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Scientific support for preparing an EU position in the 51st 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 51st session of the Codex Committee on Pesticide Residues (CCPR). In 2018, JMPR evaluated 15 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (chlorfenapyr, ethiprole, fenpicoxamid, fluazinam, fluxapyroxad, imazalil, kresoxim-methyl, lambda-cyhalothrin, mandestrobin, mandipropamid, norflurazon, pydiflumetofen, pyraclostrobin, pyriofenone, tioxazafen) and 27 active substances regarding the setting of maximum residue limits (MRLs) (abamectin, bentazone, chlorfenapyr, cyantraniliprole, cyazofamid, diquat, ethiprole, fenpicoxamid, fenpyroximate, fluazinam, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, norflurazon, oxathiapiproline, profenofos, propamocarb, pydiflumetofen, pyraclostrobin, pyriofenone, pyriproxyfen, sulfoxaflor and tioxazafen); EFSA prepared comments on the Codex MRL proposals and the proposed toxicological reference values. In addition, EFSA provided comments 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, CCPR meeting 2019

Requestor: European Commission

Question numbers: EFSA-Q-2018-00956, EFSA-Q-2018-00957, EFSA-Q-2018-00958, EFSA-Q-2018-00959, EFSA-Q-2019-00193, EFSA-Q-2018-00960, EFSA-Q-2018-00961, EFSA-Q-2018-00962, EFSA-Q-2018-00963, EFSA-Q-2018-00964, EFSA-Q-2018-00965, EFSA-Q-2018-00966, EFSA-Q-2018-00967, EFSA-Q-2018-00968, EFSA-Q-2018-00969, EFSA-Q-2018-00970, EFSA-Q-2018-00971, EFSA-Q-2018-00972, EFSA-Q-2018-00973, EFSA-Q-2018-00974, EFSA-Q-2018-00975, EFSA-Q-2018-00976,EFSA-Q-2018-00977, EFSA-Q-2018-00978, EFSA-Q-2018-00979, EFSA-Q-2018-00980, EFSA-Q-2018-00981, EFSA-Q-2018-00982, EFSA-Q-2018-00983, EFSA-Q-2018-00984, EFSA-Q-2018-00985, EFSA-Q-2018-00986, EFSA-Q-2018-00987, EFSA-Q-2018-00988

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Summary

For the preparation of the 51st session of the Codex Committee on Pesticide Residues (CCPR meeting), the European Commission asked the European Food Safety Authority (EFSA) to provide comments on the individual active substances assessed in the 2018 Joint FAO/WHO Meeting on Pesticide Residues (JMPR), in particular on the recommended toxicological reference values and the proposed MRLs at steps 3 and 6 of the Codex procedure.

In 2018, JMPR evaluated 15 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (chlorfenapyr, ethiprole, fenpicoxamid, fluazinam, fluxapyroxad, imazalil, kresoxim-methyl, lambda-cyhalothrin, mandestrobin, mandipropamid, norflurazon, pydiflumetofen, pyraclostrobin, pyriofenone, tioxazafen). 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.

As regards the setting of maximum residue limits (MRLs), JMPR assessed 27 active substances (abamectin, bentazone, chlorfenapyr, cyantraniliprole, cyazofamid, diquat, ethiprole, fenpicoxamid, fenpyroximate, fluazinam, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, norflurazon, oxathiapiproline, profenofos, propamocarb, pydiflumetofen, pyraclostrobin, pyriofenone, pyriproxyfen, sulfoxaflor and tioxazafen).

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 or other requests to perform a follow-up evaluation (benzovindiflupyr, bromopropylate, fenpyroximate, fluopyram, oxamyl, spinetoram, cyprodinil, propiconazole, 2,4-D, phosphonic acid, picoxystrobin, quinclorac) and on general issues discussed in the 2018 JMPR meeting.

It is highlighted that the JMPR report summarising the recommendations of the 2018 JMPR meeting was published on 11 January 2019. The full evaluations were published on 11 March 2019, thus after the deadline for the preparation of the draft EFSA report. Due to the limited details available and the short timelines for providing the comments, an in-depth analysis taking into account the detailed information provided in the JMPR evaluation could not always be performed. The conclusions reached in this report should be considered as indicative and might have to be reconsidered in a more detailed assessment when needed. The comments presented in this report have to be seen in the context of the currently applicable guidance documents and the MRL legislation applicable at the time of commenting. The comments may not be valid any more or may have to be modified, if the legal or scientific framework changes.

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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 FAO/WHO meeting on pesticide residues (JMPR) for assessment. The most recent JMPR evaluations of the toxicological data and the residue studies are summarised in the JMPR 2018 Report (FAO, 2018).

On 12 November 2018, the European Commission requested the European Food Safety Authority (EFSA) to provide support for the preparation of the EU-coordinated position for the 51st session of the Codex Committee on Pesticide Residues (CCPR) in April 2019 in China. In particular, EFSA was asked to give advice and to provide comments on the recommendations of the 2018 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 51st 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 2018 report, where relevant for risk assessment as well as other comments on the proposed crop groupings, the JMPR priority list and documents related to the revision of the international estimated of short-term intake (IESTI) equation.

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

Question number	Subject
EFSA-Q-2018-00956	Abamectin (177) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00957	Bentazone (172) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00983	Benzovindiflupyr (261) – EFSA comments on the follow-up assessment by JMPR in 2018
EFSA-Q-2018-00958	Chlorfenapyr (254) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00959	Cyantraniliprole (263) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2019-00193	Cyazofamid – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00984	Cyprodinil (207) – EFSA comments on the follow-up assessment by JMPR in 2018
EFSA-Q-2018-00960	Diquat (031) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00971	Ethiprole (304) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00972	Fenpicoxamid (XDE-777) (307) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00985	Fenpyroximate (193) – EFSA comments on the follow-up assessment and the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00973	Fluazinam (306) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00961	Fludioxonil (211) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00986	Fluopyram (243) – EFSA comments on the follow-up assessment of JMPR in 2018
EFSA-Q-2018-00962	Fluxapyroxad (256) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00974	Imazalil (1108) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00963	Isofetamid (290) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00975	Kresoxim-methyl (199) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018

Question number	Subject
EFSA-Q-2018-00964	Lambda-cyhalothrin (146) – EFSA comments on the toxicological reference values evaluated by JMPR in 2018
EFSA-Q-2018-00965	Lufenuron (286) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00976	Mandestrobin (307) – EFSA comments on the toxicological reference values evaluated by JMPR in 2018
EFSA-Q-2018-00966	Mandipropamid (231) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00977	Norflurazon (308) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00967	Oxathiapiproline (291) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00968	Profenofos (171) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00969	Propamocarb (148) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00987	Propiconazole (160) – EFSA comments on the follow-up assessment by JMPR in 2018
EFSA-Q-2018-00978	Pydiflumetofen (309) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00979	Pyraclostrobin (210) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00980	Pyriofenone (310) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00970	Pyriproxyfen (200) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00981	Sulfoxaflor (252) – EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00982	Tioxazafen (311) – EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2018
EFSA-Q-2018-00988	EFSA comments on the general considerations provided by JMPR in 2018 and other follow-up assessments

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

The draft scientific report was submitted for commenting to the EU Member State experts and European Commission on 19 February 2019. The comments provided by Member States were uploaded on EFSA Document Management System (DMS). All the comments received were addressed either directly in the final EFSA scientific report or though discussion during the Council Working Party meetings for the preparation of the 51st Session of the Codex Committee on Pesticide Residues.

