	Oranges	2%	Oil palm fruits	0.1%	2%
19%	DK child	3.75	3%	Apples	3%	Rye	3%	Wheat	0.0%	0.6%
18%	FR adult	3.63	5%	Wine grapes	3%	Other lettuce and other salad plants	1%	Wheat	0.1%	1%
18%	RO general	3.55	4%	Wine grapes	3%	Wheat	2%	Apples	0.0%	0.8%
18%	SE general	3.50	2%	Potatoes	2%	Wheat	2%	Rice	0.0%	3%
18%	UK infant	3.50	3%	Rice	3%	Oranges	2%	Apples	0.0%	3%
17%	ES child	3.48	4%	Oranges	3%	Wheat	2%	Rice	0.2%	5%
16%	IT toddler	3.26	4%	Wheat	2%	Other lettuce and other salad plants	1%	Apples	0.1%	1%
15%	FI 3 yr	3.06	2%	Rice	2%	Potatoes	2%	Oat	0.1%	1%
15%	IT adult	3.02	3%	Other lettuce and other salad plants	2%	Wheat	1%	Apples	0.1%	1%
14%	ES adult	2.73	3%	Oranges	1%	Wheat	1%	Barley	0.1%	3%
12%	FI 6 yr	2.32	2%	Rice	2%	Potatoes	1%	Strawberries	0.1%	0.9%
11%	UK vegetarian	2.24	2%	Wine grapes	2%	Oranges	2%	Rice	0.0%	2%
11%	FR infant	2.23	2%	Apples	2%	Beans (with pods)	0.9%	Potatoes	0.0%	0.8%
10%	UK adult	1.99	3%	Wine grapes	2%	Rice	1%	Oranges	0.0%	1%
9%	DK adult	1.79	2%	Wine grapes	1%	Apples	0.6%	Wheat	0.0%	0.5%
8%	LT adult	1.63	3%	Apples	1%	Potatoes	0.9%	Rice	0.0%	0.2%
8%	PL general	1.56	3%	Apples	2%	Potatoes	0.8%	Table grapes	0.0%	0.2%
8%	FI adult	1.55	0.8%	Coffee beans	0.8%	Apples	0.8%	Oranges	0.0%	1%
4%	IE child	0.79	1%	Rice	0.7%	Wheat	0.5%	Apples	0.0%	0.2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluxapyroxad is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
77%	Celeries	9/5.15	193	38%	Florence fennels	9/5.15	96
77%	Rhubarbs	9/5.15	192	33%	Celeries	9/5.15	82
62%	Bananas	3/1.6	155	21%	Cardoons	9/5.15	53
41%	Table grapes	3/1.4	102	19%	Chinese cabbages/pe-tsai	4/1.9	48
40%	Witloofs/Belgian endives	6/2.5	99	19%	Rhubarbs	9/5.15	48
33%	Florence fennels	9/5.15	84	19%	Table grapes	3/1.4	47
31%	Oranges	1.5/0.59	78	18%	Witloofs/Belgian endives	6/2.5	46
29%	Escaroles/broad-leaved endives	4/1.8	72	15%	Escaroles/broad-leaved endives	4/1.8	36
27%	Lettuces	4/1.8	69	14%	Blueberries	7/3.77	34
26%	Pears	0.9/0.47	65	14%	Bananas	3/1.6	34
24%	Chinese cabbages/pe-tsai	4/1.9	61	13%	Wine grapes	3/1.4	33
24%	Peaches	1.5/0.63	60	12%	Broccoli	2/1.27	30
21%	Broccoli	2/1.27	53	11%	Chards/beet leaves	3/1.44	27
20%	Apples	0.9/0.47	51	9%	Lettuces	4/1.8	22
17%	Papayas	1/1	42	9%	Strawberries	4/2.34	22

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
93%	Florence fennels/boiled	9/5.15	233	70%	Celeries/boiled	9/5.15	174
89%	Witloofs/boiled	6/2.5	222	40%	Florence fennels/boiled	9/5.15	100
77%	Rhubarbs/sauce/puree	9/5.15	192	30%	Rhubarbs/sauce/puree	9/5.15	75
48%	Escaroles/broad-leaved endives/boiled	4/1.8	119	25%	Cardoons/boiled	9/5.15	63
40%	Broccoli/boiled	2/1.27	100	18%	Witloofs/boiled	6/2.5	46
18%	Chards/beet leaves/boiled	3 1.44	45	15%	Escaroles/broad-leaved endives/boiled	4/1.8	37
10%	Leeks/boiled	0.7/0.42	24	12%	Broccoli/boiled	2/1.27	31
8%	Oranges/juice	1.5/0.4	21	7%	Chards/beet leaves/boiled	3/1.44	18
8%	Wine grapes/juice	3/0.47	21	5%	Wine grapes/wine	3/1.4	13
8%	Spinaches/frozen; boiled	3/1.44	20	5%	Spinaches/frozen; boiled	3/1.44	12
7%	Peaches/canned	1.5/0.63	16	4%	Beetroots/boiled	0.9/0.26	10
6%	Apples/juice	0.9/0.28	15	4%	Wine grapes/juice	3/0.47	9.8
5%	Sugar beets (root)/sugar	0.4/1.44	13	4%	Apples/juice	0.9/0.28	9.3
5%	Turnips/boiled	0.9/0.26	13	3%	Table grapes/raisins	3/6.58	8.1
5%	Parsnips/boiled	0.9/0.26	13	3%	Leeks/boiled	0.7/0.42	7.3

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fluxapyroxad is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Glyphosate

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.5**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2015**	Year of evaluation:	**2015**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum–maximum
0 19

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
18.8	UK Toddler	15.1	Sugar beet (root)	2.8	Wheat	0.4	Milk and cream,	
10.2	UK Infant	6.7	Sugar beet (root)	1.9	Wheat	0.8	Milk and cream,	
8.6	WHO Cluster diet B	6.2	Wheat	0.5	Maize	0.4	Sugar beet (root)	
8.2	DK child	4.0	Wheat	3.2	Rye	0.6	Oats	
6.2	WHO cluster diet D	4.7	Wheat	0.3	Barley	0.3	Rye	
5.7	WHO cluster diet E	2.8	Wheat	1.3	Barley	0.4	Rape seed	
5.2	IE adult	2.0	Barley	1.7	Wheat	0.4	Maize	
5.0	WHO Cluster diet F	2.6	Wheat	1.0	Barley	0.6	Rye	
4.9	NL child	3.4	Wheat	0.6	Milk and cream,	0.2	Oats	
4.9	IT kids/toddler	4.8	Wheat	0.0	Barley	0.0	Beans	
4.7	DE child	3.0	Wheat	0.6	Rye	0.3	Oats	
4.4	UK vegetarian	2.5	Sugar beet (root)	1.5	Wheat	0.1	Oats	
4.1	UK Adult	2.6	Sugar beet (root)	1.2	Wheat	0.1	Milk and cream,	
4.0	ES child	3.2	Wheat	0.3	Milk and cream,	0.1	Lentils	
3.5	PT General population	2.8	Wheat	0.1	Rye	0.1	Maize	
3.4	WHO regional European diet	2.1	Wheat	0.5	Barley	0.1	Milk and cream,	
3.1	IT adult	3.0	Wheat	0.0	Barley	0.0	Tomatoes	
3.1	FR toddler	1.9	Wheat	0.8	Milk and cream,	0.1	Potatoes	
3.0	SE general population 90th percentile	2.3	Wheat	0.2	Milk and cream,	0.2	Rye	
2.9	ES adult	1.7	Wheat	0.8	Barley	0.1	Milk and cream,	
2.7	FR all population	2.4	Wheat	0.1	Sunflower seed	0.1	Milk and cream,	
2.6	NL general	1.5	Wheat	0.6	Barley	0.1	Milk and cream,	
2.3	DK adult	1.5	Wheat	0.5	Rye	0.2	Oats	
2.2	LT adult	0.8	Rye	0.8	Wheat	0.2	Buckwheat	
1.6	FI adult	0.7	Wheat	0.5	Rye	0.1	Oats	
1.4	FR infant	0.6	Wheat	0.5	Milk and cream,	0.1	Potatoes	
0.1	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 glyphosate 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)
90.7	Sugar beet (root)	7.1/-	90.7	Sugar beet (root)	7.1/-	36.8	Sugar beet (root)	7.1/-	36.8	Sugar beet (root)	7.1/-
59.5	Wheat	20.6/-	59.5	Wheat	20.6/-	32.2	Wheat	20.6/-	32.2	Wheat	20.6/-
26.0	Rye	20.6/-	26.0	Rye	20.6/-	31.0	Barley	21.4/-	31.0	Barley	21.4/-
21.3	Sweet corn	1.45/-	17.0	Oats	21.4/-	20.0	Rye	20.6/-	20.0	Rye	20.6/-
18.1	Potatoes	0.59/-	15.2	Sweet corn	1.45/-	14.3	Buckwheat	20.6/-	14.3	Buckwheat	20.6/-
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)
48.7	Wheat flour	20.6/-	18.1	Bread/pizza	20.6/-
2.8	Maize flour	3.3/-	0.2	Maize flour	3.3/-
1.6	Potato puree (flakes)	0.59/-	0.1	Potato uree (flakes)	0.59/-
0.5	Apple juice	0.05/-	0.1	Orange juice	0.05/-
0.5	Orange juice	0.05/-	0.1	Fried potatoes	0.59/-

*) 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 glyphosate, 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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Isofetamid

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	1
Source of ADI:	2016/1425	Source of ARfD:	2016/1425
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
24%	DE child	4.89	8%	Apples	5%	Table grapes	2%	Tomatoes		24%
24%	NL toddler	4.82	7%	Apples	5%	Table grapes	3%	Pears		24%
19%	GEMS/Food G06	3.73	9%	Tomatoes	4%	Table grapes	1%	Sweet peppers/bell peppers		19%
16%	RO general	3.22	6%	Wine grapes	5%	Tomatoes	1%	Sweet peppers/bell peppers		16%
15%	PT general	3.09	9%	Wine grapes	2%	Tomatoes	1%	Peaches		15%
14%	NL child	2.87	4%	Apples	4%	Table grapes	1%	Tomatoes		14%
13%	GEMS/Food G15	2.52	4%	Wine grapes	3%	Tomatoes	2%	Sweet peppers/bell peppers		13%
12%	FR adult	2.39	8%	Wine grapes	1%	Tomatoes	0.5%	Peaches		12%
12%	GEMS/Food G07	2.39	5%	Wine grapes	3%	Tomatoes	1%	Table grapes		12%
12%	GEMS/Food G08	2.36	4%	Wine grapes	3%	Tomatoes	1%	Table grapes		12%
12%	IE adult	2.36	4%	Wine grapes	1%	Peaches	1.0%	Tomatoes		12%
11%	DE women 14-50 yr	2.15	3%	Wine grapes	2%	Tomatoes	2%	Apples		11%
10%	GEMS/Food G11	2.01	4%	Wine grapes	2%	Tomatoes	1%	Table grapes		10%
10%	DE general	1.97	3%	Wine grapes	2%	Apples	2%	Tomatoes		10%
9%	GEMS/Food G10	1.85	3%	Tomatoes	1%	Wine grapes	1%	Table grapes		9%
8%	FR child 3 15 yr	1.69	2%	Tomatoes	1%	Wine grapes	1%	Table grapes		8%
8%	IT toddler	1.63	3%	Tomatoes	1%	Peaches	0.6%	Apples		8%
7%	IT adult	1.48	3%	Tomatoes	2%	Peaches	0.5%	Apples		7%
7%	DK adult	1.43	3%	Wine grapes	1%	Tomatoes	0.6%	Apples		7%
7%	ES adult	1.35	2%	Tomatoes	1%	Wine grapes	0.9%	Peaches		7%
7%	DK child	1.34	2%	Apples	1%	Tomatoes	1%	Cucumbers		7%
7%	NL general	1.32	2%	Wine grapes	1%	Tomatoes	1.0%	Apples		7%
6%	FI 3 yr	1.28	1%	Tomatoes	0.9%	Strawberries	0.8%	Table grapes		6%
6%	PL general	1.25	2%	Tomatoes	1%	Apples	1%	Table grapes		6%
6%	UK vegetarian	1.23	3%	Wine grapes	1%	Tomatoes	0.4%	Apples		6%
6%	UK adult	1.21	4%	Wine grapes	1%	Tomatoes	0.3%	Apples		6%
6%	ES child	1.20	2%	Tomatoes	0.8%	Peaches	0.8%	Apples		6%
6%	FR toddler 2 3 yr	1.15	2%	Apples	1%	Tomatoes	0.8%	Wine grapes		6%
6%	SE general	1.13	2%	Tomatoes	0.7%	Apples	0.6%	Peaches		6%
5%	UK toddler	1.10	1%	Tomatoes	1%	Apples	0.9%	Table grapes		5%
5%	FI 6 yr	0.96	1%	Tomatoes	0.7%	Strawberries	0.6%	Table grapes		5%
4%	FI adult	0.85	1%	Tomatoes	1%	Wine grapes	0.4%	Apples		4%
4%	UK infant	0.84	1%	Apples	0.9%	Tomatoes	0.5%	Strawberries		4%
4%	LT adult	0.73	1%	Tomatoes	1%	Apples	0.3%	Cucumbers		4%
3%	FR infant	0.58	1%	Apples	0.4%	Strawberries	0.3%	Courgettes		3%
0.8%	IE child	0.17	0.2%	Apples	0.2%	Table grapes	0.1%	Tomatoes		0.8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Isofetamid is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
43%	Lettuces	20/11.38	433	22%	Chards/beet leaves	20/11.38	215
26%	Spinaches	20/11.38	257	14%	Lettuces	20/11.38	138
23%	Table grapes	4/3.13	228	11%	Table grapes	4/3.13	106
18%	Peaches	3/1.87	178	7%	Wine grapes	4/3.13	74
18%	Chards/beet leaves	20/11.38	178	5%	Spinaches	20/11.38	46
10%	Sweet peppers/bell peppers	3/1.66	99	4%	Cherries (sweet)	4/3.74	37
7%	Apricots	3/1.87	65	4%	Peaches	3/1.87	35
6%	Pears	0.6/0.42	58	3%	Blueberries	4/3.3	30
5%	Tomatoes	1.5/0.94	55	3%	Strawberries	4/3.1	29
5%	Strawberries	4/3.1	51	3%	Sweet peppers/bell peppers	3/1.66	27
5%	Cherries (sweet)	4/3.74	46	3%	Aubergines/egg plants	1.5/0.94	25
5%	Apples	0.6/0.42	45	2%	Currants (red, black and white)	4/3.3	22
4%	Cucumbers	1/0.56	37	2%	Purslanes	20/11.38	22
3%	Wine grapes	4/3.13	29	2%	Apricots	3/1.87	20
3%	Currants (red, black and white)	4/3.3	26	2%	Cucumbers	1/0.56	16

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
35%	Chards/beet leaves/boiled	20/11.38	354	14%	Chards/beet leaves/boiled	20/11.38	142
16%	Spinaches/frozen; boiled	20/11.38	158	9%	Spinaches/frozen; boiled	20/11.38	94
5%	Peaches/canned	1/1.87	49	5%	Purslanes/boiled	20/11.38	47
3%	Wine grapes/juice	4/0.71	31	3%	Wine grapes/wine	4 3.13	30
2%	Courgettes/boiled	1/0.56	20	2%	Table grapes/raisins	4/14.71	18
1%	Peaches/juice	3/0.84	14	1%	Peaches/canned	3/1.87	15
1%	Gherkins/pickled	1/0.56	13	1%	Wine grapes/juice	4/0.71	15
1.0%	Currants (red, black and white)/juice	4/0.34	9.7	1%	Courgettes/boiled	1/0.56	13
0.9%	Tomatoes/juice	1.5/0.48	9.1	0.4%	Apples/juice	0.6/0.14	4.5
0.8%	Raspberries/juice	3/0.68	8.0	0.4%	Currants (red, black and white)/juice	4/0.34	4.3
0.7%	Apples/juice	0.6/0.14	7.3	0.4%	Tomatoes/sauce/puree	1.5/0.48	3.9
0.5%	Tomatoes/sauce/puree	1.5/0.48	4.6	0.3%	Okra, lady's fingers/boiled	3/1.66	2.7
0.5%	Beans (with pods)/boiled	0.6/0.36	4.5	0.1%	Peas (with pods)/boiled	0.6/0.36	1.2
0.4%	Pears/juice	0.6/0.14	4.4	0.04%	Rose hips/jam	4/0.34	0.43
0.3%	Cranberries/juice	4/0.49	2.8	0.04%	Cranberries/dried	4/0.49	0.37

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Isofetamid is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Kresoxim-methyl

LOQs (mg/kg) range from:	0.01	to:	0.15
Toxicological reference values			
ADI (mg/kg bw/day):	0.4	ARfD (mg/kg bw):	Not allocated
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	5.01	0.3%	Apples	0.1%	Milk: Cattle	0.1%	Table grapes		1%
1%	DE child	4.14	0.4%	Apples	0.1%	Wheat	0.1%	Table grapes		1%
0.9%	GEMS/Food G06	3.54	0.3%	Tomatoes	0.2%	Wheat	0.1%	Table grapes		0.9%
0.8%	NL child	3.25	0.2%	Apples	0.1%	Wheat	0.1%	Sugar beet roots		0.8%
0.7%	FR child 3 15 yr	2.77	0.2%	Leeks	0.1%	Wheat	0.1%	Tomatoes		0.7%
0.7%	GEMS/Food G11	2.69	0.2%	Leeks	0.1%	Wheat	0.1%	Wine grapes		0.7%
0.7%	RO general	2.66	0.2%	Wine grapes	0.2%	Wheat	0.2%	Tomatoes		0.7%
0.6%	FR toddler 2 3 yr	2.54	0.2%	Leeks	0.1%	Apples	0.1%	Wheat		0.6%
0.6%	DK child	2.47	0.2%	Rye	0.1%	Wheat	0.1%	Apples		0.6%
0.6%	GEMS/Food G08	2.40	0.1%	Wheat	0.1%	Wine grapes	0.1%	Tomatoes		0.6%
0.6%	GEMS/Food G07	2.30	0.1%	Wine grapes	0.1%	Wheat	0.1%	Tomatoes		0.6%
0.6%	PT general	2.23	0.2%	Wine grapes	0.1%	Wheat	0.1%	Tomatoes		0.6%
0.5%	DE women 14-50 yr	2.16	0.1%	Apples	0.1%	Wine grapes	0.1%	Wheat		0.5%
0.5%	GEMS/Food G15	2.16	0.1%	Wheat	0.1%	Tomatoes	0.1%	Wine grapes		0.5%
0.5%	FR adult	2.12	0.2%	Wine grapes	0.1%	Leeks	0.1%	Wheat		0.5%
0.5%	DE general	2.04	0.1%	Wine grapes	0.1%	Apples	0.1%	Leeks		0.5%
0.5%	IE adult	2.00	0.1%	Wine grapes	0.1%	Leeks	0.1%	Wheat		0.5%
0.5%	GEMS/Food G10	1.84	0.1%	Wheat	0.1%	Tomatoes	0.0%	Wine grapes		0.5%
0.4%	IT toddler	1.75	0.2%	Wheat	0.1%	Tomatoes	0.0%	Peaches		0.4%
0.4%	NL general	1.72	0.1%	Leeks	0.1%	Wheat	0.1%	Wine grapes		0.4%
0.4%	UK toddler	1.66	0.1%	Wheat	0.1%	Milk: Cattle	0.1%	Apples		0.4%
0.4%	ES child	1.65	0.1%	Wheat	0.1%	Tomatoes	0.0%	Apples		0.4%
0.4%	FR infant	1.63	0.2%	Leeks	0.1%	Apples	0.0%	Milk: Cattle		0.4%
0.4%	SE general	1.51	0.1%	Wheat	0.1%	Tomatoes	0.0%	Leeks		0.4%
0.3%	IT adult	1.34	0.1%	Wheat	0.1%	Tomatoes	0.0%	Peaches		0.3%
0.3%	UK infant	1.34	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Apples		0.3%
0.3%	ES adult	1.30	0.1%	Wheat	0.1%	Tomatoes	0.0%	Wine grapes		0.3%
0.3%	DK adult	1.21	0.1%	Wine grapes	0.0%	Tomatoes	0.0%	Wheat		0.3%
0.3%	FI 3 yr	1.16	0.0%	Tomatoes	0.0%	Wheat	0.0%	Strawberries		0.3%
0.3%	UK vegetarian	1.15	0.1%	Wine grapes	0.1%	Wheat	0.0%	Tomatoes		0.3%
0.3%	UK adult	1.02	0.1%	Wine grapes	0.1%	Wheat	0.0%	Tomatoes		0.3%
0.2%	PL general	0.93	0.1%	Tomatoes	0.1%	Apples	0.0%	Leeks		0.2%
0.2%	FI 6 yr	0.89	0.0%	Tomatoes	0.0%	Wheat	0.0%	Strawberries		0.2%
0.2%	LT adult	0.85	0.1%	Apples	0.0%	Tomatoes	0.0%	Rye		0.2%
0.2%	FI adult	0.72	0.0%	Tomatoes	0.0%	Wine grapes	0.0%	Rye		0.2%
0.1%	IE child	0.31	0.0%	Wheat	0.0%	Apples	0.0%	Milk: Cattle		0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Kresoxim-methyl is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
143%	Leeks/boiled	10/10	573	44%	Leeks/boiled	10/10	174
7%	Pumpkins/boiled	0.3/0.3	27	4%	Pumpkins/boiled	0.3/0.3	17
4%	Wine grapes/juice	1/0.37	16	3%	Grape leaves/canned	15/15	12
2%	Currants (red, black and white)/juice	0.9/0.28	8.0	2%	Wine grapes/wine	1/1	9.5
2%	Apples/juice	0.2/0.12	6.5	2%	Wine grapes/juice	1/0.37	7.6
2%	Peaches/juice	0.01/0.37	6.1	1%	Table grapes/raisins	1/4.7	5.8
2%	Tomatoes/juice	0.6/0.32	6.0	1%	Apples/juice	0.2/0.12	4.0
1%	Sugar beets (root)/sugar	0.05/0.6	5.5	0.9%	Currants (red, black and white)/juice	0.9/0.28	3.6
1%	Shallots/boiled	0.3/0.3	4.9	0.7%	Onions/boiled	0.3/0.3	2.8
1.0%	Pears/juice	0.2/0.12	3.9	0.6%	Tomatoes/sauce/puree	0.6/0.32	2.6
0.8%	Tomatoes/sauce/puree	0.6/0.32	3.0	0.5%	Sugar beets (root)/sugar	0.05/0.6	2.2
0.6%	Turnips/boiled	0.05/0.05	2.5	0.5%	Beetroots/boiled	0.05/0.05	1.9
0.6%	Beetroots/boiled	0.05/0.05	2.2	0.5%	Shallots/boiled	0.3/0.3	1.9
0.4%	Courgettes/boiled	0.05/0.05	1.8	0.3%	Courgettes/boiled	0.05/0.05	1.1
0.4%	Cranberries/juice	0.9/0.28	1.6	0.2%	Turnips/boiled	0.05/0.05	0.95

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Kresoxim-methyl is unlikely to present a public health risk.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mandestrobin (F)