1.2. Terms of Reference

The requested advice and comments on the recommendations of the 2018 Joint FAO/WHO meeting on pesticides residues (JMPR) and, where appropriate, on other proposed Codex MRLs, retained in the step procedure and reviewed by JMPR in previous years, should contain the following information:

- Background information on all active substances under discussion regarding the status of the active substance at EU level (approval status of the active substance, availability of EFSA conclusions and availability of EFSA reasoned opinions on MRL applications or MRL review);
- In case new toxicological reference values were proposed by JMPR, a comparison of the proposed reference values with agreed EU reference values and an evaluation of the reasons for possible differences;
- As regard the proposed draft Codex MRLs for discussion in CCPR 2019, EFSA should provide any relevant comments on the proposed MRLs and specifically address the following questions:
    - Whether the residue definitions derived by JMPR are comparable with the existing EU residue definitions,
    - Whether the proposed draft Codex MRLs are comparable with the existing EU MRLs,

- Whether the proposed draft Codex MRLs are sufficiently supported by data,
- Whether the proposed Codex draft MRLs are appropriate in terms of the data that have been used to establish them and in terms of the method used for their calculation,
- Whether the proposed draft Codex MRLs are safe for European consumers with regard to chronic, and where relevant, acute exposure.

The requested comments to the general chapters of the JMPR 2018 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 12 November 2018)

EFSA agreed with the European Commission to respond to this request with a scientific report. The first draft report should be shared with the European Commission and Member States on 15 February 2019, inviting Member States to provide comments.

After discussion between EFSA and the requestor, the deadline for the first draft report was extended to 19 February 2019 to allow the presentation of a complete document.

The final draft addressing the Member State comments should be completed in time to be discussed in the second Council meeting scheduled for 25 March 2019. It was agreed with the requestor that the report is published by 31 July 2019.

2. Assessment

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

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

For assessing whether the draft Codex MRL proposals are sufficiently supported by data, EFSA took into account the currently valid EU guidance documents for consumer risk assessment and the agreed EU policies (European Commission, 1996, 1997a,b,c,d,e,f,g, 2000, 2010a, 2011a; OECD, 2011, 2013) as well as the JMPR risk assessment methodologies and policies agreed in previous CCPR meetings. 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 a EU MRL and Codex MRL request may result in different recommendations at EU level and by JMPR. In this report EFSA provides background information on the reasons for these differences. For calculating the numerical MRL value, EFSA used the same methodology as JMPR (OECD calculator) (OECD, 2011).

To assess the 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 Codex MRL proposals for animal commodities, a full assessment of the expected dietary burden at EU

[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.

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).

It should be highlighted that due to the limited information available in the JMPR reports, EFSA cannot assess the following aspects of studies that are normally assessed in detail when MRL applications are submitted in the framework of Art. 10 of Regulation (EC) No 396/2005:

- the appropriateness of analytical methods provided by the manufacturer to be used for MRL enforcement, including method validation data, confirmatory data and independent laboratory validation (ILV);
- storage stability of residues;
- the duration and the conditions of storage for samples derived from supervised field trials prior to their analysis;
- independence of residue trials;
- details of processing studies.

For the assessment of the safety of the draft Codex MRL proposals, EFSA used the EFSA PRIMo rev. 3 (EFSA, 2018e). 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 supervised trials median residues (STMRs) and including the STMR values derived by JMPR for commodities where the proposed Codex MRLs are higher than the existing EU MRLs. This approach is likely to overestimate the actual exposure, because normally the food items consumed do not all contain residues at the maximum level allowed in the European legislation; thus, this approach is a sufficiently conservative risk assessment screening. For active substances where the MRL review has not yet been completed, a less refined calculation was performed for the commodities where the EU MRL is higher than the proposed Codex MRL, using the EU MRL as input values for the risk assessment. The contribution of the individual crops under consideration in the CCPR meeting was calculated separately. The exposure assessments are usually based on the EU toxicological reference values, unless it is specifically mentioned that the JMPR values were used. In Appendix A of the report, the summary of the risk assessment calculations are provided.

For pesticides where the EU and JMPR residue definitions for risk assessment are not comparable, EFSA calculated indicative risk assessment scenarios. The assumptions and uncertainties of these scenarios are described individually.

The information related to draft Codex MRL proposals currently at step 4 or 7 is summarised in Appendix B.

It is highlighted that the JMPR report summarising the recommendations of the 2018 JMPR meeting was published on 11 January 2019. The full evaluations were published on 11 March 2019. Thus, due to the limited time available for providing the comments, an in-depth analysis could not always be performed. Thus, the conclusions reached in this report should be considered as indicative and might have to be reconsidered in a more detailed assessment, when needed. The comments presented in this report have to be seen in the context of the currently applicable guidance documents and the MRL legislation valid at the time of commenting. Thus, the comments may not be valid any more or may have to be modified, if the legal or scientific framework changes.

3. General consideration

3.1. Toxicological profiling of compounds and less-than lifetime dietary exposure assessment

In general, the initiative to critically review the currently used concepts for dietary exposure assessment and to develop a new methodology for less-than-lifetime exposure is fully supported by the EU, considering that the approaches for chronic and acute exposure assessments have been developed more than 20 years ago and are substantially unchanged, while in the meantime substantial progress has been made in the field of toxicology and with regard to availability and quality of food consumption data.

However, before the new methodology is developed, a dialogue with risk managers is necessary to define the regulatory question that should be addressed with this new exposure methodology. In particular, the following aspects should be clearly defined:

- Which period is considered as 'less-than-lifetime'?
- Which are the age groups (and the period) that are considered relevant?
- Definition of protection goal.

Toxicological considerations:

For the derivation of a short-term health-based guidance value (corresponding to a 'dietary' acceptable operator exposure level – AOEL – in the EU peer review of pesticidal active substances), similar qualitative considerations are given to those described in the text. Considering the decision-tree (page 7 of the JMPR report), the proposed factor of 3 is currently not taken into account when comparing developmental toxicity and systemic toxicity; however, it is noted that, according to the recent EFSA opinion on pesticides in foods for infants and young children (EFSA PPR Panel, 2018), pending on the completeness of the dossier (whether the active substance was sufficiently investigated, for instance through an extended one-generation reproductive toxicity study), an additional uncertainty factor of 3 may be considered in deriving the toxicological reference values to protect infant and young children > 16 weeks of age and additional considerations have to be made for infant < 16 weeks of age. This approach is not specific for less-than-lifetime exposures but would be relevant to derive any health-based guidance value.

Dietary exposure considerations:

The methodologies to estimate the chronic and acute exposure have been developed in the late nineties of the last century, making best use of food consumption data available at that time. It is acknowledged that the international estimated daily intake (IEDI) and the IESTI methodology are not sufficiently addressing the fact that within a certain developmental phase (e.g. infancy/childhood/ pregnancy) exposure to pesticide residues may exceed repeatedly the exposure calculated according to the IEDI. The frequency of these events, the extent of the exposure above the IEDI and the possible consumer risk related to these exposure peaks is not captured by the currently used risk assessment methodologies.

Before a new methodology is developed, it would be appropriate to perform an analysis of the exposure with regard to seasonal variations, variations for different subgroups of the population and to identify the relevant parameters and to develop a model that will address these aspects in the best way. The outcome of the project on the probabilistic modelling for the IESTI equations (see point 2.10) will be a useful source of information to identify the variabilities of exposure across individuals and should be used to underpin the model development for less-than-lifetime exposure.

3.2. Need for sponsors to submit all requested data

The EU supports the reminder of JMPR that all data and studies have to be submitted to JMPR within the agreed deadlines. In the interest to efficiency, JMPR should not waste time in assessing incomplete dossiers submitted by sponsors.

3.3. Hazard characterisation in the 21st century: assessing data generated using new mechanism-based approaches for JMPR evaluations

In the EU Regulation No 283/2013[3], describing the data requirements, it is recommended to undertake tests on vertebrate animals only when no other validated methods are available, and it is also noted that alternative methods to be considered shall include *in vitro* methods and *in silico* methods. The list of test methods and guidance documents relevant to the implementation of this Regulation has been published and should be regularly updated.

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

An EFSA update on the use of the benchmark dose (BMD) approach in risk assessment has been published in January 2017 (EFSA Scientific Committee, 2017), and concludes that the BMD approach is

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

applicable to all chemicals in food for the establishment of health-based guidance values or to calculate margins of exposure. Its practical implementation in the EU peer review of pesticides still needs further development and harmonisation.

EFSA has also overarching working groups on BMD and genotoxicity, both working groups (WG) dealing with specific questions from the EFSA panels, including from the pesticides Unit on request.

3.5. Microbiological effects

No comments.

3.6. Transparency of JMPR procedures

At EU level, transparency is a key requirement for risk assessment for pesticides. It is essential to describe the source of the data used, the validity of the studies, the results of studies and the assessment of the data leading to conclusions as well as the potential conflict of interest of assessors. Any initiative to increase transparency is supported.

3.7. Review of the large portion data used for IESTI equation

The EU fully supports the update of food consumption data to be used in acute exposure assessment. The EU would like to offer support to collaborate with FAO/WHO in the preparation of the guidance how to calculate the large portions; in the EU a lot of experience has been gained on the compilation and aggregation of food consumption data provided by different data providers. This experience might be of value for FAO/WHO.

3.8. Update of the IEDI and IESTI models used for the calculation of dietary exposure: commodity grouping according to the revised codex classification and new large portion data

The work done by National Institute for Public Health and the Environment (RIVM) to develop and maintain the calculation spreadsheets for IEDI and IESTI calculations is highly appreciated, in particular the efforts made to integrate the large portion (LP) data used in the EU dietary risk assessment tool (EFSA PRIMo revision 3). It should be noted that also at EU level new diets will be incorporated in future revisions of the EFSA PRIMo. Thus, to maintain a high level of consistency of the EU tool and the IEDI/IESTI models used by JMPR, the EU will keep FAO/WHO informed on progress made in the update of the EU diets.

3.9. Recommendations for (sub) group maximum residue levels for fruiting vegetables, other than cucurbits revisited

The EU appreciates the re-evaluation of the extrapolation approach for the fruiting vegetables group by JMPR. The use of normalised initial residue concentrations can give valuable indications whether the residue behaviour in different crops is comparable.

Subgroup of tomatoes: The extrapolation of residue data from tomatoes (any variety) to other crops belonging to the subgroup of tomatoes bears the risk that the MRL may not cover small varieties, such as cherry tomatoes or goji berries, which usually contain higher residues than varieties with bigger fruit size.

It is noted that for cape gooseberries the CXLs are applicable to the commodity after removal of the husk. Thus, for this crop, the CXL proposal derived from tomatoes may be too high. However, risk managers may agree on a pragmatic approach, considering that the OECD calculator implements a statistical approach that accommodates for a certain level of variability. Regarding consumer exposure, it is important that for the commodities with the highest consumption within the subgroup the risk assessment values (highest residue (HR) and STMR values) are reliable.

Subgroup of peppers: Based on the data presented in the JMPR report, it seems plausible not to accept extrapolations from peppers to okra, because pepper data are expected to underestimate the residues occurring in okra. This type of extrapolation is currently also accepted in the EU but may have to be reconsidered. The restriction proposed by JMPR to extrapolate from bell peppers and non-bell peppers to the subgroup of peppers except okra, seems plausible; as regards martynia and roselle,

considering the low relevance of these commodities in diet, a more pragmatic approach may be decided by risk managers, allowing extrapolation from peppers. Also, in chili peppers, higher residues are expected compared to bell and non-bell peppers. A case-by-case decision may be necessary to decide whether the MRL for peppers can be applied to chili peppers.

Subgroup of eggplants: At EU level, the extrapolation from tomatoes to eggplants is acceptable. Considering that the normalised initial residue concentrations in eggplants are higher than in tomatoes, trials in bell peppers may be more appropriate to derive the MRL for eggplants than residue trials in tomatoes. However, it needs to be born in mind that the growth stage of the crop at the time of treatment and the PHI are parameters that may influence the residues in the harvested product. The growth rate of eggplants is expected to be higher, leading to a higher dilution of residues compared to tomatoes or peppers. Thus, if the last application is close to harvest, the use of pepper data might be more appropriate, while in the case of earlier applications, depending on the residue decline of the pesticide, the tomato data might be also valid.

3.10. Preliminary results for probabilistic modelling of acute dietary exposure to evaluate the IESTI equation

The outcome of the probabilistic modelling of acute dietary exposure is expected with great interest and the EU is prepared to provide comments once the results are made available. This exercise is an important milestone in the project on reviewing the currently used IESTI equation and to provide answers to the question whether the currently used IESTI equations are sufficiently conservative to ensure that MRLs are set at levels that are protective for the consumers.

4. EFSA Comments on JMPR report chapter 3 (Responses to specific concerns raised by the Codex Committee on Pesticide Residues)

4.1. Benzovindiflupyr (261)

See comments in Section 5.20.

4.2. Bromopropylate (070)

The EU has submitted a concern form because the toxicological assessments are outdated (last toxicological assessment was performed in 1993; the setting of an ARfD was not yet standard practice at that time). The following arguments were provided in support of the concern form:

The active substance was first included in 1973 and re-evaluated in 1993, but not since. In the evaluation of 1993 an ADI was set at 0.03 mg/kg bw/d but no ARfD. Since no ARfD was ever set and data for evaluation are missing (supervised field trials, processing studies), the MRLs should be re-evaluated after 41 years. Since in 1993 it was not yet common practice to set an ARfD, EFSA used the ADI to assess the acute effects in the short term intake. A risk assessment was performed using the EFSA PRIMo including the existing CXLs for citrus fruits, pome fruits and grapes. The highest chronic exposure was calculated for the German child, representing 124% of the ADI. Since there were no supervised field trials complying with the critical GAP or reliable processing studies, the intake could not be further refined. The acute intake assessment (using the ADI-value) shows exceedance of the toxicological reference value for citrus fruits (884% for oranges, 594% for grapefruit, 371% for mandarins, 230% for lemons, and 134% for limes), pome fruits (653% for apples, 607% for pears), table grapes (437%) and wine grapes (158%).

JMPR recognised that the assessment is outdated, but since no new data were made available, and considering that no evidence was provided that triggered the setting of an ARfD, JMPR was of the opinion that bromopropylate was unlikely to present a major, acute health concern and therefore no further action was taken.