LOQs (mg/kg) range from:	0.01	to:	5.0
Toxicological reference values			
ADI (mg/kg bw/day):	0.19	ARfD (mg/kg bw):	3
Source of ADI:	EFSA	Source of ARfD:	JMPR
Year of evaluation:	2015	Year of evaluation:	2018

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	PT general	4.37	2%	Wine grapes	0.2%	Table grapes	0.1%	Peaches		2%
2%	FR adult	3.83	2%	Wine grapes	0.1%	Table grapes	0.1%	Strawberries		2%
2%	DE child	3.11	1%	Table grapes	0.3%	Strawberries	0.1%	Cherries (sweet)		2%
2%	RO general	3.00	1%	Wine grapes	0.1%	Table grapes	0.0%	Cherries (sweet)		2%
2%	NL toddler	2.95	1%	Table grapes	0.2%	Strawberries	0.1%	Peaches		2%
2%	GEMS/Food G07	2.92	1%	Wine grapes	0.3%	Table grapes	0.0%	Peaches		2%
1%	IE adult	2.68	1.0%	Wine grapes	0.2%	Table grapes	0.1%	Strawberries		1%
1%	GEMS/Food G08	2.33	0.8%	Wine grapes	0.3%	Table grapes	0.1%	Peaches		1%
1%	GEMS/Food G11	2.30	0.8%	Wine grapes	0.3%	Table grapes	0.0%	Strawberries		1%
1%	GEMS/Food G15	2.24	0.8%	Wine grapes	0.3%	Table grapes	0.0%	Peaches		1%
1%	NL child	2.11	0.8%	Table grapes	0.2%	Strawberries	0.1%	Peaches		1%
1%	DE women 14-50 yr	2.02	0.7%	Wine grapes	0.2%	Table grapes	0.1%	Strawberries		1%
1%	GEMS/Food G06	1.97	0.8%	Table grapes	0.1%	Peaches	0.1%	Wine grapes		1%
1%	DE general	1.90	0.6%	Wine grapes	0.2%	Table grapes	0.1%	Strawberries		1%
0.9%	DK adult	1.78	0.7%	Wine grapes	0.1%	Table grapes	0.0%	Strawberries		0.9%
0.9%	UK adult	1.75	0.8%	Wine grapes	0.0%	Table grapes	0.0%	Strawberries		0.9%
0.8%	FR child 3 15 yr	1.43	0.3%	Wine grapes	0.3%	Table grapes	0.1%	Strawberries		0.8%
0.8%	UK vegetarian	1.43	0.6%	Wine grapes	0.1%	Table grapes	0.0%	Strawberries		0.8%
0.7%	NL general	1.40	0.5%	Wine grapes	0.2%	Table grapes	0.0%	Strawberries		0.7%
0.7%	GEMS/Food G10	1.32	0.3%	Wine grapes	0.2%	Table grapes	0.1%	Strawberries		0.7%
0.5%	ES adult	0.91	0.3%	Wine grapes	0.1%	Peaches	0.0%	Table grapes		0.5%
0.4%	FI 3 yr	0.78	0.2%	Strawberries	0.2%	Table grapes	0.0%	Peaches		0.4%
0.4%	FI adult	0.73	0.2%	Wine grapes	0.1%	Strawberries	0.1%	Table grapes		0.4%
0.3%	UK toddler	0.66	0.2%	Table grapes	0.1%	Strawberries	0.0%	Wine grapes		0.3%
0.3%	FI 6 yr	0.60	0.1%	Strawberries	0.1%	Table grapes	0.0%	Peaches		0.3%
0.3%	PL general	0.60	0.2%	Table grapes	0.0%	Cherries (sweet)	0.0%	Peaches		0.3%
0.3%	IT toddler	0.57	0.1%	Peaches	0.1%	Table grapes	0.1%	Strawberries		0.3%
0.3%	FR toddler 2 3 yr	0.55	0.2%	Wine grapes	0.1%	Strawberries	0.0%	Apricots		0.3%
0.3%	IT adult	0.55	0.1%	Peaches	0.1%	Table grapes	0.0%	Apricots		0.3%
0.3%	DK child	0.49	0.1%	Table grapes	0.1%	Strawberries	0.0%	Peaches		0.3%
0.2%	UK infant	0.40	0.1%	Strawberries	0.0%	Apricots	0.0%	Cherries (sweet)		0.2%
0.2%	ES child	0.31	0.1%	Peaches	0.0%	Strawberries	0.0%	Cherries (sweet)		0.2%
0.1%	SE general	0.27	0.1%	Strawberries	0.0%	Peaches	0.0%	Apricots		0.1%
0.1%	FR infant	0.24	0.1%	Strawberries	0.0%	Wine grapes	0.0%	Apricots		0.1%
0.1%	IE child	0.12	0.0%	Table grapes	0.0%	Strawberries	0.0%	Peaches		0.1%
0.0%	LT adult	0.07	0.0%	Strawberries	0.0%	Table grapes	0.0%	Cherries (sweet)		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mandestrobin (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Table grapes	5/3.92	286	4%	Table grapes	5/3.92	133
4%	Peaches	2/1.23	117	3%	Wine grapes	5/3.92	93
1%	Apricots	2/1.23	43	0.8%	Peaches	2/1.23	23
1%	Strawberries	3/2.42	40	0.8%	Strawberries	3/2.42	23
1%	Wine grapes	5/3.92	36	0.5%	Cherries (sweet)	3/1.43	14
0.6%	Cherries (sweet)	3/1.43	17	0.4%	Apricots	2/1.23	13
0.4%	Plums	0.5/0.32	13	0.2%	Plums	0.5/0.32	5.7
0.00%	Rapeseeds/canola seeds	0.2/0.02	0.03	0.00%	Rapeseeds/canola seeds	0.2/0.02	0.01

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wine grapes/juice	5/1.48	65	1%	Wine grapes/wine	5/3.92	37
1%	Peaches/canned	2/1.23	32	1%	Wine grapes/juice	5/1.48	31
0.3%	Peaches/juice	2/0.53	8.8	0.8%	Table grapes/raisins	5/18.43	23
0.0%	Plums/juice	0.5/0.13	1.2	0.3%	Peaches/canned	2/1.23	10
0.0%	Rapeseeds/oils	0.2/0.04	0.01				

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Mandestrobin (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

mesotrione (F)			
LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.02
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
3%	NL toddler	0.27	1%	Apples	0.7%	Maize/corn	0.4%	Pears		3%
2%	DE child	0.20	1%	Apples	0.4%	Oranges	0.1%	Pears		2%
1%	NL child	0.11	0.6%	Apples	0.1%	Oranges	0.1%	Pears		1%
0.7%	FR child 3 15 yr	0.07	0.3%	Oranges	0.2%	Apples	0.0%	Maize/corn		0.7%
0.6%	GEMS/Food G06	0.06	0.2%	Sugar canes	0.1%	Maize/corn	0.1%	Oranges		0.6%
0.6%	GEMS/Food G07	0.06	0.2%	Sugar canes	0.1%	Oranges	0.1%	Apples		0.6%
0.6%	FR toddler 2 3 yr	0.06	0.3%	Apples	0.1%	Oranges	0.1%	Mandarins		0.6%
0.6%	GEMS/Food G11	0.06	0.2%	Sugar canes	0.2%	Apples	0.1%	Oranges		0.6%
0.6%	DE women 14-50 yr	0.06	0.3%	Apples	0.2%	Oranges	0.0%	Lemons		0.6%
0.6%	GEMS/Food G10	0.06	0.1%	Sugar canes	0.1%	Oranges	0.1%	Apples		0.6%
0.5%	GEMS/Food G08	0.05	0.2%	Sugar canes	0.1%	Apples	0.0%	Oranges		0.5%
0.5%	GEMS/Food G15	0.05	0.1%	Sugar canes	0.1%	Apples	0.1%	Oranges		0.5%
0.5%	DE general	0.05	0.2%	Apples	0.2%	Oranges	0.0%	Lemons		0.5%
0.5%	IE adult	0.05	0.1%	Oranges	0.1%	Apples	0.1%	Grapefruits		0.5%
0.5%	ES child	0.05	0.2%	Oranges	0.1%	Apples	0.0%	Pears		0.5%
0.4%	UK infant	0.04	0.2%	Apples	0.1%	Oranges	0.1%	Maize/corn		0.4%
0.4%	UK toddler	0.04	0.2%	Oranges	0.2%	Apples	0.0%	Mandarins		0.4%
0.4%	NL general	0.04	0.1%	Apples	0.1%	Oranges	0.0%	Coconuts		0.4%
0.4%	DK child	0.04	0.2%	Apples	0.1%	Pears	0.0%	Oranges		0.4%
0.3%	RO general	0.03	0.1%	Apples	0.1%	Maize/corn	0.0%	Oranges		0.3%
0.3%	SE general	0.03	0.1%	Apples	0.1%	Oranges	0.0%	Mandarins		0.3%
0.3%	PT general	0.03	0.1%	Apples	0.1%	Oranges	0.0%	Maize/corn		0.3%
0.3%	ES adult	0.03	0.1%	Oranges	0.1%	Apples	0.0%	Pears		0.3%
0.3%	PL general	0.03	0.2%	Apples	0.0%	Pears	0.0%	Plums		0.3%
0.3%	IT toddler	0.03	0.1%	Apples	0.0%	Oranges	0.0%	Peaches		0.3%
0.2%	FR infant	0.02	0.2%	Apples	0.0%	Oranges	0.0%	Pears		0.2%
0.2%	IT adult	0.02	0.1%	Apples	0.0%	Peaches	0.0%	Oranges		0.2%
0.2%	LT adult	0.02	0.2%	Apples	0.0%	Pears	0.0%	Oranges		0.2%
0.2%	FI 3 yr	0.02	0.1%	Apples	0.0%	Mandarins	0.0%	Pears		0.2%
0.2%	FR adult	0.02	0.1%	Apples	0.1%	Oranges	0.0%	Pears		0.2%
0.2%	UK vegetarian	0.02	0.1%	Oranges	0.1%	Apples	0.0%	Grapefruits		0.2%
0.2%	DK adult	0.02	0.1%	Apples	0.0%	Pears	0.0%	Oranges		0.2%
0.2%	FI 6 yr	0.02	0.1%	Apples	0.0%	Mandarins	0.0%	Pears		0.2%
0.1%	UK adult	0.01	0.1%	Oranges	0.0%	Apples	0.0%	Grapefruits		0.1%
0.1%	FI adult	0.01	0.1%	Apples	0.0%	Oranges	0.0%	Mandarins		0.1%
0.1%	IE child	0.01	0.0%	Apples	0.0%	Oranges	0.0%	Sweet corn		0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of mesotrione (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Pears	0.01/0.01	1.4	2%	Oranges	0.01/0.01	0.31
7%	Oranges	0.01/0.01	1.3	2%	Pears	0.01/0.01	0.31
5%	Apples	0.01/0.01	1.1	1%	Apples	0.01/0.01	0.28
5%	Peaches	0.01/0.01	0.95	0.9%	Peaches	0.01/0.01	0.19
4%	Grapefruits	0.01/0.01	0.79	0.9%	Mandarins	0.01/0.01	0.18
3%	Mandarins	0.01/0.01	0.59	0.9%	Grapefruits	0.01/0.01	0.18
2%	Sweet corn	0.01/0.01	0.43	0.9%	Plums	0.01/0.01	0.18
2%	Plums	0.01/0.01	0.42	0.8%	Sweet corn	0.01/0.01	0.16
2%	Apricots	0.01/0.01	0.35	0.8%	Quinces	0.01/0.01	0.15
2%	Lemons	0.01/0.01	0.34	0.5%	Apricots	0.01/0.01	0.11
1%	Quinces	0.01/0.01	0.25	0.5%	Cherries (sweet)	0.01/0.01	0.10
1%	Limes	0.01/0.01	0.20	0.4%	Lemons	0.01/0.01	0.09
0.7%	Coconuts	0.01/0.01	0.14	0.4%	Coconuts	0.01/0.01	0.09
0.7%	Medlar	0.01/0.01	0.14	0.4%	Limes	0.01/0.01	0.07
0.6%	Cherries (sweet)	0.01/0.01	0.12	0.3%	Medlar	0.01/0.01	0.07
0.3%	Maize/corn	0.01/0.01	0.07	0.2%	Chestnuts	0.01/0.01	0.05
0.3%	Pistachios	0.01/0.01	0.06	0.2%	Algae and prokaryotes organisms	0.05/0.05	0.04
0.2%	Chestnuts	0.01/0.01	0.04	0.1%	Pistachios	0.01/0.01	0.03
0.2%	Walnuts	0.01/0.01	0.03	0.1%	Pecans	0.01/0.01	0.02
0.2%	Hazelnuts/cobnuts	0.01/0.01	0.03	0.1%	Walnuts	0.01/0.01	0.02
0.1%	Almonds	0.01/0.01	0.03	0.1%	Maize/corn	0.01/0.01	0.02
0.1%	Pecans	0.01/0.01	0.03	0.1%	Macadamia	0.01/0.01	0.02
0.1%	Cashew nuts	0.01/0.01	0.03	0.09%	Cashew nuts	0.01/0.01	0.02
0.07%	Rapeseeds/canola seeds	0.01/0.01	0.01	0.07%	Almonds	0.01/0.01	0.01
0.05%	Linseeds	0.01/0.01	0.01	0.06%	Hazelnuts/cobnuts	0.01/0.01	0.01
0.04%	Brazil nuts	0.01/0.01	0.01	0.05%	Pine nut kernels	0.01/0.01	0.01
0.03%	Macadamia	0.01/0.01	0.01	0.04%	Poppy seeds	0.01/0.01	0.01
0.02%	Pine nut kernels	0.01/0.01	0.00	0.03%	Brazil nuts	0.01/0.01	0.01
0.01%	Sugar canes	0.01/0.01	0.00	0.03%	Rapeseeds/canola seeds	0.01 0.01	0.01
				0.02%	Linseeds	0.01/0.01	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Apples/juice	0.01/0.01	0.54	2%	Apples/juice	0.01/0.01	0.33
3%	Oranges/juice	0.01/0.01	0.53	0.8%	Oranges/juice	0.01/0.01	0.15
2%	Pears/juice	0.01/0.01	0.33	0.6%	Maize/oil	0.01/0.25	0.13
1%	Peaches/canned	0.01/0.01	0.26	0.5%	Grapefruits/juice	0.01/0.01	0.11
1%	Maize/oil	0.01/0.25	0.23	0.4%	Peaches/canned	0.01/0.01	0.08
0.8%	Peaches/juice	0.01/0.01	0.17	0.3%	Sugar canes/sugar	0.01/0.01	0.06
0.5%	Plums/juice	0.01/0.01	0.09	0.2%	Coconuts/drink	0.01/0.01	0.04
0.5%	Sugar canes/sugar	0.01/0.01	0.09	0.09%	Lemons/juice	0.01/0.01	0.02
0.4%	Coconuts/drink	0.01/0.01	0.09	0.06%	Quinces/jam	0.01/0.01	0.01
0.2%	Lemons/jam	0.01/0.01	0.03				
0.2%	Lemons/jam	0.01/0.01	0.03				
0.1%	Maize/processed (not specified)	0.01/0.01	0.02				
0.0%	Rapeseeds/oils	0.01/0.02	0.01				
0.0%	Limes/juice	0.01/0.01	0.00				

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of mesotrione (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Metconazole

LOQs (mg/kg) range from:	0.02	to:	0.15
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
44%	NL toddler	4.37	24%	Milk: Cattle	5%	Bananas	2%	Apples	33%	35%
23%	UK infant	2.30	15%	Milk: Cattle	1%	Bananas	1%	Potatoes	20%	20%
23%	NL child	2.28	10%	Milk: Cattle	2%	Bananas	2%	Sugar beet roots	16%	17%
20%	DE child	2.04	8%	Milk: Cattle	2%	Apples	2%	Wheat	16%	13%
20%	FR toddler 2 3 yr	1.96	12%	Milk: Cattle	1%	Wheat	0.7%	Potatoes	17%	16%
19%	FR child 3 15 yr	1.90	9%	Milk: Cattle	2%	Wheat	0.7%	Sugar beet roots	15%	14%
16%	UK toddler	1.62	8%	Milk: Cattle	2%	Wheat	1%	Potatoes	12%	13%
14%	DK child	1.42	5%	Milk: Cattle	2%	Wheat	1%	Bananas	10%	9%
14%	SE general	1.42	5%	Milk: Cattle	2%	Bananas	2%	Bovine: Muscle/meat	11%	11%
14%	ES child	1.37	5%	Milk: Cattle	2%	Wheat	1%	Bananas	10%	9%
13%	RO general	1.32	5%	Milk: Cattle	2%	Wheat	1%	Potatoes	9%	9%
12%	GEMS/Food G11	1.24	3%	Milk: Cattle	2%	Potatoes	1%	Wheat	9%	7%
12%	GEMS/Food G15	1.24	3%	Milk: Cattle	2%	Wheat	1%	Potatoes	8%	8%
12%	GEMS/Food G07	1.23	3%	Milk: Cattle	2%	Wheat	2%	Potatoes	8%	7%
12%	GEMS/Food G08	1.22	2%	Milk: Cattle	2%	Wheat	2%	Potatoes	8%	7%
12%	DE women 14-50 yr	1.15	5%	Milk: Cattle	0.9%	Sugar beet roots	0.9%	Wheat	9%	8%
11%	GEMS/Food G06	1.14	3%	Wheat	1.0%	Milk: Cattle	0.8%	Potatoes	6%	5%
11%	DE general	1.13	5%	Milk: Cattle	0.8%	Sugar beet roots	0.8%	Wheat	9%	8%
11%	GEMS/Food G10	1.13	2%	Milk: Cattle	2%	Wheat	1%	Potatoes	7%	6%
11%	IE adult	1.09	2%	Milk: Cattle	1%	Sweet potatoes	0.9%	Wheat	8%	7%
10%	FR infant	1.02	7%	Milk: Cattle	0.8%	Potatoes	0.3%	Apples	9%	9%
10%	NL general	0.99	3%	Milk: Cattle	1.0%	Potatoes	0.8%	Wheat	7%	7%
8%	FI adult	0.77	6%	Coffee beans	0.5%	Potatoes	0.3%	Bananas	7%	0.9%
7%	ES adult	0.71	2%	Milk: Cattle	0.9%	Wheat	0.4%	Potatoes	5%	4%
7%	PT general	0.68	2%	Potatoes	2%	Wheat	0.5%	Wine grapes	4%	3%
7%	FR adult	0.68	2%	Milk: Cattle	0.9%	Wheat	0.5%	Wine grapes	5%	4%
6%	FI 3 yr	0.61	2%	Potatoes	1%	Bananas	0.5%	Wheat	4%	4%
6%	DK adult	0.58	2%	Milk: Cattle	0.5%	Potatoes	0.5%	Bananas	5%	4%
6%	IT toddler	0.55	3%	Wheat	0.5%	Bananas	0.4%	Potatoes	2%	1%
5%	LT adult	0.54	2%	Milk: Cattle	1%	Potatoes	0.4%	Wheat	5%	4%
5%	UK vegetarian	0.48	1%	Milk: Cattle	0.8%	Wheat	0.5%	Potatoes	3%	3%
5%	FI 6 yr	0.47	2%	Potatoes	0.8%	Bananas	0.4%	Wheat	3%	3%
5%	UK adult	0.47	1%	Milk: Cattle	0.7%	Wheat	0.6%	Potatoes	3%	3%
4%	IT adult	0.38	2%	Wheat	0.2%	Potatoes	0.2%	Tomatoes	1%	0.9%
3%	PL general	0.30	1%	Potatoes	0.4%	Apples	0.2%	Bananas	2%	2%
3%	IE child	0.30	1%	Milk: Cattle	0.5%	Wheat	0.2%	Potatoes	2%	2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Metconazole is unlikely to present a public health concern.

Acute risk assessment/children | **Acute risk assessment/adults/general population**

Details – acute risk assessment/children | Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
97%	Bananas	0.1/0.1	9.7	30%	Blueberries	0.5/0.33	3.0
81%	Peaches	0.2/0.09	8.1	21%	Bananas	0.1/0.1	2.1
62%	Potatoes	0.04/0.04	6.2	16%	Peaches	0.2/0.09	1.6
50%	Milk: Cattle	0.04/0.04	5.0	15%	Milk: Cattle	0.04/0.04	1.5
30%	Apricots	0.2/0.09	3.0	14%	Cherries (sweet)	0.3/0.14	1.4
20%	Blueberries	0.5/0.33	2.0	12%	Potatoes	0.04/0.04	1.2
19%	Plums	0.1/0.05	1.9	11%	Yams	0.04/0.04	1.1
17%	Cherries (sweet)	0.3/0.14	1.7	9%	Apricots	0.2/0.09	0.92
12%	Yams	0.04/0.04	1.2	8%	Sweet potatoes	0.04/0.04	0.83
11%	Onions	0.05/0.05	1.1	8%	Plums	0.1/0.05	0.80
10%	Milk: Goat	0.04/0.04	0.97	7%	Onions	0.05/0.05	0.74
7%	Beans	0.15/0.04	0.73	7%	Milk: Goat	0.04/0.04	0.74
7%	Poultry: Muscle/meat	0.04/0.04	0.68	6%	Milk: Sheep	0.04/0.04	0.60
5%	Eggs: Chicken	0.04/0.04	0.50	5%	Poultry: Muscle	0.04/0.04	0.47
5%	Swine: Muscle/meat	0.04/0.04	0.48	3%	Beans	0.15/0.04	0.26

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
37%	Potatoes/fried	0.04/0.04	3.7	9%	Sugar beets (root)/sugar	0.07/0.24	0.88
24%	Potatoes/dried (flakes)	0.04/0.18	2.4	8%	Cassava roots/boiled	0.04/0.04	0.76
22%	Peaches/canned	0.2/0.09	2.2	7%	Peaches/canned	0.2/0.09	0.69
22%	Sugar beets (root)/sugar	0.07/0.24	2.2	6%	Sweet potatoes/boiled	0.04/0.04	0.62
20%	Sweet potatoes/boiled	0.04/0.04	2.0	5%	Onions/boiled	0.05/0.05	0.47
7%	Peaches/juice	0.2/0.05	0.75	3%	Potatoes/chips	0.04/0.04	0.34
4%	Plums/juice	0.1/0.04	0.38	3%	Beans/canned	0.15/0.04	0.29
3%	Lentils/boiled	0.15/0.04	0.34	2%	Potatoes/dried (flakes)	0.04/0.18	0.23
3%	Peas/canned	0.15/0.02	0.30	1%	Maize/oil	0.1/0.25	0.13
3%	Beans (with pods)/boiled	0.05/0.02	0.25	1%	Sugar canes/sugar	0.06/0.02	0.12
2%	Maize/oil	0.1/0.25	0.23	1%	Peas/canned	0.15/0.02	0.11
2%	Sunflower seeds/oils	1.5/0.18	0.21	0.6%	Peas (without pods)/boiled	0.02/0.02	0.06
2%	Sugar canes/sugar	0.06/0.02	0.19	0.1%	Arrowroots/starch	0.04/0.04	0.01
0.8%	Peas (without pods)/canned	0.02/0.01	0.08				
0.3%	Arrowroots/starch	0.04/0.04	0.03				

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Metconazole is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Metconazole

LOQs (mg/kg) range from:	0.02	to:	0.15
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values
Details – chronic risk assessment
Supplementary results – chronic risk assessment
Details – acute risk assessment/children
Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
44%	NL toddler	4.37	24%	Milk: Cattle	5%	Bananas	2%	Apples	33%	35%
23%	UK infant	2.30	15%	Milk: Cattle	1%	Bananas	1%	Potatoes	20%	20%
23%	NL child	2.28	10%	Milk: Cattle	2%	Bananas	2%	Sugar beet roots	16%	17%
20%	DE child	2.04	8%	Milk: Cattle	2%	Apples	2%	Wheat	16%	13%
20%	FR toddler 2 3 yr	1.96	12%	Milk: Cattle	1%	Wheat	0.7%	Potatoes	17%	16%
19%	FR child 3 15 yr	1.90	9%	Milk: Cattle	2%	Wheat	0.7%	Sugar beet roots	15%	14%
16%	UK toddler	1.62	8%	Milk: Cattle	2%	Wheat	1%	Potatoes	12%	13%
14%	DK child	1.42	5%	Milk: Cattle	2%	Wheat	1%	Bananas	10%	9%
14%	SE general	1.42	5%	Milk: Cattle	2%	Bananas	2%	Bovine: Muscle/meat	11%	11%
14%	ES child	1.37	5%	Milk: Cattle	2%	Wheat	1%	Bananas	10%	9%
13%	RO general	1.32	5%	Milk: Cattle	2%	Wheat	1%	Potatoes	9%	9%
12%	GEMS/Food G11	1.24	3%	Milk: Cattle	2%	Potatoes	1%	Wheat	9%	7%
12%	GEMS/Food G15	1.24	3%	Milk: Cattle	2%	Wheat	1%	Potatoes	8%	8%
12%	GEMS/Food G07	1.23	3%	Milk: Cattle	2%	Wheat	2%	Potatoes	8%	7%
12%	GEMS/Food G08	1.22	2%	Milk: Cattle	2%	Wheat	2%	Potatoes	8%	7%
12%	DE women 14-50 yr	1.15	5%	Milk: Cattle	0.9%	Sugar beet roots	0.9%	Wheat	9%	8%
11%	GEMS/Food G06	1.14	3%	Wheat	1.0%	Milk: Cattle	0.8%	Potatoes	6%	5%
11%	DE general	1.13	5%	Milk: Cattle	0.8%	Sugar beet roots	0.8%	Wheat	9%	8%
11%	GEMS/Food G10	1.13	2%	Milk: Cattle	2%	Wheat	1%	Potatoes	7%	6%
11%	IE adult	1.09	2%	Milk: Cattle	1%	Sweet potatoes	0.9%	Wheat	8%	7%
10%	FR infant	1.02	7%	Milk: Cattle	0.8%	Potatoes	0.3%	Apples	9%	9%
10%	NL general	0.99	3%	Milk: Cattle	1.0%	Potatoes	0.8%	Wheat	7%	7%
8%	FI adult	0.77	6%	Coffee beans	0.5%	Potatoes	0.3%	Bananas	7%	0.9%
7%	ES adult	0.71	2%	Milk: Cattle	0.9%	Wheat	0.4%	Potatoes	5%	4%
7%	PT general	0.68	2%	Potatoes	2%	Wheat	0.5%	Wine grapes	4%	3%
7%	FR adult	0.68	2%	Milk: Cattle	0.9%	Wheat	0.5%	Wine grapes	5%	4%
6%	FI 3 yr	0.61	2%	Potatoes	1%	Bananas	0.5%	Wheat	4%	4%
6%	DK adult	0.58	2%	Milk: Cattle	0.5%	Potatoes	0.5%	Bananas	5%	4%
6%	IT toddler	0.55	3%	Wheat	0.5%	Bananas	0.4%	Potatoes	2%	1%
5%	LT adult	0.54	2%	Milk: Cattle	1%	Potatoes	0.4%	Wheat	5%	4%
5%	UK vegetarian	0.48	1%	Milk: Cattle	0.8%	Wheat	0.5%	Potatoes	3%	3%
5%	FI 6 yr	0.47	2%	Potatoes	0.8%	Bananas	0.4%	Wheat	3%	3%
5%	UK adult	0.47	1%	Milk: Cattle	0.7%	Wheat	0.6%	Potatoes	3%	3%
4%	IT adult	0.38	2%	Wheat	0.2%	Potatoes	0.2%	Tomatoes	1%	0.9%
3%	PL general	0.30	1%	Potatoes	0.4%	Apples	0.2%	Bananas	2%	2%
3%	IE child	0.30	1%	Milk: Cattle	0.5%	Wheat	0.2%	Potatoes	2%	2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Metconazole is unlikely to present a public health concern.

Acute risk assessment/children | **Acute risk assessment/adults/general population**

Details – acute risk assessment/children | Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
97%	Bananas	0.1/0.1	9.7	30%	Blueberries	0.5/0.33	3.0
81%	Peaches	0.2/0.09	8.1	21%	Bananas	0.1/0.1	2.1
62%	Potatoes	0.04/0.04	6.2	16%	Peaches	0.2/0.09	1.6
50%	Milk: Cattle	0.04/0.04	5.0	15%	Milk: Cattle	0.04/0.04	1.5
30%	Apricots	0.2/0.09	3.0	14%	Cherries (sweet)	0.3/0.14	1.4
20%	Blueberries	0.5/0.33	2.0	12%	Potatoes	0.04/0.04	1.2
19%	Plums	0.1/0.05	1.9	11%	Yams	0.04/0.04	1.1
17%	Cherries (sweet)	0.3/0.14	1.7	9%	Apricots	0.2/0.09	0.92
12%	Yams	0.04/0.04	1.2	8%	Sweet potatoes	0.04/0.04	0.83
11%	Onions	0.05/0.05	1.1	8%	Plums	0.1/0.05	0.80
10%	Milk: Goat	0.04/0.04	0.97	7%	Onions	0.05/0.05	0.74
7%	Beans	0.15/0.04	0.73	7%	Milk: Goat	0.04/0.04	0.74
7%	Poultry: Muscle/meat	0.04/0.04	0.68	6%	Milk: Sheep	0.04/0.04	0.60
5%	Eggs: Chicken	0.04/0.04	0.50	5%	Poultry: Muscle	0.04/0.04	0.47
5%	Swine: Muscle/meat	0.04/0.04	0.48	3%	Beans	0.15/0.04	0.26

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
37%	Potatoes/fried	0.04/0.04	3.7	9%	Sugar beets (root)/sugar	0.07/0.24	0.88
24%	Potatoes/dried (flakes)	0.04/0.18	2.4	8%	Cassava roots/boiled	0.04/0.04	0.76
22%	Peaches/canned	0.2/0.09	2.2	7%	Peaches/canned	0.2/0.09	0.69
22%	Sugar beets (root)/sugar	0.07/0.24	2.2	6%	Sweet potatoes/boiled	0.04/0.04	0.62
20%	Sweet potatoes/boiled	0.04/0.04	2.0	5%	Onions/boiled	0.05/0.05	0.47
7%	Peaches/juice	0.2/0.05	0.75	3%	Potatoes/chips	0.04/0.04	0.34
4%	Plums/juice	0.1/0.04	0.38	3%	Beans/canned	0.15/0.04	0.29
3%	Lentils/boiled	0.15/0.04	0.34	2%	Potatoes/dried (flakes)	0.04/0.18	0.23
3%	Peas/canned	0.15/0.02	0.30	1%	Maize/oil	0.1/0.25	0.13
3%	Beans (with pods)/boiled	0.05/0.02	0.25	1%	Sugar canes/sugar	0.06/0.02	0.12
2%	Maize/oil	0.1/0.25	0.23	1%	Peas/canned	0.15/0.02	0.11
2%	Sunflower seeds/oils	1.5/0.18	0.21	0.6%	Peas (without pods)/boiled	0.02/0.02	0.06
2%	Sugar canes/sugar	0.06/0.02	0.19	0.1%	Arrowroots/starch	0.04/0.04	0.01
0.8%	Peas (without pods)/canned	0.02/0.01	0.08	#NUM!	#NUM!	#NUM!	#NUM!
0.3%	Arrowroots/starch	0.04/0.04	0.03	#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Metconazole is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Methoprene

LOQs (mg/kg) range from:	0.02	to:	0.10
Toxicological reference values			
ADI (mg/kg bw per day):	0.05	ARfD (mg/kg bw):	n.n.
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2005	Year of evaluation:	2005

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments: Chronic risk assessment conducted using the MRL set in Reg. (EU) No 899/2012, the STMR (5 mg/kg, equal to the proposed CXL) and the lower ADI set for s-methoprene

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 3

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
136%	NL toddler	67.84	70%	Maize/corn	39%	Wheat	6%	Rice	8%	1%
108%	DK child	54.15	55%	Rye	44%	Wheat	4%	Oat	2%	
104%	GEMS/Food G06	52.07	72%	Wheat	16%	Rice	13%	Maize/corn	2%	0.4%
84%	IT toddler	42.09	66%	Wheat	15%	Other cereals	2%	Rice	0.3%	0.0%
70%	GEMS/Food G10	34.83	39%	Wheat	13%	Rice	7%	Maize/corn	2%	1.0%
68%	GEMS/Food G15	34.07	45%	Wheat	8%	Barley	6%	Maize/corn	2%	0.4%
66%	GEMS/Food G08	33.24	41%	Wheat	9%	Barley	6%	Rye	2%	0.5%
66%	RO general	32.78	51%	Wheat	10%	Maize/corn	3%	Rice	2%	0.5%
61%	DE child	30.35	42%	Wheat	8%	Rye	3%	Rice	4%	0.2%
60%	GEMS/Food G07	29.88	42%	Wheat	6%	Barley	3%	Rice	2%	0.9%
60%	FR child 3 15 yr	29.78	46%	Wheat	4%	Rice	4%	Maize/corn	4%	0.1%
55%	NL child	27.53	41%	Wheat	3%	Maize/corn	3%	Peanuts/groundnuts	4%	3%
55%	ES child	27.32	44%	Wheat	5%	Rice	3%	Maize/corn	2%	0.1%
55%	PT general	27.29	39%	Wheat	8%	Rice	5%	Maize/corn	0.7%	0.1%
53%	GEMS/Food G11	26.73	36%	Wheat	8%	Barley	3%	Rice	2%	2%
51%	IT adult	25.43	41%	Wheat	7%	Other cereals	2%	Rice	0.3%	0.1%
50%	UK infant	25.13	26%	Wheat	10%	Maize/corn	6%	Rice	5%	0.1%
49%	UK toddler	24.67	39%	Wheat	6%	Rice	2%	Milk: Cattle	3%	0.5%
43%	FR toddler 2 3 yr	21.27	31%	Wheat	6%	Rice	3%	Milk: Cattle	4%	0.1%
41%	SE general	20.71	32%	Wheat	4%	Rice	3%	Rye	2%	
36%	IE adult	18.10	23%	Wheat	3%	Buckwheat and other pseudo-cereals	2%	Rice	2%	0.9%
34%	DE general	16.93	19%	Wheat	6%	Rye	5%	Barley	2%	0.3%
33%	ES adult	16.48	23%	Wheat	5%	Barley	2%	Rice	1%	0.1%
32%	DE women 14-50 yr	16.17	21%	Wheat	5%	Rye	2%	Barley	2%	0.2%
32%	FI 3 yr	15.81	12%	Wheat	7%	Rye	6%	Oat	0.6%	0.1%
29%	NL general	14.38	19%	Wheat	3%	Barley	1%	Rice	2%	1%
28%	LT adult	14.04	11%	Rye	11%	Wheat	2%	Rice	0.9%	
26%	UK vegetarian	13.22	20%	Wheat	4%	Rice	0.5%	Oat	0.7%	0.4%
26%	FR adult	13.00	22%	Wheat	2%	Rice	0.6%	Maize/corn	1%	0.1%
25%	FI 6 yr	12.38	10%	Wheat	6%	Rye	4%	Rice	0.5%	0.1%
22%	UK adult	10.96	17%	Wheat	4%	Rice	0.3%	Milk: Cattle	0.8%	0.2%
18%	DK adult	9.24	11%	Wheat	5%	Rye	0.8%	Rice	1%	
15%	IE child	7.67	12%	Wheat	3%	Rice	0.4%	Milk: Cattle	0.5%	0.0%
15%	FI adult	7.30	7%	Rye	3%	Wheat	1%	Oat	1%	0.1%
11%	FR infant	5.55	8%	Wheat	2%	Milk: Cattle	0.7%	Rice	2%	0.0%
0.5%	PL general	0.23	0.1%	Potatoes	0.1%	Apples	0.0%	Peanuts/groundnuts	0.4%	0.0%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 135.7 % of the ADI.
For 3 diet(s) the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
233%	Maize/oil	5/125	116	127%	Maize/oil	5/125	63
121%	Wheat/milling (flour)	5/5	60	72%	Barley/beer	5/1	36
61%	Rice/milling (polishing)	5/2	31	44%	Wheat/bread/pizza	5/5	22
55%	Wheat/milling (wholemeal)-baking	5/5	28	39%	Rice/milling (polishing)	5/2	19
54%	Millet/boiled	5/2	27	38%	Wheat/pasta	5/5	19
54%	Buckwheat bulgur and grits	5/5	27	35%	Wheat/bread (wholemeal)	5/5	17
36%	Rye/boiled	5/5	18	23%	Millet/boiled	5/2	11
36%	Oat/boiled	5/5	18	15%	Oat/boiled	5/5	7.6
36%	Buckwhea/boiled	5/5	18	2%	Pumpkins/boiled	0.02/0.02	1.1
36%	Barley/ cooked	5/5	18	2%	Sugar beets (root)/sugar	0.02/0.24	0.88
36%	Peanuts/peanut butter	5/5	18	2%	Cauliflowers/boiled	0.02/0.02	0.83
35%	Rye/milling (wholemeal)-baking	5/5	18	2%	Beetroots/boiled	0.02/0.02	0.78
30%	Oat/milling (flakes)	5/5	15	1%	Celeries/boiled	0.02/0.02	0.68
21%	Maize/processed (not specified)	5/5	11	1%	Apples/juice	0.02/0.02	0.67
18%	Barley/milling (flour)	5/5	9.0	1.0%	Broccoli/boiled	0.02/0.02	0.48

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Methoprene is unlikely to present a public health risk.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Omethoate

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.0003	ARfD (mg/kg bw):	**calculation with ADI (no ARfD was inserted)**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 26

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
345%	GEMS/Food G06	1.04	313%	Wheat	20%	Sugar beet roots	7%	Olives for oil production		345%
292%	NL child	0.88	178%	Wheat	113%	Sugar beet roots	0.8%	Olives for oil production		292%
289%	IT toddler	0.87	288%	Wheat	1%	Spring onions/green onions and Welsh onions	0.4%	Table olives		289%
251%	FR child 3 15 yr	0.75	199%	Wheat	49%	Sugar beet roots	2%	Olives for oil production		251%
242%	NL toddler	0.73	171%	Wheat	70%	Sugar beet roots	1.0%	Olives for oil production		242%
238%	RO general	0.71	220%	Wheat	18%	Sugar beet roots	1.0%	Table olives		238%
212%	UK toddler	0.64	170%	Wheat	43%	Sugar beet roots				212%
211%	ES child	0.63	192%	Wheat	15%	Olives for oil production	2%	Sugar beet roots		211%
207%	GEMS/Food G15	0.62	197%	Wheat	5%	Peas (with pods)	4%	Olives for oil production		207%
200%	GEMS/Food G07	0.60	183%	Wheat	10%	Peas (with pods)	6%	Olives for oil production		200%
196%	GEMS/Food G08	0.59	177%	Wheat	16%	Olives for oil production	2%	Peas (with pods)		196%
192%	DK child	0.58	191%	Wheat	0.3%	Celeriacs/turnip rooted celeries	0.1%	Spring onions/green onions and Welsh onions		192%
186%	DE child	0.56	182%	Wheat	2%	Spring onions/green onions and Welsh onions	1.0%	Olives for oil production		186%
182%	GEMS/Food G10	0.55	170%	Wheat	8%	Olives for oil production	4%	Peas (with pods)		182%
180%	IT adult	0.54	179%	Wheat	0.5%	Table olives	0.5%	Spring onions/green onions and Welsh onions		180%
177%	PT general	0.53	170%	Wheat	5%	Olives for oil production	2%	Table olives		177%
173%	FR toddler 2 3 yr	0.52	133%	Wheat	38%	Sugar beet roots	0.9%	Olives for oil production		173%
168%	GEMS/Food G11	0.50	156%	Wheat	5%	Olives for oil production	4%	Peas (with pods)		168%
157%	DE women 14-50 yr	0.47	93%	Wheat	61%	Sugar beet roots	2%	Olives for oil production		157%
145%	SE general	0.44	139%	Wheat	5%	Peas (with pods)	2%	Table olives		145%
141%	DE general	0.42	82%	Wheat	56%	Sugar beet roots	2%	Olives for oil production		141%
132%	UK infant	0.40	114%	Wheat	19%	Sugar beet roots				132%
123%	NL general	0.37	84%	Wheat	38%	Sugar beet roots	0.5%	Olives for oil production		123%
116%	IE adult	0.35	99%	Wheat	8%	Spring onions/green onions and Welsh onions	6%	Peas (with pods)		116%
113%	ES adult	0.34	102%	Wheat	8%	Olives for oil production	2%	Sugar beet roots		113%
109%	FR adult	0.33	96%	Wheat	11%	Sugar beet roots	1%	Olives for oil production		109%
99%	UK vegetarian	0.30	89%	Wheat	7%	Sugar beet roots	3%	Spring onions/green onions and Welsh onions		99%
82%	UK adult	0.25	73%	Wheat	7%	Sugar beet roots	1%	Spring onions/green onions and Welsh onions		82%
52%	FI 3 yr	0.16	52%	Wheat	0.4%	Table olives	0.2%	Olives for oil production		52%
52%	FR infant	0.16	34%	Wheat	18%	Sugar beet roots	0.2%	Olives for oil production		52%
51%	IE child	0.15	50%	Wheat	0.1%	Spring onions/green onions and Welsh onions	0.0%	Peas (with pods)		51%
49%	DK adult	0.15	49%	Wheat	0.1%	Celeriacs/turnip rooted celeries	0.0%	Spring onions/green onions and Welsh onions		49%
46%	LT adult	0.14	46%	Wheat		FRUIT AND TREE NUTS				46%
43%	FI 6 yr	0.13	42%	Wheat	0.2%	Table olives	0.2%	Olives for oil production		43%
14%	FI adult	0.04	14%	Wheat	0.3%	Table olives	0.0%	Celeriacs/turnip rooted celeries		14%
0.2%	PL general	0.00	0.2%	Celeriacs/turnip rooted celeries		FRUIT AND TREE NUTS				0.2%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 345.3 % of the ADI.
For 26 diet(s) the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1685%	Table olives	1.5/1.5	5.1
1046%	Spring onions/green onions and Welsh onions	0.2/0.2	3.1
626%	Wheat	0.01/0.13	1.9
369%	Celeriacs/turnip rooted celeries	0.02/0.02	1.1
27%	Peas (with pods)	0.01/0.01	0.08
26%	Olives for oil production	1.5/0.06	0.08

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 3

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
500%	Table olives	1.5/1.5	1.5
364%	Wheat	0.01/0.13	1.1
300%	Spring onions/green onions and Welsh onions	0.2/0.2	0.90
79%	Celeriacs/turnip rooted celeries	0.02/0.02	0.24
16%	Olives for oil production	1.5/0.06	0.05
11%	Peas (with pods)	0.01/0.01	0.03

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 3

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1469%	Sugar beets (root)/sugar	0.01/0.48	4.4
524%	Wheat/milling (flour)	0.01/0.13	1.6
240%	Wheat/milling (wholemeal)-baking	0.01/0.13	0.72
96%	Celeriacs/juice	0.02/0.02	0.29
37%	Olives for oil production/oils	1.5/0.12	0.11
34%	Table olives/canned	1.5/0.09	0.10

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 5

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
584%	Sugar beets (root)/sugar	0.01/0.48	1.8
190%	Wheat/bread/pizza	0.01/0.13	0.57
165%	Wheat/pasta	0.01/0.13	0.50
151%	Wheat/bread (wholemeal)	0.01/0.13	0.45
121%	Celeriacs/boiled	0.02/0.02	0.36
38%	Table olives/canned	1.5/0.09	0.11
11%	Peas (with pods)/boiled	0.01/0.01	0.03

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 4 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

Pendimethalin

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.125**	ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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)
1.6	NL child	0.3	Apples	0.2	Potatoes	0.2	Milk and milk products: Cattle	
1.5	DE child	0.5	Apples	0.2	Carrots	0.2	Carrots	
1.4	WHO Cluster diet B	0.3	Wheat	0.1	Tomatoes	0.1	Potatoes	
1.3	FR toddler	0.4	Carrots	0.2	Potatoes	0.2	Beans (with pods)	
1.2	FR infant	0.4	Carrots	0.2	Milk and milk products: Cattle	0.2	Potatoes	
1.1	IE adult	0.1	Parsnips	0.1	Maize	0.1	Maize	
1.0	WHO cluster diet E	0.2	Wheat	0.2	Potatoes	0.1	Carrots	
0.9	PT General population	0.2	Potatoes	0.2	Wheat	0.1	Carrots	
0.9	DK child	0.2	Wheat	0.2	Carrots	0.2	Rye	
0.9	UK Infant	0.2	Carrots	0.1	Potatoes	0.1	Wheat	
0.9	WHO cluster diet D	0.3	Wheat	0.2	Potatoes	0.0	Tomatoes	
0.9	SE general population 90th percentile	0.2	Potatoes	0.1	Carrots	0.1	Wheat	
0.8	UK Toddler	0.2	Wheat	0.1	Potatoes	0.1	Beans	
0.8	WHO regional European diet	0.2	Potatoes	0.1	Wheat	0.1	Carrots	
0.8	ES child	0.2	Wheat	0.1	Milk and milk products: Cattle	0.1	Oranges	
0.8	WHO Cluster diet F	0.1	Wheat	0.1	Potatoes	0.1	Carrots	
0.7	NL general	0.1	Potatoes	0.1	Wheat	0.1	Oranges	
0.6	FR all population	0.2	Wine grapes	0.1	Wheat	0.0	Carrots	
0.6	IT kids/toddler	0.3	Wheat	0.1	Tomatoes	0.0	Potatoes	
0.5	ES adult	0.1	Wheat	0.1	Oranges	0.0	Milk and milk products: Cattle	
0.5	UK vegetarian	0.1	Wheat	0.1	Beans	0.1	Potatoes	
0.5	LT adult	0.1	Potatoes	0.1	Apples	0.0	Rye	
0.5	IT adult	0.2	Wheat	0.0	Tomatoes	0.0	Apples	
0.4	DK adult	0.1	Wheat	0.1	Carrots	0.1	Potatoes	
0.4	PL general population	0.1	Potatoes	0.1	Apples	0.0	Carrots	
0.4	UK Adult	0.1	Wheat	0.1	Potatoes	0.0	Wine grapes	
0.3	FI adult	0.0	Potatoes	0.0	Wheat	0.0	Oranges	

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

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

The acute risk assessment is based on the ARfD.