Considering that in 2018 CCPR bromopropylate was added to the list of unsupported compounds, since no data package was presented for the 2018 periodic review, CCPR should discuss appropriate risk management actions, e.g. deletion of the existing CXLs.

4.3. Crop groups – reconsideration of maximum residue estimations made by the 2017 JMPR for fenpyroximate (193), fluopyram (243), oxamyl (126) and spinetoram (233)

In 2017, JMPR assessed the uses on tomatoes and peppers. Reconsidering the policy for extrapolation in the subgroups of tomatoes and peppers, JMPR reviewed the previously derived MRL proposals.

The revised proposals for fenpyroximate and fluopyram are reported in Sections 5.9 and 5.16.

For oxamyl (126) and spinetoram (233), the previous MRL proposals were confirmed since the Good Agricultural Practice (GAP) referred only to tomatoes and peppers and not to other crops listed in the subgroup.

4.4. Cyprodinil (207) and propiconazole (160) post-harvest uses

See Sections 5.12(cyprodinil) and 5.5 (propiconazole).

4.5. 2,4-D (020)

USA submitted a concern form requesting clarification on the conclusion of 2017 JMPR regarding the lack of stability of residues in cotton seed in frozen storage, noting that a storage stability study on soya beans indicated stability of 2,4-D in soya beans under frozen conditions.

JMPR confirmed the previous view that due to limited storage stability observed in cotton seed the residue data were considered inadequate for estimating an MRL for 2,4-D in genetically modified maize.

It is noted that in an EU import tolerance application for genetically modified maize the available data were found sufficient to demonstrate stability of parent 2,4-D.

For cotton, no import tolerance request was submitted so far to the EU. Application for authorisation of genetically modified cotton DAS-81910-7 for food and feed uses, import and processing under Regulation (EC) No 1829/2003[4] by Dow AgroSciences (EFSA-GMO-NL-2016-136) has been submitted to EFSA. The DAS-81910-7 cotton has been genetically modified to express the AAD-12 and PAT proteins. The expression of AAD-12 and PAT proteins confers tolerance to application of 2,4-D and glufosinate-ammonium herbicides, respectively.

4.6. Fluopyram (243)

See Section 5.16.

4.7. Phosphonic acid (301)/Fosetyl-Aluminium (302)

JMPR concluded that phosphonic acid is toxicologically similar to fosetyl-aluminium and is covered by the ADI for fosetyl-aluminium (1 mg/kg body weight (bw) per day).

In the EU peer review (renewal of the approval for fosetyl-aluminium), an ADI of 1 mg/kg bw per day was derived. An ARfD was not considered necessary. Since phosphonic acid is a major metabolite in rat (73% in the urine), its toxicity (including developmental and reproductive toxicity (DART)) is considered covered by the studies performed with fosetyl-Al (EFSA, 2018k).

4.8. Picoxystrobin (258)

A concern form was submitted by USA, requesting a clear explanation why the JMPR concluded that there were an inadequate number of MOR (magnitude of residue) trials for rapeseed available for review to recommend a maximum residue level for picoxystrobin on oilseed rape.

JMPR clarified that the submitted trials did not match the critical US GAP.

No further comments required.

4.9. Quinclorac (287)

The EU submitted a concern form asking to reconsider the residue definition because quinclorac methyl ester, which is ten times more toxic than quinclorac was not included in the residue definition for enforcement.

[4] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

In 2017 and 2018, JMPR confirmed the residue definition for enforcement, concluding that quinclorac plus quinclorac conjugates are appropriate marker residues and taking into account the overall low exposure.

Since no new arguments were put forward by JMPR, the previous EU position should be maintained.

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, 2018). The terms in brackets after the name of the active substance in the header of the sections refer to the code number used by JMPR; the second parenthesis provides information whether the substance was assessed for toxicological properties (T) and/or for residues (R). The substances are sorted according to the codex number.

5.1. Diquat (31) R

5.1.1. Background information

Table 1: Background information

		Comments, references
Type of JMPR evaluation	New use	Last periodic review was performed by 2013 JMPR
RMS	UK	SE accepted to take over from UK
Approval status	Not approved	Commission Implementing Regulation (EU) 2018/1532[(a)]
EFSA conclusion	Yes, see comments	EFSA (2015r)
MRL review	Yes, see comments	EFSA (2015a)
MRL applications	No	No RO issued after art 12 review; MRL application for hops under preparation (DE EMS)
Others		EFSA (2018a) (statement on non-dietary exposure)
Cut-off criteria: • Mutagen cat. 1A or 1B • Caringogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification for CMR –Annex VI: no entry for CMR EU Peer Review proposal for CMR: toxic for reproduction cat. 2.; ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; CMR: Carcinogenic, Mutagenic or Toxic for Reproduction.

(a): Commission Implementing Regulation (EU) 2018/1532 of 12 October 2018 concerning the non-renewal of approval of the active substance diquat, 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 257, 15.10.2018, p. 10–12.

(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.

5.1.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.006 mg/kg bw per day	JMPR (2013)	0.002 mg/kg bw per day (diquat ion)	European Commission (2001) confirmed in EFSA (2015r) (2-year study in rats with uncertainty factor of 100)	No
ARfD	0.8 mg/kg bw	JMPR (2013)	0.01 mg/kg bw	EFSA (2015r) (developmental toxicity study in rabbits with uncertainty factor of 100); ARfD formally not approved	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
Conclusion/ comment	The EU toxicological reference values are in general lower than the JMPR values. In the EU assessment, a lower NOAEL of 0.2 mg diquat ion/kg bw per day for eye effects (cataracts) was set in the 2-year study in rats compared to 0.6 mg/kg bw per day in the JMPR assessment The basis for setting the ARfD was different in the EU and JMPR assessment, whereas in the JMPR the basis was the acute neurotoxicity study, the peer review considered appropriate to set the ARfD based on the NOAEL of 1 mg/kg bw per day for reduced body weight gain observed at 3 mg/kg bw per day in the developmental toxicity study in rabbits. An uncertainty factor of 100 was applied. The reference values as agreed during the peer review are supported Under the MRL review, toxicological data for the major plant metabolite TOPPS were requested as confirmatory data (deadline for submission 24 June 2018) Confirmatory data for Diquat (data gaps Article 12 assessment) were submitted to the RMS, co-RMS, EFSA and the EU COM on 20 June 2018g. No new data on TOPPS was available. Syngenta considered that this was not necessary since in their opinion TOPPS is of no toxicological concern. The applicant proposed use a conversion factor of 1.5 for TOPPS to diquat residues, as a conservative approach. These confirmatory data have not yet been evaluated by UK In the EFSA conclusion (EFSA, 2015r), toxicological information was also requested for diquat monopyridone and dipyridone. Considering that in October 2018 a decision on non-approval was taken, it is unlikely that the requested toxicological data will be provided for diquat monopyridone and dipyridone. However, before new Codex MRLs are taken over in the EU legislation, this open point should be addressed JMPR did not assess the toxicological profile of the metabolites, because they were considered as not relevant due to the low amount expected in plant and animal products (FAO, 2013)				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; RMS: rapporteur Member State; MRL: maximum residue level.

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	Diquat cation	EU Reg. 2016/1002: Diquat MRL Review (EFSA, 2015a): Sum of diquat and its salts, expressed as diquat Peer-review (EFSA, 2015r): Diquat	Yes
	Animal products	Diquat cation The residue is not fat soluble	EU Reg. 2016/1002: Diquat MRL Review (EFSA, 2015a): Sum of diquat and its salts, expressed as diquat Peer-review (EFSA, 2015r): Ruminant tissues and milk: Diquat dipyridone Poultry tissues and eggs: Diquat The residue is not fat soluble	Yes (for existing RD)
RD-RA	Plant products	Diquat cation	MRL Review (EFSA, 2015a): Peer-review (EFSA, 2015r): Herbicide uses: Diquat; Desiccant uses: 1) Diquat & 2) TOPPS, to be considered separately (insufficient data to conclude on the toxicological profile of TOPPS)	Yes, except for desiccant use

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	Diquat cation Sum of diquat, its salts and TOPPS expressed as diquat (tentative)	MRL Review (EFSA, 2015a): Sum of diquat, its salts and TOPPS expressed as diquat (tentative) Peer-review (EFSA, 2015r): Diquat, diquat monopyridone and diquat dipyridone Whether residues of the two metabolites can be expressed as diquat is pending a conclusion on the toxicological properties of diquat monopyridone and diquat dipyridone	No
Conclusion/ comments	The current EU enforcement residue definitions implemented in the MRL legislation are comparable with the residue definitions of Codex For risk assessment, the EU residue definitions are broader; however, in the EU, toxicological data are still missing for the metabolites TOPPS, diquat monopyridone, diquat dipyridone to conclude that they have toxicity comparable with the parent compound. Thus, at EU level, the data gaps related to the metabolites need to be addressed, before new MRLs are established			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; RMS: rapporteur Member State; MRL: maximum residue level.

5.1.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	**5**	0.02*	Critical GAP: AU, 600 g a.i./ha, no PHI defined, but worst case would be harvest after 4 days Number of trials: 1 trial matching the GAP, 5 trials where residue concentration was interpolated from different PHIs Sufficiently supported by data: No Specific comments/observations: For barley at least 8 trials would be required Conclusion: The proposed Codex MRL is not acceptable because of insufficient number of trials. The risk assessment value derived by JMPR does not reflect the EU residue definition
Barley straw and fodder, dry	**40 (dw)**	–	In the EU, MRLs are not established for feed items The proposed Codex MRL was derived from the combined data set of trials in barley, oat and wheat (17 trials), reflecting the use of 600 g/ha shortly before harvest
Beans, dry	0.2 W	0.2	The existing CXL is proposed to be withdrawn and to be replaced by the proposed Codex MRL for dry beans, subgroup
Chick-pea (dry)	**0.9**	0.3 (peas dry)	Critical GAP: CA, 408 g a.i./ha for preharvest desiccation, no PHI defined, but worst case would be harvest after 4–5 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: The samples were analysed only for diquat; no information on the amount of TOPPS Conclusion: The proposed Codex MRL is acceptable. However, the risk assessment values derived by JMPR do not reflect the EU residue definition

Commodity	Codex MRL proposal	EU MRL	Comment
Dry beans, Subgroup of (includes all commodities in this subgroup)	**0.4**	Beans dry: 0.2; Soya bean: 0.3	Critical GAP: CA, 552 g a.i./ha for preharvest desiccation; no PHI defined, but worst case would be harvest after 4–5 days Number of trials: 24 trials for beans and 3 trials in soya beans Sufficiently supported by data: No Specific comments/observations: Additional trials in soybeans (major crop) would be required. The samples were analysed only for diquat; no information on the amount of TOPPS Conclusion: The proposed Codex MRL is not acceptable. However, the risk assessment values derived by JMPR do not reflect the EU residue definition
Dry peas, Subgroup of (except chick-pea (dry))	**0.9**	0.3	Critical GAP: CA, 552 g a.i./ha for preharvest desiccation, no PHI defined, but worst case would be harvest after 4–5 days. Number of trials: 8 trials in lentils, 21 trials in peas (dry). Since residue trials in lentils and peas differed significantly, the MRL proposal was derived from the lentil trials only Sufficiently supported by data: Yes Specific comments/observations: The samples were analysed only for diquat; no information on the amount of TOPPS Conclusion: The proposed Codex MRL is acceptable. However, the risk assessment values derived by JMPR do not reflect the EU residue definition
Mammalian fats (except milk fats)	0.01*	0.05* (ft)	From feeding studies performed with exaggerated dose rates JMPR concluded that no residues are expected in fat Conclusion: The proposed Codex MRL is acceptable
Peas (dry)	W	0.3	The existing CXL for pea of 0.3 mg/kg will be replaced by the proposed MRL for peas dry, subgroup (0.9 mg/kg)
Poultry fats	0.01*	0.05* (ft)	From feeding studies performed with exaggerated dose rates, JMPR concluded that no residues are expected in fat Conclusion: The proposed Codex MRL is acceptable
Rye	**1.5**	0.02*	Critical GAP: 600 g a.i./ha, PHI not defined Number of trials: 6 trials in wheat; residues measured 2-4 days after application Sufficiently supported by data: Yes Specific comments/observations: For rye, 5 trials are sufficient according to JMPR rules; extrapolation from wheat to rye is acceptable. At EU level, 8 trials would be required Conclusion: The proposed Codex MRL is sufficiently supported by residue trials. The risk assessment value derived by JMPR does not reflect the EU residue definition. A chronic consumer intake concern was identified for rye
Rye straw and fodder, dry	**40 (dw)**	–	See comments on barley straw
Soya bean (dry)	W		The existing CXL for soya beans of 0.3 mg/kg will be replaced by the proposed MRL for beans dry, subgroup (0.4 mg/kg)
Soya bean hulls	1.5	–	PF of 3.1 derived from two processing studies
Triticale	**1.5**	Wheat: 0.02*	Critical GAP: 600 g a.i./ha, PHI not defined Number of trials: 6 trials in wheat; residues measured 2–4 days after application Sufficiently supported by data: Yes Specific comments/observations: For triticale, 5 trials are sufficient according to JMPR rules; extrapolation from wheat to triticale is acceptable Conclusion: The proposed Codex MRL is sufficiently supported by residue trials. The risk assessment value derived by JMPR does not reflect the EU residue definition
Triticale straw and fodder, dry	40 (dw)		See comments on barley straw

Commodity	Codex MRL proposal	EU MRL	Comment
General comments	It is noted that 2013 JMPR recommended withdrawal of the CXL for barley, wheat, wheat bran, wheat flour and wheat wholemeal. Since no sufficiently supported alternative GAPs were provided, the CXL should be withdrawn in 2019 CCPR 2018 JMPR confirmed the draft MRLs for edible offal (mammalian) eggs, meat (from mammals other than marine mammals), milks, poultry meat, poultry edible offal which were maintained at step 4. If these MRL proposals are advanced, the old CXLs for these commodities should be withdrawn		

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

5.1.5. Consumer risk assessment

Table 5: 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 performed for the unprocessed food commodities for which Codex MRLs were proposed The risk assessment is indicative because information on the occurrence of TOPPS and toxicological data for TOPPs is not available The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015a) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the commodities for which the Codex MRLs are higher than the existing EU MRLs. Animal products were not included in the calculation, considering that according to the feeding studies no diquat residues are expected to occur in animal products The risk assessment is indicative because information on the occurrence of TOPPS and toxicological data for TOPPs is not available The EU ADI was used	**Specific comments:** –
Results: No short-term exposure concern was identified for the food products for which Codex MRLs were proposed (maximum 87% of the ARfD for barley)	**Results:** A long-term consumer health risk was identified The overall chronic exposure accounted for 193% of the ADI The contribution of rye to the exposure was 139% of the ADI (Danish children)	**Results:** Long-term exposure: 30% of the ADI Short-term exposure: Maximum of 10% of the ARfD

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

5.2. Imazalil (110) R,T

5.2.1. Background information

Table 6: Background information

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	NL	
Approval status	Approved	Commission Implementing Regulation (EU) No 705/2011[(a)]
EFSA conclusion	Yes, see comments	EFSA PPR Panel (2007) EFSA (2010a)
MRL review	Yes, see comments	EFSA (2017h) EFSA (2018o)

		Comments, references
MRL applications	Yes, see comments	EFSA (2018j) (Art.43)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification and labelling for CMR – Annex VI: Carc. 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not finalised

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State.
(a): Commission Implementing Regulation (EU) No 705/2011 of 20 July 2011 approving the active substance imazalil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 190, 21.7.2011, p. 43–49.
(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.