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

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
1.0	Peppers	0.05/-	0.7	Peppers	0.05/-	0.4	Aubergines (egg	0.05/-	0.4	Aubergines (egg plants)	0.05/-
1.0	Tomatoes	0.05/-	0.7	Tomatoes	0.05/-	0.3	Peppers	0.05/-	0.2	Tomatoes	0.05/-
0.7	Onions	0.05/-	0.5	Melons	0.01/-	0.3	Tomatoes	0.05/-	0.2	Peppers	0.05/-
0.5	Melons	0.01/-	0.5	Onions	0.05/-	0.2	Onions	0.05/-	0.2	Onions	0.05/-
0.4	Aubergines (egg	0.05/-	0.4	Aubergines (egg	0.05/-	0.2	Globe artichokes	0.05/-	0.2	Pumpkins	0.01/-
0.4	Watermelons	0.01/-	0.4	Watermelons	0.01/-	0.2	Pumpkins	0.01/-	0.1	Watermelons	0.01/-
0.4	Leek	0.02/-	0.3	Leek	0.02/-	0.1	Watermelons	0.01/-	0.1	Melons	0.01/-
0.3	Globe artichokes	0.05/-	0.3	Strawberries	0.05/-	0.1	Melons	0.01/-	0.1	Globe artichokes	0.05/-
0.3	Strawberries	0.05/-	0.2	Globe artichokes	0.05/-	0.1	Leek	0.02/-	0.1	Leek	0.02/-
0.2	Cucumbers	0.01/-	0.2	Cucumbers	0.01/-	0.1	Courgettes	0.01/-	0.1	Strawberries	0.05/-
0.2	Courgettes	0.01/-	0.1	Pumpkins	0.01/-	0.1	Strawberries	0.05/-	0.1	Courgettes	0.01/-
0.1	Pumpkins	0.01/-	0.1	Courgettes	0.01/-	0.1	Cucumbers	0.01/-	0.1	Cucumbers	0.01/-
0.1	Gherkins	0.01/-	0.0	Gherkins	0.01/-	0.0	Gherkins	0.01/-	0.0	Gherkins	0.01/-
0.0	Garlic	0.05/-	0.0	Garlic	0.05/-	0.0	Garlic	0.05/-	0.0	Garlic	0.05/-
0.0	Shallots	0.05/-	0.0	Shallots	0.05/-	0.0	Shallots	0.05/-	0.0	Shallots	0.05/-
0.0	Rape seed	0.01/-	0.0	Rape seed	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)	
5.9	Carrot, juice	0.41/-		0.2	Orange juice	0.05/-	
0.8	Apple juice	0.05/-		0.1	Apple juice	0.05/-	
0.8	Orange juice	0.05/-		0.1	Bread/pizza	0.05/-	
0.5	Grape juice	0.05/-		0.1	Wine	0.05/-	
0.5	Celeriac juice	0.12/-		0.0	Peach preserved with	0.05/-	

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

Conclusion:

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Penthiopyrad

LOQs (mg/kg) range from:	0.01	to:	10.0

Toxicological reference values

ADI (mg/kg bw per day):	0.1	ARfD (mg/kg bw):	0.75
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
30%	NL toddler	30.03	5%	Apples	3%	Sugar beet roots	2%	Beans (with pods)	0.8%	2%
21%	DE child	20.76	6%	Apples	2%	Tomatoes	2%	Cherries (sweet)	0.3%	1%
21%	GEMS/Food G06	20.51	7%	Tomatoes	2%	Lettuces	1.0%	Sweet peppers/bell peppers	0.1%	0.5%
19%	GEMS/Food G10	19.34	5%	Lettuces	3%	Tomatoes	2%	Head cabbages	0.2%	0.4%
19%	NL child	19.31	4%	Sugar beet roots	3%	Apples	1%	Tomatoes	0.4%	2%
18%	GEMS/Food G08	18.15	3%	Lettuces	2%	Tomatoes	2%	Head cabbages	0.2%	0.6%
17%	SE general	17.29	6%	Lettuces	3%	Head cabbages	2%	Tomatoes	0.2%	0.4%
17%	RO general	17.28	6%	Head cabbages	4%	Tomatoes	1.0%	Sunflower seeds	0.2%	0.1%
17%	GEMS/Food G15	16.63	3%	Head cabbages	2%	Tomatoes	2%	Lettuces	0.2%	0.6%
16%	IE adult	15.84	4%	Rhubarbs	1%	Lettuces	0.8%	Broccoli	0.2%	0.9%
15%	GEMS/Food G07	15.26	4%	Lettuces	2%	Tomatoes	0.7%	Peas (with pods)	0.2%	0.6%
15%	IT adult	15.06	6%	Lettuces	2%	Other lettuce and other salad plants	2%	Tomatoes	0.0%	0.5%
15%	GEMS/Food G11	14.63	2%	Rhubarbs	2%	Tomatoes	1%	Lamb's lettuce/corn salads	0.2%	0.4%
14%	ES adult	14.24	8%	Lettuces	2%	Tomatoes	0.7%	Beans (with pods)	0.1%	0.2%
14%	FR child 3 15 yr	13.96	2%	Sugar beet roots	2%	Tomatoes	2%	Other lettuce and other salad plants	0.4%	0.3%
14%	IT toddler	13.62	4%	Lettuces	3%	Tomatoes	2%	Other lettuce and other salad plants	0.0%	0.5%
14%	ES child	13.56	6%	Lettuces	2%	Tomatoes	0.7%	Beans (with pods)	0.2%	0.2%
13%	FR toddler 2 3 yr	12.72	2%	Beans (with pods)	2%	Apples	1%	Sugar beet roots	0.4%	0.1%
12%	DE women 14-50 yr	12.47	2%	Sugar beet roots	2%	Lettuces	1%	Tomatoes	0.2%	0.5%
11%	DE general	11.50	2%	Sugar beet roots	1%	Lettuces	1%	Tomatoes	0.2%	0.5%
10%	DK child	10.45	2%	Lettuces	1%	Apples	1%	Cucumbers	0.2%	0.1%
10%	NL general	10.43	1%	Sugar beet roots	1%	Lettuces	0.8%	Tomatoes	0.2%	0.4%
9%	FR infant	9.20	1%	Beans (with pods)	1%	Cauliflowers	0.8%	Apples	0.2%	0.1%
9%	UK toddler	8.79	2%	Sugar beet roots	1%	Tomatoes	0.9%	Apples	0.3%	0.8%
9%	FR adult	8.59	2%	Other lettuce and other salad plants	0.9%	Tomatoes	0.7%	Beans (with pods)	0.1%	0.2%
9%	FI 3 yr	8.53	1%	Tomatoes	1%	Strawberries	0.7%	Cucumbers	0.0%	1%
8%	UK infant	7.79	1%	Cauliflowers	0.8%	Carrots	0.8%	Apples	0.5%	0.4%
7%	PT general	7.50	2%	Tomatoes	2%	Lettuces	0.5%	Apples	0.1%	0.3%
7%	UK vegetarian	7.44	2%	Lettuces	1%	Tomatoes	0.5%	Cauliflowers	0.1%	0.2%
7%	FI 6 yr	7.28	1%	Lettuces	0.9%	Tomatoes	0.9%	Strawberries	0.0%	0.7%
7%	PL general	7.18	2%	Tomatoes	1%	Head cabbages	1%	Apples	0.0%	0.2%
6%	FI adult	6.24	2%	Lettuces	1%	Tomatoes	0.4%	Strawberries	0.1%	0.3%
6%	LT adult	6.23	2%	Head cabbages	1%	Tomatoes	1.0%	Lettuces	0.1%	0.1%
6%	DK adult	5.56	1%	Lettuces	1%	Tomatoes	0.5%	Apples	0.1%	0.1%
5%	UK adult	5.46	2%	Lettuces	0.9%	Tomatoes	0.3%	Broccoli	0.1%	0.1%
2%	IE child	1.73	0.2%	Broccoli	0.2%	Rhubarbs	0.2%	Apples	0.1%	0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Penthiopyrad is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
90%	Spinaches	30/30	678	76%	Chards/beet leaves	30/30	567
76%	Lettuces	15/15	571	24%	Lettuces	15/15	182
74%	Rhubarbs	15/15	558	22%	Head cabbages	4/4	168
62%	Chards/beet leaves	30/30	468	21%	Cardoons	15/15	156
51%	Peaches	4/4	380	19%	Rhubarbs	15/15	139
37%	Celeries	20/7.4	277	18%	Florence fennels	20/7.4	138
31%	Cauliflowers	4/4	232	16%	Spinaches	30/30	120
24%	Head cabbages	4/4	177	16%	Celeries	20/7.4	118
24%	Leeks	3/3	177	13%	Broccoli	4/4	95
22%	Broccoli	4/4	166	12%	Cauliflowers	4/4	93
19%	Apricots	4/4	140	11%	Red mustards	15/15	80
16%	Florence fennels	20/7.4	120	10%	Peaches	4/4	75
16%	Sweet peppers/bell peppers	2/2	119	8%	Purslanes	30/30	57
16%	Tomatoes	2/2	116	7%	Aubergines/egg plants	2/2	54
12%	Melons	0.6/0.6	91	6%	Apricots	4/4	44

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
124%	Chards/beet leaves/boiled	30/30	934	50%	Chards/beet leaves/boiled	30/30	375
75%	Rhubarbs/sauce/puree	15/15	559	33%	Celeries/boiled	20/7.4	250
56%	Spinaches/frozen; boiled	30/30	417	33%	Spinaches/frozen; boiled	30/30	248
45%	Florence fennels/boiled	20/7.4	335	29%	Rhubarbs/sauce/puree	15/15	219
42%	Broccoli/boiled	4/4	315	24%	Cardoons/boiled	15/15	182
37%	Cauliflowers/boiled	4/4	278	22%	Cauliflowers/boiled	4/4	167
23%	Leeks/boiled	3/3	172	19%	Florence fennels/boiled	20/7.4	143
14%	Peaches/canned	4/4	104	16%	Purslanes/boiled	30/30	124
7%	Sugar beets (root)/sugar	0.5/6	55	13%	Broccoli/boiled	4/4	96
7%	Pumpkins/boiled	0.6/0.6	53	7%	Leeks/boiled	3/3	52
6%	Currants (red, black and white)/juice	7/1.7	49	5%	Head cabbages/canned	4/4	38
6%	Raspberries/juice	10/3.7	43	4%	Pumpkins/boiled	0.6/0.6	33
5%	Tomatoes/juice	2/2	38	4%	Peaches/canned	4/4	33
5%	Beans (with pods)/boiled	3/3	38	3%	Beetroots/boiled	0.6/0.6	23
4%	Turnips/boiled	0.6/0.6	30	3%	Sugar beets (root)/sugar	0.5/6	22

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Penthiopyrad is unlikely to present a public health risk.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

PAM (metabolite of penthiopyrad)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.0024	ARfD (mg/kg bw):	0.024
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
60%	NL toddler	1.45	25%	Milk: Cattle	7%	Spinaches	4%	Apples	32%	26%
30%	NL child	0.73	10%	Milk: Cattle	4%	Sugar beet roots	2%	Apples	15%	15%
28%	DE child	0.68	8%	Milk: Cattle	5%	Apples	2%	Spinaches	14%	14%
26%	UK infant	0.61	16%	Milk: Cattle	1%	Potatoes	1%	Wheat	19%	6%
25%	FR toddler 2 3 yr	0.61	12%	Milk: Cattle	1%	Spinaches	1%	Apples	16%	9%
24%	FR child 3 15 yr	0.59	10%	Milk: Cattle	2%	Wheat	2%	Sugar beet roots	15%	9%
19%	GEMS/Food G11	0.46	3%	Milk: Cattle	2%	Potatoes	2%	Soyabeans	8%	11%
19%	UK toddler	0.46	9%	Milk: Cattle	2%	Wheat	1%	Potatoes	12%	7%
18%	DK child	0.42	5%	Milk: Cattle	2%	Rye	2%	Wheat	8%	9%
18%	SE general	0.42	5%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Potatoes	9%	8%
18%	ES child	0.42	5%	Milk: Cattle	2%	Wheat	1%	Lettuces	10%	8%
17%	GEMS/Food G06	0.42	3%	Wheat	1%	Tomatoes	1%	Milk: Cattle	5%	12%
17%	GEMS/Food G10	0.41	2%	Milk: Cattle	2%	Wheat	1%	Soyabeans	7%	10%
17%	GEMS/Food G07	0.41	3%	Milk: Cattle	2%	Wheat	2%	Potatoes	8%	9%
17%	GEMS/Food G08	0.41	2%	Milk: Cattle	2%	Wheat	2%	Potatoes	7%	10%
16%	IE adult	0.39	2%	Milk: Cattle	1%	Sweet potatoes	1%	Spinaches	6%	10%
16%	GEMS/Food G15	0.39	3%	Milk: Cattle	2%	Wheat	1%	Potatoes	7%	9%
16%	RO general	0.38	5%	Milk: Cattle	2%	Wheat	2%	Potatoes	7%	9%
16%	DE women 14-50 yr	0.38	5%	Milk: Cattle	2%	Sugar beet roots	1%	Apples	8%	7%
16%	FR infant	0.38	7%	Milk: Cattle	2%	Spinaches	0.9%	Leeks	8%	8%
15%	DE general	0.37	5%	Milk: Cattle	2%	Sugar beet roots	1%	Apples	8%	7%
14%	NL general	0.34	4%	Milk: Cattle	1%	Spinaches	1%	Sugar beet roots	6%	8%
11%	ES adult	0.27	2%	Milk: Cattle	1%	Lettuces	1.0%	Wheat	5%	6%
10%	FR adult	0.23	2%	Milk: Cattle	1.0%	Wine grapes	0.9%	Wheat	5%	5%
9%	IT toddler	0.22	3%	Wheat	0.8%	Lettuces	0.6%	Other cereals	1%	8%
9%	PT general	0.21	2%	Potatoes	2%	Wheat	1%	Wine grapes	2%	7%
8%	IT adult	0.20	2%	Wheat	1.0%	Lettuces	0.9%	Spinaches	0.9%	7%
8%	FI 3 yr	0.20	2%	Potatoes	0.6%	Spinaches	0.6%	Bananas	2%	7%
8%	FI adult	0.20	5%	Coffee beans	0.5%	Potatoes	0.4%	Lettuces	5%	3%
7%	DK adult	0.17	2%	Milk: Cattle	0.5%	Potatoes	0.5%	Wheat	4%	3%
7%	LT adult	0.17	2%	Milk: Cattle	1%	Potatoes	0.8%	Apples	3%	4%
7%	UK vegetarian	0.17	1%	Milk: Cattle	0.9%	Wheat	0.6%	Potatoes	3%	4%
7%	FI 6 yr	0.16	2%	Potatoes	0.5%	Spinaches	0.4%	Wheat	1%	5%
6%	UK adult	0.15	1%	Milk: Cattle	0.7%	Wheat	0.6%	Potatoes	3%	3%
4%	PL general	0.10	1%	Potatoes	0.9%	Apples	0.4%	Tomatoes	0.3%	4%
3%	IE child	0.08	1%	Milk: Cattle	0.5%	Wheat	0.3%	Potatoes	2%	1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of PAM (metabolite of penthiopyrad) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
78%	Kaki/Japanese persimmons	0.4/0.4	19	46%	Chards/beet leaves	30/0.58	11
64%	Leeks	3/0.26	15	37%	Kaki/Japanese persimmons	0.4/0.4	8.8
55%	Spinaches	30/0.58	13	14%	Leeks	3/0.26	3.4
40%	Lettuces	15/0.26	9.7	13%	Lettuces	15/0.26	3.1
38%	Chards/beet leaves	30/0.58	9.1	11%	Head cabbages	4/0.07	2.7
28%	Rhubarbs	15/0.18	6.7	10%	Spinaches	30/0.58	2.3
17%	Spring onions/green onions	4/0.26	4.1	8%	Cardoons	15/0.18	1.9
17%	Melons	0.6/0.03	4.0	7%	Rhubarbs	15/0.18	1.7
14%	Watermelons	0.6/0.03	3.2	6%	Red mustards	15/0.26	1.4
12%	Head cabbages	4/0.07	2.9	5%	Spring onions/green onions	4/0.26	1.2
12%	Pears	0.5/0.02	2.8	5%	Purslanes	30/0.58	1.1
9%	Apples	0.5/0.02	2.2	4%	Watermelons	0.6/0.03	1.1
6%	Sweet peppers/bell peppers	2/0.03	1.5	4%	Melons	0.6/0.03	1.0
6%	Potatoes	0.05/0.01	1.5	3%	Florence fennels	20/0.04	0.71
6%	Celeries	20/0.04	1.4	3%	Pears	0.5/0.02	0.61

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
75%	Chards/beet leaves/boiled	30/0.58	18	30%	Chards/beet leaves/boiled	30/0.58	7.3
62%	Leeks/boiled	3/0.26	15	20%	Spinaches/frozen; boiled	30/0.58	4.8
34%	Spinaches/frozen; boiled	30/0.58	8.1	19%	Leeks/boiled	3/0.26	4.5
28%	Rhubarbs/sauce/puree	15/0.18	6.7	11%	Rhubarbs/sauce/puree	15/0.18	2.6
10%	Pumpkins/boiled	0.6/0.03	2.4	10%	Purslanes/boiled	30/0.58	2.4
8%	Broccoli/boiled	4/0.02	1.9	9%	Cardoons/boiled	15/0.18	2.2
7%	Florence fennels/boiled	20/0.04	1.7	6%	Pumpkins/boiled	0.6/0.03	1.5
7%	Cauliflowers/boiled	4/0.02	1.7	5%	Celeries/boiled	20/0.04	1.3
5%	Sugar beets (root)/sugar	0.5/0.12	1.1	4%	Cauliflowers/boiled	4/0.02	1.00
4%	Potatoes/fried	0.05/0.01	0.93	3%	Florence fennels/boiled	20/0.04	0.74
3%	Courgettes/boiled	0.7/0.02	0.64	2%	Broccoli/boiled	4/0.02	0.58
2%	Potatoes/dried (flakes)	0.05/0.05	0.59	2%	Sugar beets (root)/sugar	0.5/0.12	0.44
2%	Apples/juice	0.5/0.01	0.54	2%	Courgettes/boiled	0.7/0.02	0.41
2%	Turnips/boiled	0.6/0.01	0.51	2%	Beetroots/boiled	0.6/0.01	0.39
2%	Parsnips/boiled	0.6/0.01	0.51	1%	Apples/juice	0.5/0.01	0.33

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of PAM (metabolite of penthiopyrad) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Picoxystrobin

LOQs (mg/kg) range from:	0.01	to:	15.0
Toxicological reference values			
ADI (mg/kg bw per day):	**No ADI**	ARfD (mg/kg bw):	**not assessed**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments: EFSA 2011, EFSA 2014

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)											

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Picoxystrobin is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ADI, since acute effects have not been assessed.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Picoxystrobin is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Potassium Phosponates

LOQs (mg/kg) range from:	0.5	to:	5.0

Toxicological reference values

ADI (mg/kg bw per day):	1	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
98%	NL toddler	976.04	25%	Apples	11%	Potatoes	10%	Pears		98%
95%	DE child	947.63	29%	Apples	15%	Oranges	10%	Wheat		95%
86%	GEMS/Food G06	859.43	27%	Tomatoes	17%	Wheat	6%	Watermelons		86%
63%	NL child	626.48	13%	Apples	10%	Wheat	9%	Potatoes		63%
60%	RO general	603.29	15%	Tomatoes	12%	Wheat	10%	Potatoes		60%
56%	GEMS/Food G08	558.71	11%	Potatoes	9%	Wheat	9%	Tomatoes		56%
56%	GEMS/Food G15	558.51	11%	Wheat	10%	Potatoes	9%	Tomatoes		56%
54%	GEMS/Food G11	543.91	11%	Potatoes	8%	Wheat	7%	Tomatoes		54%
53%	GEMS/Food G07	532.69	10%	Potatoes	10%	Wheat	8%	Tomatoes		53%
53%	GEMS/Food G10	530.93	10%	Tomatoes	9%	Wheat	8%	Potatoes		53%
52%	FR child 3 15 yr	521.83	13%	Oranges	11%	Wheat	6%	Tomatoes		52%
48%	PT general	477.43	14%	Potatoes	9%	Wheat	7%	Tomatoes		48%
47%	IE adult	465.03	6%	Potatoes	5%	Wheat	4%	Oranges		47%
45%	ES child	448.14	10%	Wheat	8%	Oranges	7%	Tomatoes		45%
44%	SE general	439.75	11%	Potatoes	7%	Wheat	6%	Tomatoes		44%
41%	UK toddler	411.71	9%	Potatoes	9%	Wheat	7%	Oranges		41%
41%	IT toddler	411.64	15%	Wheat	11%	Tomatoes	2%	Potatoes		41%
40%	FR toddler 2 3 yr	400.49	7%	Apples	7%	Wheat	5%	Oranges		40%
40%	DE women 14-50 yr	396.56	7%	Oranges	6%	Apples	6%	Tomatoes		40%
38%	DK child	376.83	10%	Wheat	7%	Potatoes	5%	Apples		38%
36%	DE general	359.41	6%	Oranges	6%	Apples	5%	Tomatoes		36%
33%	NL general	334.68	7%	Potatoes	4%	Wheat	4%	Oranges		33%
33%	FI 3 yr	333.33	13%	Potatoes	4%	Tomatoes	3%	Wheat		33%
33%	IT adult	328.28	10%	Wheat	9%	Tomatoes	2%	Apples		33%
33%	ES adult	325.50	6%	Tomatoes	5%	Wheat	5%	Oranges		33%
31%	UK infant	305.05	9%	Potatoes	6%	Wheat	5%	Oranges		31%
27%	FI 6 yr	273.80	10%	Potatoes	3%	Tomatoes	2%	Wheat		27%
27%	FR adult	273.33	6%	Wine grapes	5%	Wheat	3%	Tomatoes		27%
27%	PL general	266.25	9%	Potatoes	7%	Tomatoes	5%	Apples		27%
26%	UK vegetarian	257.89	5%	Wheat	5%	Tomatoes	4%	Potatoes		26%
23%	LT adult	228.78	9%	Potatoes	5%	Tomatoes	4%	Apples		23%
21%	UK adult	205.71	4%	Wheat	4%	Potatoes	3%	Tomatoes		21%
20%	DK adult	202.40	4%	Tomatoes	3%	Potatoes	3%	Wheat		20%
20%	FR infant	201.34	5%	Potatoes	4%	Apples	2%	Wheat		20%
16%	FI adult	161.38	4%	Tomatoes	3%	Potatoes	2%	Oranges		16%
7%	IE child	70.06	3%	Wheat	2%	Potatoes	0.8%	Apples		7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Potassium Phosponates
is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Propiconazole

LOQs (mg/kg) range from:	4	to:	4.0

Toxicological reference values

ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	0.1
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments: EFSA 2015

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	IT adult	0.64	2%	Peaches						2%
2%	PT general	0.61	2%	Peaches		FRUIT AND TREE NUTS				2%
1%	IT toddler	0.59	1%	Peaches		FRUIT AND TREE NUTS				1%
1%	IE adult	0.54	1%	Peaches		FRUIT AND TREE NUTS				1%
1%	DE child	0.48	1%	Peaches		FRUIT AND TREE NUTS				1%
1%	NL toddler	0.46	1%	Peaches		FRUIT AND TREE NUTS				1%
1%	GEMS/Food G06	0.44	1%	Peaches		FRUIT AND TREE NUTS				1%
0.9%	GEMS/Food G08	0.37	0.9%	Peaches		FRUIT AND TREE NUTS				0.9%
0.9%	ES adult	0.36	0.9%	Peaches		FRUIT AND TREE NUTS				0.9%
0.9%	NL child	0.35	0.9%	Peaches		FRUIT AND TREE NUTS				0.9%
0.8%	ES child	0.33	0.8%	Peaches		FRUIT AND TREE NUTS				0.8%
0.7%	GEMS/Food G10	0.29	0.7%	Peaches		FRUIT AND TREE NUTS				0.7%
0.6%	DE women 14-50 yr	0.25	0.6%	Peaches		FRUIT AND TREE NUTS				0.6%
0.6%	GEMS/Food G07	0.25	0.6%	Peaches		FRUIT AND TREE NUTS				0.6%
0.6%	FR child 3 15 yr	0.25	0.6%	Peaches		FRUIT AND TREE NUTS				0.6%
0.6%	SE general	0.25	0.6%	Peaches		FRUIT AND TREE NUTS				0.6%
0.5%	FR adult	0.22	0.5%	Peaches		FRUIT AND TREE NUTS				0.5%
0.5%	DE general	0.22	0.5%	Peaches		FRUIT AND TREE NUTS				0.5%
0.5%	GEMS/Food G15	0.21	0.5%	Peaches		FRUIT AND TREE NUTS				0.5%
0.5%	FI 3 yr	0.19	0.5%	Peaches		FRUIT AND TREE NUTS				0.5%
0.5%	DK child	0.19	0.5%	Peaches		FRUIT AND TREE NUTS				0.5%
0.4%	RO general	0.17	0.4%	Peaches		FRUIT AND TREE NUTS				0.4%
0.4%	FI 6 yr	0.17	0.4%	Peaches		FRUIT AND TREE NUTS				0.4%
0.3%	DK adult	0.12	0.3%	Peaches		FRUIT AND TREE NUTS				0.3%
0.3%	UK toddler	0.12	0.3%	Peaches		FRUIT AND TREE NUTS				0.3%
0.3%	GEMS/Food G11	0.10	0.3%	Peaches		FRUIT AND TREE NUTS				0.3%
0.3%	PL general	0.10	0.3%	Peaches		FRUIT AND TREE NUTS				0.3%
0.2%	NL general	0.10	0.2%	Peaches		FRUIT AND TREE NUTS				0.2%
0.2%	UK infant	0.08	0.2%	Peaches		FRUIT AND TREE NUTS				0.2%
0.1%	UK vegetarian	0.05	0.1%	Peaches		FRUIT AND TREE NUTS				0.1%
0.1%	UK adult	0.05	0.1%	Peaches		FRUIT AND TREE NUTS				0.1%
0.1%	FI adult	0.04	0.1%	Peaches		FRUIT AND TREE NUTS				0.1%
0.1%	FR toddler 2 3 yr	0.03	0.1%	Peaches		FRUIT AND TREE NUTS				0.1%
0.1%	FR infant	0.03	0.1%	Peaches		FRUIT AND TREE NUTS				0.1%
0.0%	IE child	0.01	0.0%	Peaches		FRUIT AND TREE NUTS				0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Propiconazole is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults /general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
238%	Peaches	4/2.5	238

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
47%	Peaches	4/2.5	47

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
65%	Peaches/canned	4/2.5	65
28%	Peaches/juice	4/1.7	28

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
20%	Peaches/canned	4/2.5	20

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Pydiflumetofen (F)

LOQs (mg/kg) range from: 0.01 to: 40.0

Toxicological reference values

ADI (mg/kg bw per day): 0.09 | ARfD (mg/kg bw): 0.3

Source of ADI: | Source of ARfD:

Year of evaluation: | Year of evaluation:

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
17%	NL toddler	15.72	10%	Spinaches	3%	Escaroles/broad-leaved endives	1%	Milk: Cattle	0.2%	17%
11%	ES adult	9.88	7%	Lettuces	1%	Chards/beet leaves	1%	Spinaches	0.0%	11%
10%	IT adult	9.22	5%	Lettuces	1%	Spinaches	0.9%	Other spinach and similar	0.0%	10%
10%	ES child	8.61	6%	Lettuces	1%	Spinaches	1%	Chards/beet leaves	0.1%	9%
8%	GEMS/Food G10	7.54	5%	Lettuces	0.9%	Cress and other sprouts and shoots	0.7%	Spinaches	0.1%	8%
8%	SE general	7.46	6%	Lettuces	0.9%	Spinaches	0.3%	Milk: Cattle	0.1%	8%
8%	IT toddler	7.41	4%	Lettuces	0.8%	Chards/beet leaves	0.8%	Spinaches	0.0%	8%
8%	NL child	7.31	3%	Spinaches	1%	Escaroles/broad-leaved endives	1%	Lettuces	0.1%	8%
8%	GEMS/Food G11	7.13	1%	Celeries	1%	Spinaches	1%	Lamb's lettuce/corn salads	0.1%	8%
7%	GEMS/Food G08	6.56	3%	Lettuces	1.0%	Lamb's lettuce/corn salads	0.4%	Spinaches	0.1%	7%
7%	DE child	6.45	3%	Spinaches	1%	Lettuces	0.4%	Milk: Cattle	0.1%	7%
7%	GEMS/Food G07	6.40	3%	Lettuces	0.6%	Celeries	0.5%	Spinaches	0.1%	7%
7%	IE adult	6.09	2%	Spinaches	1%	Rhubarbs	1%	Lettuces	0.1%	7%
6%	NL general	5.53	2%	Spinaches	1%	Escaroles/broad-leaved endives	1%	Lettuces	0.0%	6%
6%	GEMS/Food G06	5.19	1%	Lettuces	0.9%	Tomatoes	0.7%	Spinaches	0.1%	6%
5%	FR infant	4.82	4%	Spinaches	0.4%	Chards/beet leaves	0.4%	Milk: Cattle	0.0%	5%
4%	GEMS/Food G15	3.82	2%	Lettuces	0.4%	Celeries	0.3%	Wheat	0.1%	4%
4%	DE women 14-50 yr	3.73	2%	Lettuces	0.7%	Spinaches	0.3%	Lamb's lettuce/corn salads	0.1%	4%
4%	FR toddler 2 3 yr	3.65	2%	Spinaches	0.7%	Milk: Cattle	0.2%	Wheat	0.1%	4%
4%	DK child	3.47	2%	Lettuces	0.4%	Rye	0.3%	Wheat	0.0%	4%
4%	FR child 3 15 yr	3.44	1%	Spinaches	0.5%	Milk: Cattle	0.3%	Wheat	0.1%	4%
4%	DE general	3.42	1%	Lettuces	0.6%	Spinaches	0.3%	Milk: Cattle	0.0%	4%
3%	UK vegetarian	3.15	2%	Lettuces	0.5%	Spinaches	0.2%	Wine grapes	0.0%	3%
3%	PT general	2.93	1%	Lettuces	0.7%	Wine grapes	0.3%	Wheat	0.0%	3%
3%	FR adult	2.56	0.7%	Spinaches	0.7%	Wine grapes	0.3%	Lamb's lettuce/corn salads	0.0%	3%
3%	FI adult	2.49	2%	Lettuces	0.2%	Spinaches	0.1%	Tomatoes	0.1%	3%
3%	UK adult	2.48	2%	Lettuces	0.3%	Wine grapes	0.3%	Spinaches	0.0%	3%
3%	FI 6 yr	2.38	1%	Lettuces	0.8%	Spinaches	0.1%	Tomatoes	0.0%	3%
2%	DK adult	2.12	1%	Lettuces	0.3%	Wine grapes	0.2%	Spinaches	0.0%	2%
2%	FI 3 yr	2.09	0.9%	Spinaches	0.5%	Lettuces	0.1%	Oat	0.0%	2%
2%	UK toddler	2.01	0.5%	Milk: Cattle	0.4%	Spinaches	0.3%	Lettuces	0.1%	2%
2%	RO general	1.91	0.5%	Wine grapes	0.5%	Tomatoes	0.4%	Wheat	0.0%	2%
2%	UK infant	1.71	0.9%	Milk: Cattle	0.2%	Wheat	0.2%	Spinaches	0.0%	2%
2%	LT adult	1.40	0.9%	Lettuces	0.2%	Tomatoes	0.1%	Milk: Cattle	0.0%	2%
0.8%	PL general	0.68	0.2%	Tomatoes	0.2%	Lettuces	0.1%	Table grapes	0.0%	0.7%
0.5%	IE child	0.46	0.1%	Lettuces	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	0.5%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pydiflumetofen (F) is unlikely to present a public health concern.

Acute risk assessment/children | **Acute risk assessment/adults/general population**

Details – acute risk assessment/children | Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 5

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
228%	Escaroles/broad-leaved	40/17	683	114%	Escaroles/broad-leaved	40/17	343
216%	Lettuces	40/17	647	107%	Chards/beet leaves	40/17	321
128%	Spinaches	40/17	384	69%	Lettuces	40/17	206
116%	Celeries	15/9.3	348	58%	Florence fennels	15/9.3	173
115%	Rhubarbs	15/9.3	346	50%	Celeries	15/9.3	149
88%	Chards/beet leaves	40/17	265	40%	Globe artichokes	15/9.3	120
55%	Globe artichokes	15/9.3	164	32%	Cardoons	15/9.3	97
50%	Florence fennels	15/9.3	151	29%	Rhubarbs	15/9.3	86
30%	Kales	4/2.05	90	23%	Spinaches	40/17	68
29%	Table grapes	2/1.19	87	13%	Table grapes	2/1.19	40
16%	Lamb's lettuce/corn salads	40/17	48	13%	Kales	4/2.05	39
14%	Melons	0.4/0.27	41	11%	Purslanes	40/17	32
11%	Watermelons	0.4/0.27	33	11%	Lamb's lettuce/corn salads	40/17	32
9%	Tomatoes	0.9/0.45	26	9%	Wine grapes	2/1.19	28
8%	Sweet peppers/bell peppers	0.5/0.42	25	4%	Aubergines/egg plants	0.5/0.42	11

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 6

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 4

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
376%	Escaroles/broad-leaved endi	40/17	1127	116%	Escaroles/broad-leaved	40/17	347
176%	Chards/beet leaves/boiled	40/17	529	105%	Celeries/boiled	15/9.3	314
141%	Florence fennels/boiled	15/9.3	422	71%	Chards/beet leaves/boiled	40/17	213
116%	Rhubarbs/sauce/puree	15/9.3	347	60%	Florence fennels/boiled	15/9.3	180
79%	Spinaches/frozen; boiled	40/17	236	47%	Spinaches/frozen; boiled	40/17	141
19%	Kales/boiled	4/2.05	57	45%	Rhubarbs/sauce/puree	15/9.3	136
8%	Pumpkins/boiled	0.4/0.27	24	38%	Cardoons/boiled	15/9.3	113
4%	Wine grapes/juice	2/0.27	12	23%	Purslanes/boiled	40/17	70
3%	Courgettes/boiled	0.4/0.27	9.6	5%	Pumpkins/boiled	0.4/0.27	15
3%	Broccoli/boiled	0.15/0.12	9.5	4%	Wine grapes/wine	2/1.19	11
3%	Potatoes/fried	0.1/0.08	7.8	2%	Table grapes/raisins	2/5.59	6.9
2%	Cauliflowers/boiled	0.07/0.09	6.3	2%	Courgettes/boiled	0.4/0.27	6.2
2%	Gherkins/pickled	0.4/0.27	6.2	2%	Wine grapes/juice	2/0.27	5.6
1%	Sweet potatoes/boiled	0.1/0.08	4.2	1%	Cauliflowers/boiled	0.07/0.09	3.7
1%	Tomatoes/juice	0.9/0.22	4.2	1.0%	Broccoli/boiled	0.15/0.12	2.9

Expand/collapse list

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 6 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Pyflubumide

LOQs (mg/kg) range from:	0.01	to:	0.01

Toxicological reference values

ADI (mg/kg bw per day):	0.007	ARfD (mg/kg bw):	0.008
Source of ADI:	JMPR 2019	Source of ARfD:	JMPR 2019
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
82%	DE child	5.74	73%	Apples	3%	Milk: Cattle	2%	Tea (dried leaves of Camellia sinensis)	3%	78%
81%	NL toddler	5.70	63%	Apples	9%	Milk: Cattle	2%	Tea (dried leaves of Camellia sinensis)	7%	74%
46%	NL child	3.19	34%	Apples	3%	Milk: Cattle	3%	Tea (dried leaves of Camellia sinensis)	4%	41%
34%	FR adult	2.40	27%	Tea (dried leaves of Camellia sinensis)	4%	Apples	0.6%	Milk: Cattle	1%	33%
34%	IE adult	2.38	25%	Tea (dried leaves of Camellia sinensis)	4%	Apples	0.6%	Milk: Cattle	3%	30%
29%	UK infant	2.01	11%	Tea (dried leaves of Camellia sinensis)	9%	Apples	6%	Milk: Cattle	2%	26%
27%	FR toddler 2 3 yr	1.87	19%	Apples	4%	Milk: Cattle	0.9%	Tea (dried leaves of Camellia sinensis)	2%	24%
25%	DE women 14-50 yr	1.78	15%	Apples	6%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	23%
25%	DE general	1.72	14%	Apples	6%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	22%
22%	FR child 3 15 yr	1.53	10%	Apples	5%	Tea (dried leaves of Camellia sinensis)	3%	Milk: Cattle	3%	19%
22%	GEMS/Food G11	1.53	9%	Apples	7%	Tea (dried leaves of Camellia sinensis)	1%	Milk: Cattle	3%	18%
21%	UK toddler	1.50	10%	Apples	5%	Tea (dried leaves of Camellia sinensis)	3%	Milk: Cattle	3%	19%
20%	GEMS/Food G07	1.43	9%	Tea (dried leaves of Camellia sinensis)	6%	Apples	0.9%	Milk: Cattle	3%	17%
20%	GEMS/Food G06	1.43	10%	Tea (dried leaves of Camellia sinensis)	5%	Apples	1%	Wheat	4%	16%
19%	NL general	1.34	9%	Apples	7%	Tea (dried leaves of Camellia sinensis)	1%	Milk: Cattle	2%	17%
19%	DK child	1.34	14%	Apples	2%	Milk: Cattle	0.8%	Rye	3%	16%
18%	GEMS/Food G08	1.24	7%	Apples	6%	Tea (dried leaves of Camellia sinensis)	0.8%	Milk: Cattle	3%	14%
15%	GEMS/Food G10	1.07	6%	Tea (dried leaves of Camellia sinensis)	4%	Apples	0.8%	Milk: Cattle	3%	12%
15%	UK vegetarian	1.05	10%	Tea (dried leaves of Camellia sinensis)	3%	Apples	0.5%	Milk: Cattle	1%	14%
15%	UK adult	1.03	10%	Tea (dried leaves of Camellia sinensis)	2%	Apples	0.4%	Milk: Cattle	1.0%	13%
14%	GEMS/Food G15	1.00	6%	Apples	3%	Tea (dried leaves of Camellia sinensis)	1%	Milk: Cattle	3%	11%
14%	FR infant	0.97	10%	Apples	2%	Milk: Cattle	0.3%	Potatoes	1%	12%
13%	RO general	0.94	8%	Apples	2%	Milk: Cattle	0.7%	Wheat	2%	10%
13%	PL general	0.91	12%	Apples	0.5%	Potatoes	0.1%	Tomatoes	0.9%	12%
13%	LT adult	0.91	11%	Apples	0.6%	Milk: Cattle	0.5%	Potatoes	1%	12%
12%	ES child	0.81	7%	Apples	2%	Milk: Cattle	0.6%	Wheat	2%	9%
11%	SE general	0.79	6%	Apples	2%	Milk: Cattle	0.6%	Bovine: Muscle/meat	2%	9%
10%	DK adult	0.67	6%	Apples	2%	Tea (dried leaves of Camellia sinensis)	0.8%	Milk: Cattle	0.8%	8%
9%	PT general	0.63	6%	Apples	0.8%	Potatoes	0.6%	Wheat	2%	6%
8%	FI 3 yr	0.54	6%	Apples	0.7%	Potatoes	0.2%	Bananas	2%	6%
7%	IT toddler	0.52	5%	Apples	0.9%	Wheat	0.2%	Other cereals	2%	5%
7%	ES adult	0.51	5%	Apples	0.7%	Milk: Cattle	0.3%	Wheat	1%	6%
6%	IT adult	0.44	5%	Apples	0.6%	Wheat	0.2%	Tomatoes	1%	5%
5%	FI 6 yr	0.36	3%	Apples	0.6%	Potatoes	0.1%	Wheat	2%	3%
5%	FI adult	0.36	3%	Apples	0.8%	Coffee beans	0.2%	Potatoes	2%	3%
3%	IE child	0.24	2%	Apples	0.5%	Milk: Cattle	0.4%	Tea (dried leaves of Camellia sinensis)	0.4%	3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyflubumide is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
741%	Apples	1/0.55	59
258%	Tea (dried leaves of Camellia sinensis)	0.01/13.5	21
2%	Poultry: Muscle/meat	0.01/0.01	0.17
2%	Eggs: Chicken	0.01/0.01	0.12
2%	Swine: Muscle/meat	0.01/0.01	0.12
1%	Bovine: Liver	0.01/0.01	0.08
0.9%	Bovine: Edible offals (other than liver and kidney)	0.01/0.01	0.07
0.9%	Bovine: Muscle/meat	0.01/0.01	0.07
0.8%	Equine: Muscle/meat	0.01/0.01	0.06
0.7%	Sheep: Muscle/meat	0.01/0.01	0.05
0.5%	Bovine: Kidney	0.01/0.01	0.04
0.4%	Swine: Edible offals (other than liver and kidney)	0.01/0.01	0.03
0.3%	Bovine: Fat tissue	0.01/0.01	0.02
0.2%	Swine: Fat tissue	0.01/0.01	0.02
0.2%	Swine: Kidney	0.01/0.01	0.01

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
193%	Apples	1/0.55	15
84%	Tea (dried leaves of Camellia sinensis)	0.01/13.5	6.8
1%	Poultry: Muscle	0.01/0.01	0.12
0.7%	Bovine: Muscle	0.01/0.01	0.06
0.6%	Swine: Muscle/meat	0.01/0.01	0.05
0.6%	Equine: Muscle/meat	0.01/0.01	0.05
0.6%	Sheep: Muscle/meat	0.01/0.01	0.05
0.6%	Poultry: Liver	0.01/0.01	0.05
0.5%	Eggs: Chicken	0.01/0.01	0.04
0.5%	Bovine: Liver	0.01/0.01	0.04
0.4%	Bovine: Edible offals (other than liver and kidney)	0.01/0.01	0.03
0.4%	Sheep: Liver	0.01/0.01	0.03
0.3%	Swine: Edible offals (other than liver and kidney)	0.01/0.01	0.03
0.3%	Swine: Kidney	0.01/0.01	0.02
0.3%	Bovine: Kidney	0.01/0.01	0.02

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 2

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
277%	Apples/juice	1/0.41	22
59%	Tea (dried leaves of Camellia sinensis)/infusion	0.01/0.14	4.7

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
171%	Apples/juice	1/0.41	14
34%	Tea (dried leaves of Camellia sinensis)/infusion	0.01/0.14	2.7

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Pyraclostrobin (F)

LOQs (mg/kg) range from:	0.01	to:	0.50
Toxicological reference values			
ADI (mg/kg bw per day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
18%	NL toddler	5.30	5%	Apples	2%	Pears	2%	Table grapes	0.0%	18%
14%	DE child	4.28	6%	Apples	2%	Table grapes	0.9%	Oranges	0.0%	14%
11%	NL child	3.25	3%	Apples	1%	Table grapes	1%	Sugar beet roots	0.0%	11%
9%	GEMS/Food G11	2.55	2%	Wine grapes	0.9%	Barley	0.7%	Apples	0.0%	9%
8%	GEMS/Food G07	2.51	2%	Wine grapes	0.7%	Barley	0.5%	Apples	0.0%	8%
8%	GEMS/Food G08	2.49	2%	Wine grapes	1%	Barley	0.6%	Apples	0.0%	8%
8%	GEMS/Food G15	2.28	2%	Wine grapes	0.9%	Barley	0.5%	Apples	0.0%	8%
7%	GEMS/Food G06	2.25	1%	Table grapes	1%	Tomatoes	0.5%	Wheat	0.0%	7%
7%	PT general	2.12	4%	Wine grapes	0.5%	Apples	0.4%	Potatoes		7%
7%	IE adult	2.09	2%	Wine grapes	0.3%	Blackberries	0.3%	Apples	0.0%	7%
7%	DE general	2.06	1%	Wine grapes	1%	Apples	0.6%	Barley	0.0%	7%
7%	DE women 14-50 yr	2.06	1%	Wine grapes	1%	Apples	0.6%	Sugar beet roots	0.0%	7%
7%	GEMS/Food G10	2.04	0.7%	Barley	0.7%	Wine grapes	0.5%	Cress and other sprouts and shoots	0.0%	7%
7%	RO general	2.04	3%	Wine grapes	0.7%	Apples	0.6%	Tomatoes		7%
6%	FR child 3 15 yr	1.92	0.8%	Apples	0.8%	Oranges	0.6%	Wine grapes	0.0%	6%
6%	FR adult	1.88	4%	Wine grapes	0.4%	Apples	0.2%	Tomatoes	0.0%	6%
6%	DK child	1.71	1%	Apples	0.8%	Cucumbers	0.5%	Carrots		6%
6%	FR toddler 2 3 yr	1.68	1%	Apples	0.4%	Sugar beet roots	0.4%	Wine grapes	0.0%	6%
5%	NL general	1.53	0.9%	Wine grapes	0.7%	Apples	0.4%	Sugar beet roots	0.0%	5%
5%	FI 3 yr	1.47	0.7%	Oat	0.5%	Raspberries (red and yellow)	0.5%	Cucumbers	0.0%	5%
5%	UK toddler	1.45	0.8%	Apples	0.5%	Oranges	0.4%	Sugar beet roots	0.0%	5%
5%	SE general	1.38	0.7%	Bovine: Muscle/meat	0.5%	Apples	0.3%	Carrots		5%
4%	UK infant	1.26	0.7%	Apples	0.5%	Carrots	0.3%	Oranges		4%
4%	ES adult	1.14	0.7%	Wine grapes	0.6%	Barley	0.4%	Apples		4%
4%	ES child	1.11	0.5%	Apples	0.5%	Oranges	0.3%	Tomatoes		4%
4%	DK adult	1.11	2%	Wine grapes	0.4%	Apples	0.2%	Table grapes	0.0%	4%
3%	FI 6 yr	1.03	0.4%	Raspberries (red and yellow)	0.4%	Oat	0.4%	Cucumbers	0.0%	3%
3%	UK adult	1.00	2%	Wine grapes	0.2%	Apples	0.1%	Tomatoes	0.0%	3%
3%	UK vegetarian	1.00	1%	Wine grapes	0.3%	Apples	0.2%	Tomatoes	0.0%	3%
3%	FR infant	0.96	0.8%	Apples	0.4%	Carrots	0.2%	Leeks	0.0%	3%
3%	IT toddler	0.88	0.5%	Tomatoes	0.4%	Wheat	0.4%	Apples		3%
3%	FI adult	0.88	0.6%	Coffee beans	0.5%	Wine grapes	0.3%	Apples	0.0%	3%
3%	PL general	0.87	1.0%	Apples	0.4%	Table grapes	0.3%	Tomatoes		3%
3%	IT adult	0.76	0.4%	Tomatoes	0.4%	Apples	0.3%	Wheat	0.0%	3%
3%	LT adult	0.75	0.9%	Apples	0.2%	Potatoes	0.2%	Tomatoes		3%
0.8%	IE child	0.24	0.2%	Apples	0.1%	Currants (red, black and white)	0.1%	Wheat	0.0%	0.8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyraclostrobin (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 3