5.2.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.03 mg/kg bw per day	JMPR (2018)	0.025 mg/kg bw per day	EFSA (2010a) European Commission (2011b)	No
ARfD	0.05 mg/kg bw	JMPR (2018)	0.05 mg/kg bw	EFSA PPR Panel (2007)	Yes
Conclusion/ comment	Studies with **parent imazalil** assessed **by JMPR:** It seems that not all of the studies reported in the JMPR report have been evaluated in the RAR or addendum to the RAR of imazalil (to be verified in the JMPR evaluation). However, according to the RMS, most of the new studies are not expected to influence the outcome of the evaluation in the RAR: e.g. acute tox results are in line with studies RAR and lead to same classification category; genotoxicity studies are negative, confirming the studies and conclusions reached in the RAR; mechanistic studies demonstrating liver enzyme induction and a CAR-dependent mechanism for liver effects Assessment of **metabolites:** The **JMPR Meeting** concluded that, based on the structure of R014821, its acute toxicity profile as well as its detection in rats at significant levels, this metabolite would be covered by the health-based guidance values for the parent compound. As regards R061000 (FK-772) JMPR was of the opinion that the toxicity would be covered by the parent compound, given its toxicity profile as well as its detection in rats at significant levels. For R043449 (FK-284) JMPR considered that the expected exposure was below the threshold Cramer Class III In the JMPR evaluation, all *in vitro* genotoxicity assays were concluded to be negative In 2018, **EFSA concluded** that insufficient data are available to conclude on the toxicological profile of metabolites formed in plants after post-harvest treatment (R014821) and observed in animal metabolism (FK-772 and FK-284) (EFSA, 2018j,o). In the EU evaluation, one study for metabolite R14821 and one study for metabolite FK772 was considered to give equivocal results, as the findings did not comply to either negative or positive outcome as defined in the respective OECD guidelines. Furthermore, the genotoxic endpoint of aneugenicity was not sufficiently addressed for any of the metabolites as the *in vitro* studies provided are not specifically designed to address this endpoint. Therefore, it was concluded that additional data are required regarding genotoxicity. Furthermore, EFSA set a data gap for a repeated dose study to be able to set specific reference values for these three metabolites Although the same studies were available for the metabolites, **different conclusions were derived by JMPR and at EU level**				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; RAR: renewal assessment report; OECD: Organisation for Economic Co-operation and Development.

5.2.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Imazalil	Reg. (EU) No 750/2010: Imazalil EFSA (2018j,o): Imazalil (any ratio of constituent isomers)	Yes
	Animal products	Imazalil	Reg. (EU) No 750/2010: Imazalil EFSA (2017h): Sum of imazalil and metabolite FK-772 (any ratio of constituent isomers), expressed as imazalil (tentative, pending full assessment of toxicological properties of FK-772) (not implemented in MRL legislation)	JMPR RD is comparable with the currently implemented RD, but comparison not appropriate with recent proposals
		The residue is not fat soluble	EFSA (2018j,o): Open The residue is not fat soluble	
RD-RA	Plant products	Free and conjugated imazalil	EFSA (2018j,o): Open for post-harvest use Imazalil (any ratio of constituent isomers) for foliar treatment and seed treatment	See comment below
	Animal products	Sum of imazalil and the metabolite R061000 (FK-772) ((*RS*)-3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy) ethyl] imidazolidine- 2,4-dione (+)-1-[2-(2,4-dichlorophenyl)-2-[(2,3-dihydroxypropyl)oxy] ethyl]- dihydroxypropyl)oxy] ethyl]-2,5-imidazolidinedione), expressed as imazalil equivalents	EFSA (2018j,o): Open	See comment below
Conclusion/ comments	It should be noted that the last EFSA recommendations derived under Article 43 (i.e. no residue definition for risk assessment can be derived for post-harvest uses and for livestock commodities) will be discussed at PAFF meeting of February 2019 For all plant commodities for which the critical GAP is a post-harvest use as well as for animal commodities, a comparison of the residue definition for risk assessment derived by JMPR with the EU residue definition is not appropriate, as long as the toxicological information requested for R014821, and FK-772 and FK-284 is not available The RMS proposed to discuss with MS in the PAFF committee (February 2019) to set the residue definition for risk assessment (plant commodities) tentatively as the sum of imazalil and R014821, expressed as imazalil. For animal products, the RMS proposed to set the residue definition for risk assessment as the sum of imazalil and all identified/characterised metabolites observed in the goat metabolism study. CF from enforcement to risk assessment can be derived tentatively from the metabolism study			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MS: Member State; RMS: rapporteur Member State; MRL: maximum residue level.

5.2.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL/ proposed MRL (Art. 43, EFSA, 2018o,j)	Comment
Citrus fruit	W 5Po	5/–	JMPR proposed to withdraw the existing CXL and to replace it with MRLs for the subgroup of lemons and limes and oranges
Lemons and limes, Subgroup of (includes all commodities in this subgroup)	**15Po**	5/–	Critical GAP: USA, post-harvest application (dip or drench) at 0.075 kg a.i./hl + post-harvest wax application at 0.2 kg a.i./hl (total: 0.275 kg a.i./hl); withholding period: 0 day Number of trials: 9 on lemons Sufficiently supported by data: Yes Specific comments/observations: See general comment for post-harvest applications and RMS proposal to re-discuss the residue definitions Conclusion: The proposed Codex MRL is not acceptable because the toxicity of metabolite R014821 (released after post-harvest treatment) is not sufficiently addressed
Oranges, sweet, sour, Subgroup of (includes all commodities in this subgroup)	**8Po**	5/–	USA, post-harvest application (dip or drench) at 0.075 kg a.i./hl + post-harvest wax application at 0.2 kg a.i./hl (total: 0.275 kg a.i./hl); withholding period: 0 day Number of trials: 12 on oranges Sufficiently supported by data: Yes Specific comments/observations: See general comment for post-harvest applications Conclusion: The proposed Codex MRL is not acceptable because the toxicity of metabolite R014821 (released after post-harvest treatment) is not addressed See also proposal of RMS below (General comments)
Pome fruits	**5W**	2/–	JMPR proposed to withdraw the existing CXL because not supported any longer by the manufacturer
Banana	**3Po**	2/–	Critical GAP: FR, post-harvest dip application at 0.0375 kg a.i./hl; withholding period: 0 day Number of trials: 13 trials available Sufficiently supported by data: Yes Specific comments/observations: See general comment for post-harvest applications. It is expected that following the recent EFSA assessment under Art. 43, the French GAP will be withdrawn Conclusion: The proposed Codex MRL is not acceptable because the toxicity of metabolite R014821 (released after post-harvest treatment) is not addressed
Raspberries, red and black	**W2**	0.05*	JMPR proposed to withdraw the existing CXL because not supported any longer by the manufacturer
Strawberry	**W2**	0.05*	JMPR proposed to withdraw the existing CXL because not supported any longer by the manufacturer