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
134%	Pears	0.5/0.29	40	100%	Wine grapes	2/1.27	30
109%	Table grapes	1/0.45	33	74%	Red mustards	10/4.16	22
104%	Apples	0.5/0.29	31	64%	Blueberries	4/2.1	19
92%	Mangoes	0.6/0.35	28	62%	Globe artichokes	3/1.44	19
90%	Cucumbers	0.5/0.41	27	53%	Cherries (sweet)	3/1.6	16
89%	Kales	1.5/0.61	27	51%	Chinese cabbages/pe-tsai	1.5/0.61	15
84%	Globe artichokes	3/1.44	25	51%	Chards/beet leaves	1.5/0.81	15
80%	Oranges	2/0.18	24	51%	Table grapes	1/0.45	15
76%	Celeries	1.5/0.61	23	46%	Currants (red, black and white)	3/2.1	14
73%	Apricots	1/0.63	22	39%	Kales	1.5/0.61	12
73%	Melons	0.5/0.15	22	38%	Cucumbers	0.5/0.41	11
65%	Chinese cabbages/pe-tsai	1.5/0.61	20	38%	Florence fennels	1.5/0.61	11
65%	Cherries (sweet)	3/1.6	20	36%	Blackberries	3/1.3	11
59%	Watermelons	0.5/0.15	18	34%	Swedes/rutabagas	0.5/0.3	10
58%	Plums	0.8/0.41	17	33%	Celeries	1.5/0.61	9.8
57%	Beetroots	0.5/0.3	17	32%	Gooseberries (green, red and yellow)	3/2.1	9.5
57%	Leeks	0.8/0.29	17	31%	Head cabbages	0.4/0.22	9.3
55%	Celeriacs/turnip rooted celeries	0.5/0.3	17	30%	Mangoes	0.6/0.35	9.1
55%	Currants (red, black and white)	3/2.1	17	30%	Pears	0.5/0.29	8.9
52%	Swedes/rutabagas	0.5/0.3	16	27%	Apples	0.5/0.29	8.1
51%	Carrots	0.5/0.24	15	26%	Lamb's lettuce/corn salads	10/4.16	7.8
50%	Tomatoes	0.3/0.26	15	24%	Plums	0.8/0.41	7.3
50%	Sweet peppers/bell peppers	0.5/0.25	15	24%	Strawberries	1.5/0.78	7.3
46%	Blackberries	3/1.3	14	23%	Aubergines/egg plants	0.3/0.26	7.0
42%	Strawberries	1.5/0.78	13	23%	Raspberries (red and yellow)	3/1.3	7.0
42%	Chards/beet leaves	1.5/0.81	13	23%	Beetroots	0.5/0.3	6.9
42%	Courgettes	0.5/0.27	13	23%	Apricots	1/0.63	6.9
42%	Blueberries	4/2.1	13	21%	Courgettes	0.5/0.27	6.3
41%	Peaches	0.3/0.13	12	20%	Watermelons	0.5/0.15	5.9
41%	Gooseberries (green, red and yellow)	3/2.1	12	19%	Melons	0.5/0.15	5.7
40%	Raspberries (red and yellow)	3/1.3	12	19%	Escaroles/broad-leaved endives	0.4/0.28	5.6
39%	Wine grapes	2/1.27	12	19%	Oranges	2/0.18	5.6
39%	Lamb's lettuce/corn salads	10/4.16	12	16%	Roman rocket/rucola	10/4.16	4.9
37%	Escaroles/broad-leaved endives	0.4/0.28	11	16%	Carrots	0.5/0.24	4.7
37%	Roman rocket/rucola	10/4.16	11	15%	Rose hips	3/2.1	4.6
37%	Cauliflowers	0.5/0.19	11	15%	Broccoli	0.5/0.19	4.5
36%	Parsnips	0.5/0.3	11	15%	Quinces	0.5/0.29	4.4
36%	Turnips	0.5/0.3	11	15%	Cauliflowers	0.5/0.19	4.4
34%	Grapefruits	2/0.13	10	14%	Parsnips	0.5/0.3	4.2
33%	Florence fennels	1.5/0.61	9.9	14%	Tomatoes	0.3/0.26	4.1
32%	Head cabbages	0.4/0.22	9.7	14%	Sweet peppers/bell peppers	0.5/0.25	4.1
31%	Cranberries	3/2.1	9.4	13%	Leeks	0.8/0.29	3.8
31%	Spring onions/green onions and Welsh onions	1.5/0.6	9.4	12%	Celeriacs/turnip rooted celeries	0.5/0.3	3.6
31%	Salsifies	0.5/0.3	9.3	11%	Turnips	0.5/0.3	3.3

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
92%	Florence fennels/boiled	1.5/0.61	28	69%	Celeries/boiled	1.5/0.61	21
90%	Currants (red, black and white)/juice	3/0.94	27	53%	Pumpkins/boiled	0.5/0.29	16
86%	Oranges/juice	2/0.49	26	40%	Wine grapes/wine	2/1.27	12
86%	Pumpkins/boiled	0.5/0.29	26	40%	Currants (red, black and white)/juice	3/0.94	12
84%	Chards/beet leaves/boiled	1.5/0.81	25	39%	Florence fennels/boiled	1.5/0.61	12
70%	Wine grapes/juice	2/0.48	21	39%	Beetroots/boiled	0.5/0.3	12
62%	Escaroles/broad-leaved endives/boiled	0.4/0.28	19	34%	Chards/beet leaves/boiled	1.5/0.81	10
56%	Kales/boiled	1.5/0.61	17	33%	Wine grapes/juice	2/0.48	10.0
55%	Leeks/boiled	0.8/0.29	17	29%	Elderberries/juice	3/0.94	8.6
51%	Turnips/boiled	0.5/0.3	15	26%	Cauliflowers/boiled	0.5/0.19	7.9
51%	Parsnips/boiled	0.5/0.3	15	25%	Oranges/juice	2/0.49	7.4
50%	Elderberries/juice	3/0.94	15	21%	Parsnips/boiled	0.5/0.3	6.4
50%	Broccoli/boiled	0.5/0.19	15	21%	Courgettes/boiled	0.5/0.27	6.2
44%	Beetroots/boiled	0.5/0.3	13	20%	Grapefruits/juice	2/0.54	5.9
44%	Cauliflowers/boiled	0.5/0.19	13	19%	Turnips/boiled	0.5/0.3	5.7

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 4 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
92%	Florence fennels/boiled	1.5/0.61	28	69%	Celeries/boiled	1.5/0.61	21
90%	Currants (red, black and whit	3/0.94	27	53%	Pumpkins/boiled	0.5/0.29	16
86%	Oranges/juice	2/0.49	26	40%	Wine grapes/wine	2/1.27	12
86%	Pumpkins/boiled	0.5/0.29	26	40%	Currants (red, black and	3/0.94	12
84%	Chards/beet leaves/boiled	1.5/0.81	25	39%	Florence fennels/boiled	1.5/0.61	12
70%	Wine grapes/juice	2/0.48	21	39%	Beetroots/boiled	0.5/0.3	12
62%	Escaroles/broad-leaved endi	0.4/0.28	19	34%	Chards/beet leaves/boiled	1.5/0.81	10
56%	Kales/boiled	1.5/0.61	17	33%	Wine grapes/juice	2/0.48	10.0
55%	Leeks/boiled	0.8/0.29	17	29%	Elderberries/juice	3/0.94	8.6
51%	Turnips/boiled	0.5/0.3	15	26%	Cauliflowers/boiled	0.5/0.19	7.9
51%	Parsnips/boiled	0.5/0.3	15	25%	Oranges/juice	2/0.49	7.4
50%	Elderberries/juice	3/0.94	15	21%	Parsnips/boiled	0.5/0.3	6.4
50%	Broccoli/boiled	0.5/0.19	15	21%	Courgettes/boiled	0.5/0.27	6.2
44%	Beetroots/boiled	0.5/0.3	13	20%	Grapefruits/juice	2/0.54	5.9
44%	Cauliflowers/boiled	0.5/0.19	13	19%	Turnips/boiled	0.5/0.3	5.7
Expand/collapse list							

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 4 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Pyriofenone

LOQs (mg/kg) range from:	0.01	to:	0.01

Toxicological reference values

ADI (mg/kg bw per day):	0.07	ARfD (mg/kg bw):	Not applicable
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments: EFSA 2019

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	0.81	0.9%	Milk: Cattle	0.2%	Table grapes	0.1%	Wheat		0.0%
0.6%	UK infant	0.43	0.6%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.0%
0.6%	NL child	0.40	0.3%	Milk: Cattle	0.1%	Table grapes	0.1%	Wheat		0.0%
0.6%	DE child	0.39	0.3%	Milk: Cattle	0.2%	Table grapes	0.1%	Wheat		0.0%
0.5%	FR toddler 2 3 yr	0.36	0.4%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.0%
0.5%	FR child 3 15 yr	0.36	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Table grapes		0.0%
0.5%	RO general	0.32	0.2%	Wine grapes	0.2%	Milk: Cattle	0.1%	Wheat		0.0%
0.4%	UK toddler	0.29	0.3%	Milk: Cattle	0.1%	Wheat	0.0%	Table grapes		0.0%
0.4%	GEMS/Food G07	0.28	0.2%	Wine grapes	0.1%	Milk: Cattle	0.1%	Wheat		0.0%
0.4%	FR adult	0.27	0.3%	Wine grapes	0.1%	Milk: Cattle	0.0%	Wheat		0.0%
0.4%	PT general	0.27	0.3%	Wine grapes	0.1%	Wheat	0.0%	Table grapes		
0.4%	DK child	0.26	0.2%	Milk: Cattle	0.1%	Rye	0.1%	Wheat		0.0%
0.4%	DE women 14-50 yr	0.26	0.2%	Milk: Cattle	0.1%	Wine grapes	0.0%	Table grapes		0.0%
0.4%	GEMS/Food G11	0.26	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Table grapes		0.0%
0.4%	DE general	0.25	0.2%	Milk: Cattle	0.1%	Wine grapes	0.0%	Table grapes		0.0%
0.4%	GEMS/Food G15	0.25	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Wheat		0.0%
0.3%	GEMS/Food G08	0.23	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Wheat		0.0%
0.3%	GEMS/Food G06	0.22	0.2%	Table grapes	0.1%	Wheat	0.0%	Milk: Cattle		0.0%
0.3%	IE adult	0.21	0.1%	Wine grapes	0.1%	Milk: Cattle	0.0%	Table grapes		0.0%
0.3%	SE general	0.20	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Wheat		0.1%
0.3%	ES child	0.19	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Bovine: Muscle/meat		0.0%
0.3%	NL general	0.19	0.1%	Milk: Cattle	0.1%	Wine grapes	0.0%	Table grapes		0.0%
0.3%	FR infant	0.18	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.0%
0.3%	GEMS/Food G10	0.18	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Wine grapes		0.0%
0.2%	DK adult	0.17	0.1%	Wine grapes	0.1%	Milk: Cattle	0.0%	Table grapes		0.0%
0.2%	UK adult	0.15	0.1%	Wine grapes	0.0%	Milk: Cattle	0.0%	Wheat		0.0%
0.2%	UK vegetarian	0.13	0.1%	Wine grapes	0.0%	Milk: Cattle	0.0%	Wheat		0.0%
0.2%	ES adult	0.12	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	IT toddler	0.08	0.1%	Wheat	0.0%	Table grapes	0.0%	Barley		
0.1%	LT adult	0.07	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.0%
0.1%	IT adult	0.05	0.1%	Wheat	0.0%	Table grapes	0.0%	Barley		
0.1%	IE child	0.05	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Table grapes		0.0%
0.1%	FI 3 yr	0.05	0.0%	Table grapes	0.0%	Wheat	0.0%	Rye		
0.1%	FI adult	0.04	0.0%	Wine grapes	0.0%	Table grapes	0.0%	Rye		
0.1%	FI 6 yr	0.04	0.0%	Table grapes	0.0%	Wheat	0.0%	Rye		
0.0%	PL general	0.03	0.0%	Table grapes		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyriofenone is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Wine grapes/juice	0.3/0.08	3.5	7%	Table grapes/raisins	0.3/4.23	5.2
0.2%	Wheat/milling (flour)	0.01/0.01	0.12	4%	Wine grapes/wine	0.3/0.3	2.8
0.1%	Wheat/milling (wholemeal)-baking	0.01/0.01	0.06	2%	Wine grapes/juice	0.3/0.08	1.7
0.1%	Rye/boiled	0.01/0.01	0.04	0.1%	Barley/beer	0.03/0	0.07
0.1%	Oat/boiled	0.03/0.01	0.04	0.06%	Wheat/bread/pizza	0.01/0.01	0.04
0.1%	Barley/cooked	0.03/0.01	0.04	0.05%	Wheat/pasta	0.01/0.01	0.04
0.1%	Rye/milling (wholemeal)-baking	0.01/0.01	0.04	0.05%	Wheat/bread (wholemeal)	0.01/0.01	0.03
0.0%	Oat/milling (flakes)	0.03/0.01	0.03	0.02%	Oat/boiled	0.03/0.01	0.02
0.0%	Barley/milling (flour)	0.03/0.01	0.02				

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Pyriofenone is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Pyriproxyfen

LOQs (mg/kg) range from:	0.02	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.05	ARfD (mg/kg bw):	1
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
22%	NL toddler	10.89	6%	Milk: Cattle	4%	Apples	3%	Oranges	10%	0.0%
18%	DE child	9.01	5%	Apples	5%	Oranges	2%	Tomatoes	4%	0.0%
15%	GEMS/Food G06	7.41	7%	Tomatoes	1%	Oranges	1.0%	Sweet peppers/bell peppers	3%	0.0%
12%	NL child	6.21	2%	Milk: Cattle	2%	Apples	2%	Oranges	5%	0.0%
12%	FR child 3 15 yr	5.90	4%	Oranges	2%	Milk: Cattle	2%	Tomatoes	5%	0.0%
10%	FR toddler 2 3 yr	5.00	3%	Milk: Cattle	2%	Oranges	1%	Apples	5%	0.0%
10%	RO general	4.85	4%	Tomatoes	1%	Milk: Cattle	0.8%	Sweet peppers/bell peppers	3%	0.0%
9%	UK infant	4.58	4%	Milk: Cattle	2%	Oranges	0.7%	Tomatoes	6%	0.0%
9%	GEMS/Food G10	4.52	3%	Tomatoes	1%	Oranges	0.5%	Milk: Cattle	3%	0.0%
9%	UK toddler	4.44	2%	Oranges	2%	Milk: Cattle	1%	Tomatoes	4%	0.0%
9%	DE women 14-50 yr	4.42	2%	Oranges	1%	Tomatoes	1%	Milk: Cattle	3%	0.0%
9%	GEMS/Food G07	4.42	2%	Tomatoes	2%	Oranges	0.6%	Milk: Cattle	3%	0.0%
9%	GEMS/Food G15	4.39	2%	Tomatoes	1%	Sweet peppers/bell peppers	0.8%	Oranges	3%	0.0%
9%	IE adult	4.37	1%	Oranges	1%	Tea (dried leaves of Camellia sinensis)	0.8%	Grapefruits	3%	0.0%
9%	ES child	4.35	3%	Oranges	2%	Tomatoes	1%	Milk: Cattle	3%	0.0%
9%	GEMS/Food G11	4.31	2%	Tomatoes	0.9%	Oranges	0.8%	Milk: Cattle	3%	0.0%
8%	GEMS/Food G08	4.13	2%	Tomatoes	0.6%	Sweet peppers/bell peppers	0.6%	Milk: Cattle	3%	0.0%
8%	DE general	4.04	2%	Oranges	1%	Tomatoes	1%	Milk: Cattle	3%	0.0%
8%	SE general	3.79	2%	Tomatoes	1%	Milk: Cattle	0.9%	Oranges	3%	0.0%
7%	DK child	3.43	1%	Milk: Cattle	1%	Tomatoes	0.9%	Apples	3%	0.0%
6%	NL general	2.96	1%	Oranges	0.8%	Milk: Cattle	0.8%	Tomatoes	2%	0.0%
6%	IT toddler	2.95	3%	Tomatoes	0.7%	Wheat	0.6%	Oranges	1%	0.0%
6%	ES adult	2.91	2%	Tomatoes	2%	Oranges	0.5%	Milk: Cattle	2%	0.0%
5%	PT general	2.74	2%	Tomatoes	0.7%	Oranges	0.5%	Potatoes	2%	0.0%
5%	FR adult	2.58	1%	Tea (dried leaves of Camellia sinensis)	0.9%	Tomatoes	0.7%	Oranges	2%	0.0%
5%	IT adult	2.40	2%	Tomatoes	0.4%	Oranges	0.4%	Wheat	0.8%	0.0%
5%	UK vegetarian	2.29	1%	Tomatoes	1%	Oranges	0.4%	Tea (dried leaves of Camellia sinensis)	1%	0.0%
4%	FR infant	2.08	2%	Milk: Cattle	0.7%	Apples	0.3%	Oranges	3%	0.0%
4%	FI 3 yr	1.95	1%	Tomatoes	0.5%	Potatoes	0.5%	Mandarins	1%	0.0%
4%	PL general	1.85	2%	Tomatoes	0.8%	Apples	0.3%	Potatoes	0.6%	0.0%
4%	LT adult	1.82	1%	Tomatoes	0.7%	Apples	0.4%	Milk: Cattle	1%	
4%	DK adult	1.79	1%	Tomatoes	0.5%	Milk: Cattle	0.4%	Apples	1%	0.0%
4%	UK adult	1.79	0.9%	Tomatoes	0.7%	Oranges	0.4%	Tea (dried leaves of Camellia sinensis)	1%	0.0%
3%	FI adult	1.62	1%	Tomatoes	0.6%	Coffee beans	0.5%	Oranges	1%	0.0%
3%	FI 6 yr	1.57	0.9%	Tomatoes	0.4%	Mandarins	0.4%	Potatoes	1.0%	0.0%
1%	IE child	0.57	0.4%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	0.7%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyriproxyfen is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Oranges	0.6/0.6	80	3%	Aubergines/egg plants	1/1	27
7%	Bananas	0.7/0.7	68	2%	Oranges	0.6/0.6	18
6%	Sweet peppers/bell peppers	1/1	60	2%	Sweet peppers/bell peppers	1/1	16
6%	Tomatoes	1/1	58	2%	Tomatoes	1/1	16
5%	Peaches	0.5/0.5	48	1%	Bananas	0.7/0.7	15
5%	Grapefruits	0.6/0.6	47	1%	Mandarins	0.6/0.6	11
4%	Mandarins	0.6/0.6	36	1%	Grapefruits	0.6/0.6	11
3%	Pears	0.2/0.2	28	1%	Cherries (sweet)	1/1	10.0
3%	Aubergines/egg plants	1/1	25	0.9%	Peaches	0.5/0.5	9.4
2%	Melons	0.07/0.15	23	0.6%	Pears	0.2/0.2	6.1
2%	Apples	0.2/0.2	22	0.6%	Melons	0.07/0.15	5.9
2%	Lemons	0.6/0.6	21	0.6%	Apples	0.2/0.2	5.6
1%	Plums	0.3/0.3	13	0.5%	Lemons	0.6/0.6	5.4
1%	Cherries (sweet)	1/1	12	0.5%	Plums	0.3/0.3	5.3
1%	Limes	0.6/0.6	12	0.4%	Limes	0.6/0.6	4.2

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Oranges/juice	0.6/0.6	32	0.9%	Oranges/juice	0.6/0.6	9.1
2%	Tomatoes/juice	1/1	19	0.8%	Tomatoes/sauce/puree	1/1	8.2
1%	Peaches/canned	0.5/0.5	13	0.7%	Apples/juice	0.2/0.2	6.7
1%	Apples/juice	0.2/0.2	11	0.7%	Grapefruits/juice	0.6/0.6	6.5
1.0%	Tomatoes/sauce/puree	1/1	9.5	0.4%	Peaches/canned	0.5/0.5	4.1
0.7%	Pears/juice	0.2/0.2	6.5	0.3%	Pumpkins/boiled	0.05/0.05	2.8
0.6%	Cranberries/juice	1/1	5.8	0.2%	Sugar beets (root)/sugar	0.05/0.6	2.2
0.6%	Sugar beets (root)/sugar	0.05/0.6	5.5	0.2%	Cauliflowers/boiled	0.05/0.05	2.1
0.5%	Potatoes/fried	0.05/0.05	4.7	0.2%	Beetroots/boiled	0.05/0.05	1.9
0.4%	Pumpkins/boiled	0.05/0.05	4.4	0.2%	Celeries/boiled	0.05/0.05	1.7
0.4%	Witloofs/boiled	0.05/0.05	4.4	0.2%	Okra, lady's fingers/boiled	1/1	1.6
0.4%	Broccoli/boiled	0.05/0.05	3.9	0.1%	Broccoli/boiled	0.05/0.05	1.2
0.3%	Cauliflowers/boiled	0.05/0.05	3.5	0.1%	Courgettes/boiled	0.05/0.05	1.1
0.3%	Escaroles/broad-leaved endives/boiled	0.05/0.05	3.3	0.1%	Lemons/juice	0.6/0.6	1.1
0.3%	Potatoes/dried (flakes)	0.05/0.23	3.0	0.1%	Parsnips/boiled	0.05/0.05	1.1

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Pyriproxyfen is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Spirotetramat			
LOQs (mg/kg) range from:	0.01	to:	0.10
Toxicological reference values			
ADI (mg/kg bw per day):	0.05	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
27%	NL toddler	13.25	5%	Spinaches	3%	Apples	2%	Beans (with pods)	0.6%	26%
19%	DE child	9.51	4%	Apples	2%	Oranges	1%	Spinaches	0.4%	17%
15%	IE adult	7.62	3%	Other leafy brassica	1%	Wine grapes	1.0%	Peaches	0.4%	12%
15%	GEMS/Food G06	7.40	4%	Tomatoes	0.9%	Soyabeans	0.9%	Table grapes	0.6%	14%
15%	GEMS/Food G10	7.36	3%	Soyabeans	2%	Lettuces	1%	Tomatoes	0.4%	14%
15%	NL child	7.30	2%	Spinaches	2%	Apples	0.9%	Table grapes	0.3%	14%
14%	GEMS/Food G11	6.83	3%	Soyabeans	0.9%	Tomatoes	0.9%	Wine grapes	0.4%	13%
14%	GEMS/Food G07	6.80	2%	Lettuces	1%	Soyabeans	1%	Wine grapes	0.4%	12%
13%	IT adult	6.66	3%	Lettuces	2%	Other lettuce and other salad plants	1%	Tomatoes	0.2%	9%
13%	GEMS/Food G08	6.48	2%	Soyabeans	1%	Lettuces	1%	Tomatoes	0.4%	12%
12%	SE general	5.90	3%	Lettuces	1%	Chinese cabbages/pe-tsai	0.9%	Potatoes	0.2%	12%
12%	IT toddler	5.86	2%	Lettuces	2%	Other lettuce and other salad plants	1%	Tomatoes	0.3%	8%
12%	GEMS/Food G15	5.81	1%	Soyabeans	1%	Tomatoes	0.9%	Wine grapes	0.4%	11%
11%	FR child 3 15 yr	5.63	2%	Other lettuce and other salad plants	1%	Oranges	1%	Beans (with pods)	0.4%	9%
11%	ES child	5.44	3%	Lettuces	1%	Tomatoes	0.9%	Oranges	0.3%	10%
10%	PT general	5.24	2%	Wine grapes	1%	Kales	1%	Potatoes	0.2%	10%
10%	ES adult	5.21	4%	Lettuces	0.8%	Tomatoes	0.7%	Peaches	0.2%	10%
10%	RO general	4.75	2%	Tomatoes	1%	Wine grapes	1%	Head cabbages	0.3%	9%
9%	FR toddler 2 3 yr	4.59	2%	Beans (with pods)	1%	Spinaches	0.9%	Apples	0.3%	8%
9%	DE women 14-50 yr	4.48	0.8%	Lettuces	0.8%	Oranges	0.8%	Tomatoes	0.3%	8%
9%	NL general	4.35	1%	Spinaches	0.7%	Escaroles/broad-leaved endives	0.7%	Lettuces	0.2%	8%
9%	FR adult	4.33	2%	Other lettuce and other salad plants	2%	Wine grapes	0.6%	Beans (with pods)	0.2%	6%
8%	DE general	4.13	0.7%	Wine grapes	0.7%	Lettuces	0.7%	Apples	0.3%	8%
6%	UK toddler	3.17	0.8%	Oranges	0.8%	Potatoes	0.6%	Tomatoes	0.2%	6%
6%	FR infant	3.07	2%	Spinaches	1%	Beans (with pods)	0.5%	Apples	0.0%	6%
6%	UK infant	3.05	0.7%	Potatoes	0.6%	Peas (without pods)	0.5%	Oranges	0.2%	6%
6%	DK child	2.89	1%	Lettuces	0.7%	Apples	0.6%	Tomatoes	0.4%	5%
5%	FI 3 yr	2.71	1%	Potatoes	0.6%	Tomatoes	0.5%	Spinaches	0.2%	5%
5%	UK vegetarian	2.68	1%	Lettuces	0.7%	Wine grapes	0.6%	Tomatoes	0.1%	5%
5%	PL general	2.38	0.9%	Tomatoes	0.8%	Potatoes	0.6%	Apples	0.0%	5%
5%	FI adult	2.35	1%	Coffee beans	1%	Lettuces	0.6%	Tomatoes	1%	4%
5%	FI 6 yr	2.34	0.9%	Potatoes	0.6%	Lettuces	0.5%	Tomatoes	0.2%	5%
4%	UK adult	2.23	0.9%	Wine grapes	0.9%	Lettuces	0.5%	Tomatoes	0.1%	4%
4%	DK adult	2.15	0.8%	Wine grapes	0.7%	Lettuces	0.5%	Tomatoes	0.1%	4%
3%	LT adult	1.66	0.7%	Potatoes	0.6%	Tomatoes	0.5%	Apples	0.1%	3%
1%	IE child	0.52	0.1%	Potatoes	0.1%	Beans (without pods)	0.1%	Apples	0.1%	1.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Spirotetramat is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Kales	7/6.5	286	16%	Chinese cabbages/pe-tsai	7/6.5	165
26%	Escaroles/broad-leaved endives	7/6.5	261	13%	Escaroles/broad-leaved endives	7/6.5	131
25%	Lettuces	7/6.5	247	13%	Kales	7/6.5	125
21%	Chinese cabbages/pe-tsai	7/6.5	209	12%	Chards/beet leaves	7/6.5	123
18%	Peaches	3/1.92	182	9%	Head cabbages	2/2.14	90
15%	Spinaches	7/6.5	147	8%	Lettuces	7/6.5	79
12%	Kiwi fruits (green, red, yellow)	3/1.97	122	5%	Table grapes	2/1.4	47
12%	Litchis/lychees	15/9.88	117	4%	Florence fennels	4/2.04	38
10%	Table grapes	2/1.4	102	4%	Peaches	3/1.92	36
10%	Chards/beet leaves	7/6.5	101	3%	Red mustards	7/6.5	35
9%	Head cabbages	2/2.14	95	3%	Plums	3/1.92	34
9%	Pears	0.7/0.64	88	3%	Wine grapes	2/1.4	33
8%	Plums	3/1.92	81	3%	Celeries	4/2.04	33
8%	Celeries	4/2.04	76	3%	Strawberry leaves	50/50	30
8%	Rhubarbs	4/2.04	76	3%	Aubergines/egg plants	1/1.06	29

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
43%	Escaroles/broad-leaved endives/boiled	7/6.5	431	13%	Escaroles/broad-leaved endives/boiled	7/6.5	133
20%	Chards/beet leaves/boiled	7/6.5	202	8%	Chards/beet leaves/boiled	7/6.5	81
18%	Kales/boiled	7/6.5	179	7%	Celeries/boiled	4/2.04	69
9%	Florence fennels/boiled	4/2.04	92	5%	Spinaches/frozen; boiled	7/6.5	54
9%	Spinaches/frozen; boiled	7/6.5	90	4%	Cauliflowers/boiled	1/1.05	44
8%	Broccoli/boiled	1/1.05	83	4%	Florence fennels/boiled	4/2.04	40
8%	Rhubarbs/sauce/puree	4/2.04	76	3%	Rhubarbs/sauce/puree	4/2.04	30
7%	Cauliflowers/boiled	1/1.05	73	3%	Purslanes/boiled	7/6.5	27
5%	Peaches/canned	3/1.92	50	3%	Broccoli/boiled	1/1.05	25
4%	Potatoes/fried	0.8/0.48	45	2%	Pumpkins/boiled	0.2/0.38	21
3%	Beans (with pods)/boiled	2/2.75	34	2%	Peaches/canned	3/1.92	16
3%	Pumpkins/boiled	0.2/0.38	33	1%	Kohlrabies/boiled	1.5/0.64	14
3%	Peaches/juice	3/1.56	26	0.9%	Peas (with pods)/boiled	2/2.75	9.4
1%	Plums/juice	3/1.56	15	0.9%	Courgettes/boiled	0.2/0.38	8.6
1%	Courgettes/boiled	0.2/0.38	13	0.7%	Wine grapes/wine	2/0.78	7.4

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Spirotetramat is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Tebuconazole

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.03**	ARfD (mg/kg bw):	**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 17

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)
16.5	WHO Cluster diet B	2.4	Tomatoes	2.2	Wine grapes	1.7	Beans (without pods)	
14.7	DE child	5.2	Apples	1.0	Milk and cream,	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 cream,	0.8	Wheat	
12.5	WHO cluster diet E	2.0	Wine grapes	1.8	Barley	1.5	Beans (without pods)	
10.9	FR toddler	2.6	Milk and cream,	1.2	Carrots	1.2	Beans (with pods)	
9.1	PT General population	3.1	Wine grapes	1.7	Beans (without pods)	0.7	Tomatoes	
8.8	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	
8.2	WHO Cluster diet F	1.4	Barley	0.7	Wine grapes	0.6	Wheat	
7.7	DK child	1.0	Apples	0.9	Wheat	0.9	Oats	
7.6	UK Infant	2.6	Milk and cream,	0.7	Apples	0.7	Carrots	
7.3	FR infant	1.7	Milk and cream,	1.3	Carrots	1.1	Apples	
7.3	ES child	0.8	Milk and cream,	0.8	Tomatoes	0.7	Wheat	
7.0	SE general population 90th percentile	0.8	Milk and cream,	0.6	Tomatoes	0.6	Beans (without pods)	
6.9	WHO cluster diet D	1.1	Wheat	0.8	Tomatoes	0.5	Barley	
6.5	NL general	0.8	Barley	0.8	Wine grapes	0.5	Apples	
6.4	ES adult	1.1	Barley	0.6	Tomatoes	0.5	Wine grapes	
6.3	UK Toddler	1.4	Milk and cream,	0.7	Apples	0.7	Wheat	
4.8	DK adult	1.7	Wine grapes	0.4	Milk and cream,	0.3	Apples	
4.3	IT kids/toddler	1.1	Wheat	1.1	Tomatoes	0.4	Apples	
4.2	UK vegetarian	1.0	Wine grapes	0.5	Tomatoes	0.3	Wheat	
3.9	UK Adult	1.3	Wine grapes	0.3	Tomatoes	0.3	Rice	
3.8	LT adult	0.8	Apples	0.5	Tomatoes	0.3	Swine: Meat	
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)	
3.0	FI adult	0.4	Milk and cream,	0.4	Wine grapes	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 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)
59.4	Mandarins	0.32/-	44.6	Mandarins	0.32/-	14.3	Mandarins	0.32/-	11.1	Mandarins	0.32/-
30.9	Oranges	0.07/-	22.4	Oranges	0.07/-	6.0	Oranges	0.07/-	4.9	Oranges	0.07/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

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

*) 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.

- **Thiabendazole: Scenario 1**

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Thiabendazole			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.1	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

Input values
Details – chronic risk assessment
Supplementary results – chronic risk assessment
Details – acute risk assessment/children
Details – acute risk assessment/adults

Comments: Acute exposure assessment for Mango: Scenario 1 based on the HR for the whole fruit (4.5 mg/kg).

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
39%	NL toddler	38.52	19%	Apples	10%	Milk: Cattle	8%	Pears		39%
29%	DE child	29.24	22%	Apples	3%	Milk: Cattle	2%	Eggs: Chicken		29%
21%	IE adult	21.10	17%	Sweet potatoes	1%	Apples	0.8%	Pears		21%
18%	NL child	18.06	10%	Apples	4%	Milk: Cattle	2%	Pears		18%
13%	FR toddler 2 3 yr	12.79	6%	Apples	5%	Milk: Cattle	1%	Eggs: Chicken		13%
12%	UK infant	12.12	6%	Milk: Cattle	3%	Apples	2%	Eggs: Chicken		12%
10%	FR child 3 15 yr	9.80	4%	Milk: Cattle	3%	Apples	2%	Eggs: Chicken		10%
9%	DK child	9.35	4%	Apples	2%	Milk: Cattle	1%	Eggs: Chicken		9%
9%	UK toddler	8.58	3%	Milk: Cattle	3%	Apples	2%	Eggs: Chicken		9%
8%	DE women 14-50 yr	7.83	5%	Apples	2%	Milk: Cattle	0.6%	Eggs: Chicken		8%
7%	DE general	7.43	4%	Apples	2%	Milk: Cattle	0.5%	Eggs: Chicken		7%
7%	SE general	7.01	2%	Milk: Cattle	2%	Apples	2%	Eggs: Chicken		7%
7%	ES child	6.61	2%	Apples	2%	Milk: Cattle	1%	Eggs: Chicken		7%
6%	FR infant	6.48	3%	Apples	3%	Milk: Cattle	0.3%	Pears		6%
6%	RO general	5.96	3%	Apples	2%	Milk: Cattle	1%	Eggs: Chicken		6%
6%	GEMS/Food G11	5.69	3%	Apples	1%	Milk: Cattle	0.8%	Kumquats		6%
5%	NL general	5.18	3%	Apples	1%	Milk: Cattle	0.6%	Eggs: Chicken		5%
5%	LT adult	4.98	3%	Apples	0.6%	Milk: Cattle	0.6%	Eggs: Chicken		5%
4%	PL general	4.23	4%	Apples	0.5%	Pears	0.0%	Potatoes		4%
4%	GEMS/Food G15	4.03	2%	Apples	1%	Milk: Cattle	0.3%	Pears		4%
4%	DK adult	4.00	2%	Apples	0.8%	Milk: Cattle	0.6%	Eggs: Chicken		4%
4%	GEMS/Food G08	3.99	2%	Apples	0.9%	Milk: Cattle	0.3%	Kumquats		4%
4%	GEMS/Food G07	3.99	2%	Apples	1%	Milk: Cattle	0.3%	Pears		4%
4%	ES adult	3.85	1%	Apples	0.8%	Eggs: Chicken	0.8%	Milk: Cattle		4%
4%	GEMS/Food G10	3.57	1%	Apples	0.9%	Milk: Cattle	0.4%	Sweet potatoes		4%
4%	GEMS/Food G06	3.52	2%	Apples	0.5%	Sweet potatoes	0.4%	Milk: Cattle		4%
3%	FR adult	3.32	1%	Apples	0.7%	Eggs: Chicken	0.7%	Milk: Cattle		3%
3%	PT general	2.93	2%	Apples	0.6%	Pears	0.3%	Sweet potatoes		3%
2%	UK vegetarian	2.43	1%	Apples	0.6%	Eggs: Chicken	0.5%	Milk: Cattle		2%
2%	IT toddler	2.29	2%	Apples	0.6%	Pears	0.0%	Bananas		2%
2%	FI 3 yr	2.16	2%	Apples	0.3%	Pears	0.1%	Bananas		2%
2%	UK adult	2.03	0.7%	Apples	0.5%	Eggs: Chicken	0.5%	Milk: Cattle		2%
2%	IT adult	1.89	1%	Apples	0.4%	Pears	0.0%	Bananas		2%
2%	IE child	1.55	0.6%	Apples	0.6%	Milk: Cattle	0.3%	Eggs: Chicken		2%
1%	FI 6 yr	1.47	1%	Apples	0.3%	Pears	0.1%	Bananas		1%
1%	FI adult	1.20	1%	Apples	0.1%	Pears	0.0%	Bananas		1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Thiabendazole is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
415%	Pears	4/3	415
354%	Mangoes	7/4.5	354
323%	Apples	4/3	323
216%	Papayas	10/5.1	216
74%	Avocados	20/1.47	74
49%	Quinces	3/2	49
37%	Sweet potatoes	9/6.97	37
28%	Medlar	3/2	28
22%	Eggs: Chicken	2/1.74	22
20%	Milk: Cattle	0.2/0.16	20
10%	Bananas	6/0.1	9.7
9%	Kumquats	7/5.2	9.3
5%	Oranges	7/0.03	4.5
4%	Milk: Goat	0.2/0.17	4.1
3%	Potatoes	0.04/0.02	3.1

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
145%	Sweet potatoes	9/6.97	145
116%	Mangoes	7/4.5	116
92%	Pears	4/3	92
84%	Apples	4/3	84
71%	Papayas	10/5.1	71
30%	Quinces	3/2	30
22%	Avocados	20/1.47	22
14%	Medlar	3/2	14
7%	Eggs: Chicken	2/1.74	7.4
6%	Milk: Cattle	0.2/0.16	6.2
3%	Milk: Goat	0.2/0.17	3.1
3%	Milk: Sheep	0.2/0.17	2.6
2%	Eggs: Quail	2/1.74	2.4
2%	Bananas	6/0.1	2.1
1%	Bovine: Kidney	1/0.6	1.3

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 5

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
351%	Sweet potatoes/boiled	9/6.97	351
97%	Apples/juice	4/1.8	97
59%	Pears/juice	4/1.8	59
52%	Oranges/juice	7/0.98	52
5%	Quinces/jam	3/1.7	5.1
4%	Witloofs/boiled	0.05/0.05	4.4
3%	Lemons/jam	7/0.98	3.0
2%	Potatoes/fried	0.04/0.02	1.9
0.6%	Potatoes/dried (flakes)	0.04/0.05	0.59
0.1%	Beans (with pods)/boiled	0.01/0.01	0.13
0.1%	Limes/juice	7/0.98	0.09
0.1%	Lentils/boiled	0.01/0.01	0.08
0.1%	Peas (without pods)/canned	0.01/0.01	0.08
0.1%	Peas/canned	0.01/0	0.07

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
107%	Sweet potatoes/boiled	9/6.97	107
60%	Apples/juice	4/1.8	60
15%	Oranges/juice	7/0.98	15
11%	Grapefruits/juice	7/0.98	11
2%	Quinces/jam	3/1.7	2.1
2%	Lemons/juice	7/0.98	1.9
0.9%	Witloofs/boiled	0.05/0.05	0.92
0.08%	Potatoes/chips	0.04/0.01	0.08
0.07%	Beans/canned	0.01/0.01	0.07
0.06%	Potatoes/dried (flakes)	0.04/0.05	0.06
0.05%	Beans (without pods)/boiled	0.01/0.01	0.05
0.03%	Peas (with pods)/boiled	0.01/0.01	0.03
0.03%	Peas (without pods)/boiled	0.01/0.01	0.03
0.03%	Peas/canned	0.01/0	0.03

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 5 commodities.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

- **Thiabendazole: Scenario 2**

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Thiabendazole			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments: Acute exposure assessment for Mango: Scenario 2 based on HR edible part of the crop measured immediately after the treatment (DAT 0 days) (0.03 mg/kg).

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
39%	NL toddler	38.52	19%	Apples	10%	Milk: Cattle	8%	Pears		39%
29%	DE child	29.24	22%	Apples	3%	Milk: Cattle	2%	Eggs: Chicken		29%
21%	IE adult	21.10	17%	Sweet potatoes	1%	Apples	0.8%	Pears		21%
18%	NL child	18.06	10%	Apples	4%	Milk: Cattle	2%	Pears		18%
13%	FR toddler 2 3 yr	12.79	6%	Apples	5%	Milk: Cattle	1%	Eggs: Chicken		13%
12%	UK infant	12.12	6%	Milk: Cattle	3%	Apples	2%	Eggs: Chicken		12%
10%	FR child 3 15 yr	9.80	4%	Milk: Cattle	3%	Apples	2%	Eggs: Chicken		10%
9%	DK child	9.35	4%	Apples	2%	Milk: Cattle	1%	Eggs: Chicken		9%
9%	UK toddler	8.58	3%	Milk: Cattle	3%	Apples	2%	Eggs: Chicken		9%
8%	DE women 14-50 yr	7.83	5%	Apples	2%	Milk: Cattle	0.6%	Eggs: Chicken		8%
7%	DE general	7.43	4%	Apples	2%	Milk: Cattle	0.5%	Eggs: Chicken		7%
7%	SE general	7.01	2%	Milk: Cattle	2%	Apples	2%	Eggs: Chicken		7%
7%	ES child	6.61	2%	Apples	2%	Milk: Cattle	1%	Eggs: Chicken		7%
6%	FR infant	6.48	3%	Apples	3%	Milk: Cattle	0.3%	Pears		6%
6%	RO general	5.96	3%	Apples	2%	Milk: Cattle	1%	Eggs: Chicken		6%
6%	GEMS/Food G11	5.69	3%	Apples	1%	Milk: Cattle	0.8%	Kumquats		6%
5%	NL general	5.18	3%	Apples	1%	Milk: Cattle	0.6%	Eggs: Chicken		5%
5%	LT adult	4.98	3%	Apples	0.6%	Milk: Cattle	0.6%	Eggs: Chicken		5%
4%	PL general	4.23	4%	Apples	0.5%	Pears	0.0%	Potatoes		4%
4%	GEMS/Food G15	4.03	2%	Apples	1%	Milk: Cattle	0.3%	Pears		4%
4%	DK adult	4.00	2%	Apples	0.8%	Milk: Cattle	0.6%	Eggs: Chicken		4%
4%	GEMS/Food G08	3.99	2%	Apples	0.9%	Milk: Cattle	0.3%	Kumquats		4%
4%	GEMS/Food G07	3.99	2%	Apples	1%	Milk: Cattle	0.3%	Pears		4%
4%	ES adult	3.85	1%	Apples	0.8%	Eggs: Chicken	0.8%	Milk: Cattle		4%
4%	GEMS/Food G10	3.57	1%	Apples	0.9%	Milk: Cattle	0.4%	Sweet potatoes		4%
4%	GEMS/Food G06	3.52	2%	Apples	0.5%	Sweet potatoes	0.4%	Milk: Cattle		4%
3%	FR adult	3.32	1%	Apples	0.7%	Eggs: Chicken	0.7%	Milk: Cattle		3%
3%	PT general	2.93	2%	Apples	0.6%	Pears	0.3%	Sweet potatoes		3%
2%	UK vegetarian	2.43	1%	Apples	0.6%	Eggs: Chicken	0.5%	Milk: Cattle		2%
2%	IT toddler	2.29	2%	Apples	0.6%	Pears	0.0%	Bananas		2%
2%	FI 3 yr	2.16	2%	Apples	0.3%	Pears	0.1%	Bananas		2%
2%	UK adult	2.03	0.7%	Apples	0.5%	Eggs: Chicken	0.5%	Milk: Cattle		2%
2%	IT adult	1.89	1%	Apples	0.4%	Pears	0.0%	Bananas		2%
2%	IE child	1.55	0.6%	Apples	0.6%	Milk: Cattle	0.3%	Eggs: Chicken		2%
1%	FI 6 yr	1.47	1%	Apples	0.3%	Pears	0.1%	Bananas		1%
1%	FI adult	1.20	1%	Apples	0.1%	Pears	0.0%	Bananas		1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Thiabendazole is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 3

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
415%	Pears	4/3	415	145%	Sweet potatoes	9/6.97	145
323%	Apples	4/3	323	92%	Pears	4/3	92
216%	Papayas	10/5.1	216	84%	Apples	4/3	84
74%	Avocados	20/1.47	74	71%	Papayas	10/5.1	71
49%	Quinces	3/2	49	30%	Quinces	3/2	30
37%	Sweet potatoes	9/6.97	37	22%	Avocados	20/1.47	22
28%	Medlar	3/2	28	14%	Medlar	3/2	14
22%	Eggs: Chicken	2/1.74	22	7%	Eggs: Chicken	2/1.74	7.4
20%	Milk: Cattle	0.2/0.16	20	6%	Milk: Cattle	0.2/0.16	6.2
10%	Bananas	6/0.1	9.7	3%	Milk: Goat	0.2/0.17	3.1
9%	Kumquats	7/5.2	9.3	3%	Milk: Sheep	0.2/0.17	2.6
5%	Oranges	7/0.03	4.5	2%	Eggs: Quail	2/1.74	2.4
4%	Milk: Goat	0.2/0.17	4.1	2%	Bananas	6/0.1	2.1
3%	Potatoes	0.04/0.02	3.1	1%	Bovine: Kidney	1/0.6	1.3
3%	Grapefruits	7/0.03	2.7	1%	Oranges	7/0.03	1.0