Commodity	Codex MRL proposal	EU MRL/ proposed MRL (Art. 43, EFSA, 2018o,j)	Comment
Potato	**9Po**	3/0.01*	Critical GAP: EU post-harvest application at 0.015 kg a.i./tonne; with-holding period of 0 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: In the framework of the MRL review, EFSA assessed the post-harvest use reported to JMPR, resulting in a similar MRL proposal (9 mg/kg). However, since intake concerns were identified, the EU MRL was derived for an alternative GAP; thus the GAP assessed by JMPR is no longer valid in the EU. See general comment for post-harvest applications. See also results of acute risk assessment Conclusion: The proposed Codex MRL is not acceptable because it is based on a GAP that is no longer valid for the EU and because of acute intake concerns. In addition, the comments regarding the toxicity of metabolite R014821 (released after post-harvest treatment) are not addressed
Persimmon, Japanese	**W 2Po**	0.05*/–	JMPR proposed to withdraw the existing CXL because not supported any longer by the manufacturer
Tomato	0.3	0.5/0.3	Critical GAP: Belgium, foliar (indoor) 3 × 0.02 kg a.i./hL; PHI 1 day (corresponding to 3 × 300 g a.i./ha assuming 1,500 L water/ha is applied) Number of trials: 6 Sufficiently supported by data: No Specific comments/observations: 2 additional trials would be required. However, in the EU assessment (art. 43), the critical EU use (indoor, 3 × 300 g /ha, PHI 1 day) was fully supported by data and lead to similar MRL. It is noted that for the EU assessment in total 8 trials were provided Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Cucumber	W 0.5	0.2/0.5	JMPR proposed to withdraw the existing CXL because of insufficient data to support critical GAP or alternative GAP
Gherkins	W 0.5	0.2/0.5	JMPR proposed to withdraw the existing CXL because not supported any longer by the manufacturer
Melons, except Watermelon	W 2Po	2/–	JMPR proposed to withdraw the existing CXL because not supported any longer by the manufacturer
Barley	0.01*	0.05*/0.01*	Critical GAP: seed treatment at 0.1 kg a.i./tonnes Number of trials: 5 trials on barley (all < LOQ) + 5-fold overdosed metabolism study on spring wheat (all < LOQ) Sufficiently supported by data: Yes Specific comments/observations: acceptable as no-residue situation is expected Conclusion: The proposed Codex MRL is acceptable
Triticale	0.01*	0.05*/0.01*	See barley
Barley straw and fodder (dry)	0.01	0.05*	Critical GAP: seed treatment at 0.1 kg a.i./tonnes Number of trials: 5 on barley (all < LOQ) Sufficiently supported by data: Yes Specific comments/observations: acceptable as no-residue situation is expected and similar residue behaviour expected in barley and wheat straw Conclusion: The proposed Codex MRL is acceptable
Wheat straw and fodder (dry)	0.01	0.05*	See barley straw

Commodity	Codex MRL proposal	EU MRL/ proposed MRL (Art. 43, EFSA, 2018o,j)	Comment
Triticale straw and fodder (dry)	0.01	0.05*	See barley straw
Meat (from mammals other than marine mammals)	0.02*	0.05*	Max estimated burden for beef cattle: 28.9 ppm (EU) Feeding study available that covers the estimated burden for imazalil; samples were analysed for parent, R043449 and R061000 Sufficiently supported by data: Yes Specific comments/observations: The feeding studies seem acceptable. See also general comment Conclusion: The proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	0.02*	0.05*	Conclusion: The proposed Codex MRL is not acceptable because of the lack of toxicological studies for metabolite FK-772 and FK-284 The RMS proposed to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Edible offal (mammalian)	**0.3**	0.05*	See Mammalian fats (except milk fats)
Milks	0.02*	0.05*	See Mammalian fats (except milk fats)
Poultry meat	0.02*	0.05*	Max estimated burden for poultry: 2.3 ppm (EU) Feeding study available that covers the estimated burden for imazalil; samples were analysed for parent, R042639 (FK-284), R043449 (FK-772) and R044085 Sufficiently supported by data: Yes Specific comments/observations: The feeding studies seem acceptable Conclusion: The proposed Codex MRL is acceptable
Poultry fats	0.02*	0.05*	See poultry meat
Poultry, edible offal	0.02*	0.05*	See poultry meat
Eggs	0.01*	0.05*	See poultry meat
General comments	The proposed Codex MRLs for post-harvest uses are not acceptable because the toxicity of metabolite R014821 (formed after post-harvest treatment) is not sufficiently addressed. This recommendation is in line with the recommendations derived in the recently published reasoned opinions of EFSA (2018j,o) which were supported by MS in a MS consultation The RMS proposed to discuss with MS whether the proposed Codex MRLs are compatible with the EU policy on setting MRLs although the toxicity of metabolite R014821 is not sufficiently addressed. The recommendations to be updated for lemons, oranges, bananas, after the PAFF meeting Although toxicological data for metabolites expected in animal commodities are also missing, the Codex MRL proposals for livestock commodities except edible offal might be acceptable, considering that at the relevant feed levels the total imazalil residues (sum of imazalil, R061000 (FK-772) and R043449 (FK-284) in animal matrices (except liver and kidney) were below the LOQ. The MRL proposal for edible offal mammalian is not supported since the occurrence of FK-772 and FK-284 cannot be excluded		

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

5.2.5. Consumer risk assessment

Table 10: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An indicative short-term dietary risk assessment was performed for all commodities for which JMPR has derived MRL proposals higher than the existing EU MRLs. The risk assessment is indicative, because the residue definitions for risk assessment could not be finalised for all MRLs derived from a post-harvest uses The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2018o) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for all commodities for which an MRL was derived by JMPR. The risk assessment is indicative, because the residue definitions for risk assessment could not be finalised for all MRLs derived from a post-harvest uses	**Specific comments:** JMPR calculated acute risk assessment for potatoes, using the HR and a PF for baked potatoes (with peel), resulting in a HR-p of 2.8. The exposure accounted for 60% of the ARfD. JMPR should be asked to explain why the risk assessment was not performed with the processing factor derived for microwaved potatoes with peel (HR-p = 6.5)
Results: Short-term exposure concern was identified for potatoes (1,415% of the ARfD), noting that for this commodity EFSA does not support any proposal due to the open issues regarding the residue definition for risk assessment	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 61% of the ADI	**Results:** Long-term exposure: 2–40% of the ADI Short-term exposure: 0–40% of the ARfD (children) 0-90% ARfD (adults)

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

5.3. Lambda-cyhalothrin (146) T

5.3.1. Background information

Table 11: Background information

		Comments, references
Type of JMPR evaluation	Other evaluation, see comment	New toxicological data was submitted to JMPR
RMS	SE	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) 2016/146[(a)]
EFSA conclusion	Yes, see comments	EFSA (2014c)
MRL review	Yes, see comments	EFSA (2014a) EFSA (2015t) (Art.43) EFSA (2017g) (Art.43)
MRL applications	Yes, see comments	EFSA (2019a) (celeries, fennel and rice)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: no classification ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not finalised

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

(a): Commission Implementing Regulation (EU) 2016/146 of 4 February 2016 renewing the approval of the active substance lambda-cyhalothrin, 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 30, 5.2.2016, 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.

5.3.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.02 mg/kg bw per day	JMPR (2007)	0.0025 mg/kg bw per day	Multigeneration rat study (cyhalothrin), EFSA (2014a) confirmed in European Commission (2015c)	No
ARfD	0.02 mg/kg bw	JMPR (2007)	0.005 mg/kg bw	1-year dog, EFSA (2014a) confirmed in European Commission (2015c)	No
Conclusion/ comment	At EU level, the toxicological reference values were lowered in the framework of the renewal of the approval of the active substance. Compared to the JMPR toxicological reference values, the EU ADI/ARfD are significantly lower. The available data on cyhalothrin and lambda-cyhalothrin were interpreted differently by the JMPR and at EU level. The EU assessment considered that lambda-cyhalothrin is about twice as toxic as cyhalothrin while the JMPR concluded on a similar level of toxicity of the two a.s. The EU peer review applied an additional uncertainty factor of 2 (overall 200) on studies performed with cyhalothrin to derive the toxicological reference values for lambda-cyhalothrin (i.e. the ADI) while the JMPR used a reduced uncertainty factor of 25 based on toxicokinetic considerations. The point of departure to derive the ADI was the same for the two assessments although based on different studies Regarding the ARfD setting, the point of departure was the same value based on the same study, however a different uncertainty factor was applied (100 in the EU vs. 25 in the JMPR assessment) resulting in different ARfDs. In the EU dossier toxicological data (acute oral toxicity and genotoxicity studies) were provided on metabolites 1a, II, III, VI and XIII showing that these metabolites are less acutely toxic than lambda-cyhalothrin and are unlikely to be genotoxic. Metabolite V (PBA) was shown to be less acutely toxic than the parent, but no genotoxicity or repeated dose toxicity data are available for this metabolite. Confirmatory data have been required by the EC for the applicant to address the toxicological profile (including the genotoxicity potential) of the metabolites V (3-phenoxybenzoic acid or PBA) and XXIII (3-(4-hydroxyphenoxy) benzoic acid or PBA(OH)) that are relevant to consumer exposure, and to clarify sperm effects reported upon lambda-cyhalothrin administration in the published literature; these data are currently being peer reviewed In 2018, JMPR assessed new toxicological studies with lambda-cyhalothrin (biliary elimination and biotransformation study in rats, 21-day dermal toxicity study, 21-day toxicity study by inhalation, two bacterial gene mutation assays and a preliminary developmental neurotoxicity study Furthermore, toxicological studies R119890, R41207 and R110649 (all three are plant metabolites) were assessed According to JMPR, these studies did not have an impact on the ADI and ARfD established in 2007 The new toxicological studies assessed by JMPR were probably not all made available at EU level				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; RMS: rapporteur Member State; MRL: maximum residue level.

5.3.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyhalothrin (sum of all isomers). The residue is fat soluble	EU Reg. 2019/50: lambda-cyhalothrin Art. 43 (EFSA, 2017g): lambda-cyhalothrin The residue is fat soluble	Yes
	Animal products			Yes
RD-RA	Plant products		Art. 43 (EFSA, 2017g): Lambda-cyhalothrin	Yes
	Animal products			Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion/ comments	The residue definitions derived by JMPR cover all isomers of cyhalothrin, while in the EU only lambda-cyhalothrin was included. However, the Codex MRLs refer to the use of lambda-cyhalothrin. Therefore, the JMPR residue definition has been considered in the past as equivalent to the EU residue definitions			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.3.4. Codex MRL proposals

No new codex MRL proposals were derived by 2018 JMPR.

5.3.5. Consumer risk assessment

Not relevant since no new Codex MRL proposals were derived.

5.4. Propamocarb (148) R

5.4.1. Background information

Table 14: Background information

		Comments, references
Type of JMPR evaluation	Other evaluation, see comment	A new livestock feeding study was provided to JMPR
RMS	PT	
Approval status	Renewal of the approval	Commission Directive 2007/25/EC[(a)] as amended by Commission Implementing Regulation (EU) 2018/917[(b)]
EFSA conclusion	Yes, see comments	EFSA (2006b) Renewal peer-review ongoing
MRL review	Yes, see comments	EFSA (2013d)
MRL applications	Yes, see comments	EFSA (2013e) (rocket and leek) EFSA (2014f) (spring onions and cabbage) EFSA (2015j) (bulb vegetables and leeks) EFSA (2015s) (various corps) EFSA (2017l) (chards/beet leaves) Art.10 on poppy seeds (ongoing, currently on clock-stop)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Cut-off criteria not met according to the Draft RAR -> To be discussed in April experts' meeting	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI Peer review ongoing – Experts' meeting in April 2019

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

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

(b): 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.

5.4.2. Toxicological reference values

Table 15: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.4 mg/kg bw per day	JMPR (2005) (1-year study in dogs, SF 100)	0.24 mg/kg bw per day	EFSA (2006b); European Commission (2007a) (52-week rat study, UF 100)	No
ARfD	2 mg/kg bw	JMPR (2005) (acute neurotoxicity study, SF 100)	0.84 mg/kg bw	EFSA (2006b); European Commission (2007a) (28-day gavage study in rats, UF 100)	No
Conclusion/ comment	The currently agreed ADI and ARfD values reported in the table above were recalculated to propamocarb free base Peer review ongoing – The toxicological reference values proposed by the RMS will be discussed in April experts' meeting The proposed ADI from the draft RAR is 0.29 mg propamocarb hydrochloride/kg bw per day based on the NOAEL of 29 mg/kg bw per day from a 52-week rat study and a safety factor of 100 The proposed ARfD is 1.0 mg propamocarb hydrochloride/kg bw per day, based on the NOAEL of 100 mg/kg bw from a 28-day rat gavage study and a safety factor of 100 Also, the ADI and ARfD of JMPR are expressed for propamocarb free base In 2005, JMPR derived an ADI of 0.4 mg/kg bw per day is set based on a NOAEL of 39 mg/kg bw per day, on the basis of vacuolisation observed in a range of organs in a 52-week study in dogs, and using a safety factor of 100. An ARfD of 2 mg/kg bw is set based on a NOAEL of 200 mg/kg bw, on the basis of a decreased in activity in rats 1 h after dosing from the rat acute neurotoxicity study and using a safety factor of 100				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; RMS: rapporteur Member State; MRL: maximum residue level; UF: uncertainty factor.

5.4.3. Residue definitions

Table 16: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Propamocarb	EU Reg. 2018/832: Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb)	Yes
	Animal products	Propamocarb The residue is not fat soluble	EU Reg. 2018/832: *N*-oxide propamocarb (products of animal origin, except poultry/birds eggs) *N*-desmethyl propamocarb (poultry, birds eggs) The residue is not fat soluble	No
RD-RA	Plant products	Propamocarb	MRL review (EFSA, 2013e): Sum of propamocarb and its salts, expressed as propamocarb	Yes
	Animal products	Propamocarb	MRL review (EFSA, 2013e): Sum of