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
351%	Sweet potatoes/boiled	9/6.97	351	107%	Sweet potatoes/boiled	9/6.97	107
97%	Apples/juice	4/1.8	97	60%	Apples/juice	4/1.8	60
59%	Pears/juice	4/1.8	59	15%	Oranges/juice	7/0.98	15
52%	Oranges/juice	7/0.98	52	11%	Grapefruits/juice	7/0.98	11
5%	Quinces/jam	3/1.7	5.1	2%	Quinces/jam	3/1.7	2.1
4%	Witloofs/boiled	0.05/0.05	4.4	2%	Lemons/juice	7/0.98	1.9
3%	Lemons/jam	7/0.98	3.0	0.9%	Witloofs/boiled	0.05/0.05	0.92
2%	Potatoes/fried	0.04/0.02	1.9	0.08%	Potatoes/chips	0.04/0.01	0.08
0.6%	Potatoes/dried (flakes)	0.04/0.05	0.59	0.07%	Beans/canned	0.01/0.01	0.07
0.1%	Beans (with pods)/boiled	0.01/0.01	0.13	0.06%	Potatoes/dried (flakes)	0.04/0.05	0.06
0.1%	Limes/juice	7/0.98	0.09	0.05%	Beans (without pods)/boiled	0.01/0.01	0.05
0.1%	Lentils/boiled	0.01/0.01	0.08	0.03%	Peas (with pods)/boiled	0.01/0.01	0.03
0.1%	Peas (without pods)/canned	0.01/0.01	0.08	0.03%	Peas (without pods)/boiled	0.01/0.01	0.03
0.1%	Peas/canned	0.01/0	0.07	0.03%	Peas/canned	0.01/0	0.03

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 4 commodities.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Tolclofos-methyl (F)			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.064	ARfD (mg/kg bw):	0.14
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
3%	NL toddler	1.85	0.9%	Milk: Cattle	0.8%	Potatoes	0.2%	Escaroles/broad-leaved endives	0.9%	2%
2%	NL child	1.12	0.6%	Potatoes	0.4%	Milk: Cattle	0.1%	Sugar beet roots	0.5%	1%
2%	SE general	1.01	0.8%	Potatoes	0.3%	Lettuces	0.2%	Milk: Cattle	0.2%	1%
2%	DE child	0.98	0.5%	Potatoes	0.3%	Milk: Cattle	0.2%	Apples	0.6%	0.9%
2%	UK infant	0.97	0.6%	Potatoes	0.6%	Milk: Cattle	0.0%	Wheat	0.2%	1%
1%	GEMS/Food G11	0.95	0.7%	Potatoes	0.1%	Milk: Cattle	0.1%	Lamb's lettuce/corn salads	0.4%	1%
1%	GEMS/Food G08	0.95	0.7%	Potatoes	0.1%	Lettuces	0.1%	Milk: Cattle	0.4%	1%
1%	GEMS/Food G07	0.91	0.7%	Potatoes	0.2%	Lettuces	0.1%	Milk: Cattle	0.4%	1%
1%	GEMS/Food G10	0.89	0.6%	Potatoes	0.2%	Lettuces	0.1%	Milk: Cattle	0.4%	1%
1%	UK toddler	0.84	0.7%	Potatoes	0.3%	Milk: Cattle	0.1%	Wheat	0.3%	1%
1%	PT general	0.84	1.0%	Potatoes	0.1%	Lettuces	0.1%	Wheat	0.2%	1%
1%	GEMS/Food G15	0.83	0.7%	Potatoes	0.1%	Milk: Cattle	0.1%	Lettuces	0.4%	0.9%
1%	RO general	0.80	0.7%	Potatoes	0.2%	Milk: Cattle	0.1%	Wheat	0.3%	1.0%
1%	FR toddler 2 3 yr	0.79	0.5%	Milk: Cattle	0.3%	Potatoes	0.0%	Apples	0.3%	0.9%
1%	FR child 3 15 yr	0.78	0.4%	Milk: Cattle	0.3%	Potatoes	0.1%	Other lettuce and other salad plants	0.4%	0.8%
1%	ES child	0.75	0.3%	Potatoes	0.3%	Lettuces	0.2%	Milk: Cattle	0.3%	0.9%
1%	DK child	0.73	0.5%	Potatoes	0.2%	Milk: Cattle	0.1%	Lettuces	0.3%	0.8%
1%	FI 3 yr	0.71	0.9%	Potatoes	0.0%	Lettuces	0.0%	Bananas	0.2%	0.9%
1%	GEMS/Food G06	0.68	0.4%	Potatoes	0.1%	Wheat	0.1%	Lettuces	0.5%	0.6%
1%	NL general	0.66	0.5%	Potatoes	0.1%	Milk: Cattle	0.1%	Escaroles/broad-leaved endives	0.2%	0.8%
1.0%	IE adult	0.63	0.4%	Potatoes	0.1%	Milk: Cattle	0.1%	Lettuces	0.4%	0.6%
0.9%	FI 6 yr	0.61	0.7%	Potatoes	0.1%	Lettuces	0.0%	Cocoa beans	0.2%	0.8%
0.9%	DE women 14-50 yr	0.56	0.2%	Potatoes	0.2%	Milk: Cattle	0.1%	Lettuces	0.3%	0.5%
0.9%	DE general	0.56	0.2%	Potatoes	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.3%	0.6%
0.8%	FI adult	0.54	0.4%	Coffee beans	0.2%	Potatoes	0.1%	Lettuces	0.5%	0.3%
0.8%	LT adult	0.54	0.6%	Potatoes	0.1%	Milk: Cattle	0.0%	Lettuces	0.1%	0.7%
0.8%	ES adult	0.53	0.4%	Lettuces	0.2%	Potatoes	0.1%	Milk: Cattle	0.2%	0.7%
0.8%	FR infant	0.51	0.4%	Potatoes	0.3%	Milk: Cattle	0.0%	Apples	0.1%	0.7%
0.8%	PL general	0.49	0.6%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.1%	0.7%
0.7%	IT toddler	0.44	0.2%	Lettuces	0.2%	Potatoes	0.1%	Wheat	0.2%	0.5%
0.7%	IT adult	0.43	0.2%	Lettuces	0.1%	Other lettuce and other salad plants	0.1%	Potatoes	0.2%	0.5%
0.6%	FR adult	0.39	0.1%	Potatoes	0.1%	Other lettuce and other salad plants	0.1%	Milk: Cattle	0.2%	0.4%
0.6%	UK vegetarian	0.36	0.3%	Potatoes	0.1%	Lettuces	0.1%	Milk: Cattle	0.1%	0.4%
0.5%	DK adult	0.34	0.2%	Potatoes	0.1%	Milk: Cattle	0.1%	Lettuces	0.1%	0.4%
0.5%	UK adult	0.34	0.3%	Potatoes	0.1%	Lettuces	0.0%	Milk: Cattle	0.1%	0.4%
0.2%	IE child	0.15	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	0.2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Tolclofos-methyl (F) is unlikely to present a public health concern.

Acute risk assessment/children | **Acute risk assessment/adults/general population**

Details – acute risk assessment/children | Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
138%	Potatoes	0.3/1.26	194	27%	Potatoes	0.3/1.26	38
22%	Escaroles/broad-leaved	0.9/0.78	31	11%	Escaroles/broad-leaved	0.9/0.78	16
21%	Lettuces	2/0.78	30	7%	Lettuces	2/0.78	9.5
2%	Lamb's lettuce/corn salads	0.9/0.78	2.2	3%	Red mustards	0.9/0.78	4.1
1%	Roman rocket/rucola	0.9/0.78	2.1	1%	Lamb's lettuce/corn salads	0.9/0.78	1.5
1%	Melons	0.01/0.01	1.5	0.7%	Roman rocket/rucola	0.9/0.78	0.92
1%	Radishes	0.1/0.06	1.5	0.6%	Head cabbages	0.01/0.02	0.84
1.0%	Pears	0.01/0.01	1.4	0.4%	Radishes	0.1/0.06	0.63
0.9%	Oranges	0.01/0.01	1.3	0.3%	Broccoli	0.01/0.02	0.48
0.9%	Milk: Cattle	0.01/0.01	1.2	0.3%	Cauliflowers	0.01/0.02	0.46
0.9%	Watermelons	0.01/0.01	1.2	0.3%	Watermelons	0.01/0.01	0.41
0.8%	Cauliflowers	0.01/0.02	1.2	0.3%	Melons	0.01/0.01	0.39
0.8%	Apples	0.01/0.01	1.1	0.3%	Milk: Cattle	0.01/0.01	0.39
0.7%	Pineapples	0.01/0.01	1.0	0.2%	Swedes/rutabagas	0.01/0.01	0.34
0.7%	Chervil	0.7/0.78	1.0	0.2%	Table grapes	0.01/0.01	0.34

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
84%	Potatoes/fried	0.3/1.26	118	11%	Escaroles/broad-leaved	0.9/0.78	16
37%	Escaroles/broad-leaved endi	0.9/0.78	52	0.7%	Potatoes/chips	0.3/0.12	1.0
5%	Potatoes/dried (flakes)	0.3/0.55	7.1	0.6%	Cauliflowers/boiled	0.01/0.02	0.83
1%	Broccoli/boiled	0.01/0.02	1.6	0.5%	Potatoes/dried (flakes)	0.3/0.55	0.69
1.0%	Cauliflowers/boiled	0.01/0.02	1.4	0.4%	Pumpkins/boiled	0.01/0.01	0.55
0.8%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.3%	Broccoli/boiled	0.01/0.02	0.48
0.6%	Pumpkins/boiled	0.01/0.01	0.89	0.3%	Sugar beets (root)/sugar	0.01/0.12	0.44
0.6%	Witloofs/boiled	0.01/0.01	0.89	0.3%	Beetroots/boiled	0.01/0.01	0.39
0.4%	Leeks/boiled	0.01/0.01	0.57	0.2%	Celeries/boiled	0.01/0.01	0.34
0.4%	Apples/juice	0.01/0.01	0.54	0.2%	Apples/juice	0.01/0.01	0.33
0.4%	Oranges/juice	0.01/0.01	0.53	0.2%	Coffee beans/extraction	0.05/0.01	0.24
0.4%	Turnips/boiled	0.01/0.01	0.51	0.2%	Courgettes/boiled	0.01/0.01	0.23
0.4%	Parsnips/boiled	0.01/0.01	0.51	0.2%	Parsnips/boiled	0.01/0.01	0.21
0.4%	Sweet potatoes/boiled	0.01/0.01	0.50	0.2%	Kohlrabies/boiled	0.01/0.01	0.21
0.3%	Florence fennels/boiled	0.01/0.01	0.45	0.1%	Wine grapes/juice	0.01/0.01	0.21

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Tolfenpyrad (F)

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw per day):	0.006	ARfD (mg/kg bw):	0.01
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2013	Year of evaluation:	2013

Input values
Details – chronic risk assessment
Supplementary results – chronic risk assessment
Details – acute risk assessment/children
Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
20%	NL toddler	1.23	4%	Milk: Cattle	2%	Oranges	2%	Tomatoes		12%
17%	GEMS/Food G06	0.99	8%	Tomatoes	1%	Wheat	1%	Oranges		12%
15%	DE child	0.89	4%	Oranges	2%	Tomatoes	2%	Apples		10%
12%	NL child	0.74	2%	Milk: Cattle	1%	Oranges	1%	Sugar beet roots		7%
11%	FR child 3 15 yr	0.69	3%	Oranges	2%	Tomatoes	1%	Milk: Cattle		8%
11%	GEMS/Food G07	0.63	2%	Tomatoes	1%	Oranges	0.7%	Wheat		7%
10%	GEMS/Food G10	0.62	3%	Tomatoes	1%	Oranges	0.7%	Wheat		7%
10%	RO general	0.62	4%	Tomatoes	0.8%	Wheat	0.8%	Sweet peppers/bell peppers		8%
10%	GEMS/Food G15	0.62	3%	Tomatoes	1%	Sweet peppers/bell peppers	0.8%	Wheat		7%
10%	IE adult	0.60	1%	Sheep: Liver	1%	Oranges	0.9%	Tomatoes		7%
10%	GEMS/Food G08	0.57	2%	Tomatoes	0.7%	Wheat	0.7%	Potatoes		6%
9%	GEMS/Food G11	0.57	2%	Tomatoes	0.7%	Oranges	0.7%	Potatoes		6%
9%	FR toddler 2 3 yr	0.56	2%	Milk: Cattle	1%	Oranges	1%	Mandarins		7%
9%	UK infant	0.55	2%	Milk: Cattle	1%	Oranges	0.8%	Tomatoes		7%
9%	ES child	0.54	2%	Oranges	2%	Tomatoes	0.8%	Milk: Cattle		7%
9%	UK toddler	0.53	2%	Oranges	1%	Milk: Cattle	1%	Tomatoes		6%
8%	DE women 14-50 yr	0.49	2%	Oranges	2%	Tomatoes	0.8%	Milk: Cattle		6%
8%	SE general	0.47	2%	Tomatoes	0.8%	Milk: Cattle	0.8%	Oranges		6%
8%	DE general	0.45	2%	Oranges	1%	Tomatoes	0.8%	Milk: Cattle		5%
8%	DK child	0.45	1%	Tomatoes	0.9%	Rye	0.8%	Milk: Cattle		4%
7%	IT toddler	0.40	3%	Tomatoes	1%	Wheat	0.5%	Oranges		4%
6%	PT general	0.38	2%	Tomatoes	0.9%	Potatoes	0.7%	Wheat		4%
6%	ES adult	0.36	2%	Tomatoes	1%	Oranges	0.4%	Wheat		5%
6%	NL general	0.36	1%	Oranges	0.9%	Tomatoes	0.5%	Milk: Cattle		4%
5%	IT adult	0.32	3%	Tomatoes	0.7%	Wheat	0.4%	Oranges		4%
5%	FI 3 yr	0.28	1%	Tomatoes	0.8%	Potatoes	0.6%	Mandarins		3%
5%	FR adult	0.28	1%	Tomatoes	0.6%	Oranges	0.4%	Wine grapes		3%
4%	UK vegetarian	0.26	1%	Tomatoes	0.9%	Oranges	0.3%	Wheat		3%
4%	FI adult	0.23	1%	Tomatoes	0.9%	Coffee beans	0.4%	Oranges		2%
4%	FI 6 yr	0.23	0.9%	Tomatoes	0.6%	Potatoes	0.5%	Mandarins		2%
4%	DK adult	0.23	1%	Tomatoes	0.3%	Milk: Cattle	0.2%	Potatoes		3%
4%	FR infant	0.23	1%	Milk: Cattle	0.3%	Potatoes	0.3%	Apples		2%
4%	LT adult	0.22	1%	Tomatoes	0.5%	Potatoes	0.3%	Apples		3%
4%	PL general	0.22	2%	Tomatoes	0.6%	Potatoes	0.3%	Apples		3%
3%	UK adult	0.21	0.9%	Tomatoes	0.6%	Oranges	0.3%	Wheat		2%
1%	IE child	0.07	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Tomatoes		0.7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Tolfenpyrad (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 5

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
291%	Tomatoes	0.7/0.5	29	135%	Aubergines/egg plants	0.7/0.5	14
190%	Sweet peppers/bell peppers	0.5/0.32	19	79%	Tomatoes	0.7/0.5	7.9
172%	Oranges	0.6/0.13	17	52%	Sweet peppers/bell peppers	0.5/0.32	5.2
125%	Aubergines/egg plants	0.7/0.5	13	40%	Oranges	0.6/0.13	4.0
107%	Mandarins	0.9/0.18	11	32%	Mandarins	0.9/0.18	3.2
78%	Grapefruits	0.6/0.1	7.8	18%	Grapefruits	0.6/0.1	1.8
62%	Lemons	0.9/0.18	6.2	16%	Lemons	0.9/0.18	1.6
36%	Limes	0.9/0.18	3.6	15%	Bovine: Liver	0.4/0.38	1.5
31%	Bovine: Liver	0.4/0.38	3.1	13%	Limes	0.9/0.18	1.3
28%	Bovine: Edible offals (other than liver and kidney)	0.4/0.38	2.8	13%	Bovine: Edible offals (other than liver and kidney)	0.4/0.38	1.3
14%	Bovine: Kidney	0.4/0.38	1.4	11%	Sheep: Liver	0.4/0.38	1.1
13%	Onions	0.09/0.06	1.3	10%	Swine: Edible offals (other than liver and kidney)	0.4/0.38	0.99
11%	Swine: Edible offals (other than liver and kidney)	0.4/0.38	1.1	8%	Onions	0.09/0.06	0.85
5%	Swine: Kidney	0.4/0.38	0.48	8%	Swine: Kidney	0.4/0.38	0.84
5%	Milk: Cattle	0.01/0	0.47	8%	Bovine: Kidney	0.4/0.38	0.80

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 5

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
32%	Oranges/juice	0.6/0.06	3.2	11%	Tomatoes/sauce/puree	0.7/0.13	1.1
25%	Tomatoes/juice	0.7/0.13	2.5	9%	Oranges/juice	0.6/0.06	0.92
12%	Tomatoes/sauce/puree	0.7/0.13	1.2	5%	Onions/boiled	0.09/0.06	0.54
9%	Potatoes/fried	0.01/0.01	0.93	5%	Grapefruits/juice	0.6/0.04	0.46
9%	Shallots/boiled	0.09/0.06	0.92	4%	Shallots/boiled	0.09/0.06	0.35
6%	Potatoes/dried (flakes)	0.01/0.05	0.59	2%	Lemons/juice	0.9/0.09	0.16
3%	Lemons/jam	0.9/0.09	0.26	0.8%	Potatoes/chips	0.01/0.01	0.08
0.1%	Limes/juice	0.9/0.09	0.01	0.6%	Potatoes/dried (flakes)	0.01/0.05	0.06

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 5 commodities.

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

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Valifenalate

LOQs (mg/kg) range from: 0.01 to: 0.02

Toxicological reference values

ADI (mg/kg bw per day):	0.07	ARfD (mg/kg bw):	Not necessary
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	NL toddler	1.59	0.9%	Milk: Cattle	0.3%	Tomatoes	0.2%	Table grapes	2%	1%
2%	GEMS/Food G06	1.47	1%	Tomatoes	0.1%	Lettuces	0.1%	Table grapes	0.5%	2%
2%	GEMS/Food G10	1.07	0.4%	Tomatoes	0.4%	Lettuces	0.1%	Milk: Cattle	0.5%	1%
1%	RO general	1.04	0.6%	Tomatoes	0.2%	Wine grapes	0.2%	Milk: Cattle	0.5%	1%
1%	DE child	1.02	0.3%	Tomatoes	0.3%	Milk: Cattle	0.2%	Apples	0.8%	0.9%
1%	GEMS/Food G07	0.99	0.4%	Tomatoes	0.3%	Lettuces	0.2%	Wine grapes	0.5%	1%
1%	ES child	0.99	0.6%	Lettuces	0.3%	Tomatoes	0.2%	Milk: Cattle	0.5%	1%
1%	SE general	0.97	0.5%	Lettuces	0.3%	Tomatoes	0.2%	Milk: Cattle	0.5%	1%
1%	GEMS/Food G08	0.94	0.4%	Tomatoes	0.3%	Lettuces	0.1%	Wine grapes	0.5%	1.0%
1%	ES adult	0.93	0.7%	Lettuces	0.3%	Tomatoes	0.1%	Milk: Cattle	0.3%	1%
1%	NL child	0.93	0.3%	Milk: Cattle	0.2%	Tomatoes	0.1%	Sugar beet roots	0.9%	0.8%
1%	GEMS/Food G15	0.89	0.4%	Tomatoes	0.2%	Lettuces	0.1%	Wine grapes	0.5%	0.9%
1%	FR child 3 15 yr	0.80	0.3%	Milk: Cattle	0.3%	Tomatoes	0.1%	Wheat	0.7%	0.8%
1%	GEMS/Food G11	0.79	0.3%	Tomatoes	0.1%	Wine grapes	0.1%	Milk: Cattle	0.5%	0.8%
1%	IT toddler	0.79	0.5%	Tomatoes	0.4%	Lettuces	0.1%	Wheat	0.2%	0.9%
1%	IT adult	0.77	0.5%	Lettuces	0.4%	Tomatoes	0.1%	Wheat	0.1%	1.0%
1%	PT general	0.72	0.3%	Tomatoes	0.3%	Wine grapes	0.1%	Lettuces	0.2%	0.8%
1%	DE women 14-50 yr	0.71	0.2%	Tomatoes	0.2%	Milk: Cattle	0.2%	Lettuces	0.5%	0.8%
1%	UK infant	0.70	0.6%	Milk: Cattle	0.1%	Tomatoes	0.0%	Potatoes	0.9%	0.7%
1.0%	DK child	0.69	0.2%	Lettuces	0.2%	Milk: Cattle	0.2%	Tomatoes	0.6%	0.7%
1.0%	FR toddler 2 3 yr	0.69	0.4%	Milk: Cattle	0.2%	Tomatoes	0.0%	Apples	0.8%	0.7%
1.0%	IE adult	0.68	0.1%	Wine grapes	0.1%	Tomatoes	0.1%	Lettuces	0.4%	0.6%
0.9%	DE general	0.66	0.2%	Tomatoes	0.2%	Milk: Cattle	0.1%	Lettuces	0.5%	0.7%
0.9%	UK toddler	0.63	0.3%	Milk: Cattle	0.2%	Tomatoes	0.1%	Wheat	0.6%	0.6%
0.8%	NL general	0.54	0.1%	Tomatoes	0.1%	Lettuces	0.1%	Milk: Cattle	0.4%	0.5%
0.7%	UK vegetarian	0.50	0.2%	Tomatoes	0.2%	Lettuces	0.1%	Wine grapes	0.2%	0.6%
0.7%	FR adult	0.49	0.3%	Wine grapes	0.2%	Tomatoes	0.1%	Milk: Cattle	0.2%	0.6%
0.7%	FI adult	0.48	0.2%	Lettuces	0.2%	Tomatoes	0.2%	Coffee beans	0.2%	0.4%
0.6%	DK adult	0.45	0.2%	Tomatoes	0.1%	Lettuces	0.1%	Wine grapes	0.2%	0.6%
0.6%	UK adult	0.43	0.2%	Lettuces	0.1%	Tomatoes	0.1%	Wine grapes	0.2%	0.5%
0.5%	FI 3 yr	0.37	0.2%	Tomatoes	0.1%	Potatoes	0.0%	Lettuces	0.2%	0.3%
0.5%	LT adult	0.36	0.2%	Tomatoes	0.1%	Lettuces	0.1%	Milk: Cattle	0.2%	0.4%
0.5%	PL general	0.35	0.3%	Tomatoes	0.0%	Potatoes	0.0%	Onions	0.1%	0.4%
0.5%	FI 6 yr	0.34	0.1%	Tomatoes	0.1%	Lettuces	0.1%	Potatoes	0.2%	0.3%
0.5%	FR infant	0.33	0.2%	Milk: Cattle	0.0%	Tomatoes	0.0%	Potatoes	0.4%	0.3%
0.2%	IE child	0.11	0.1%	Milk: Cattle	0.0%	Tomatoes	0.0%	Wheat	0.1%	0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Valifenalate is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion: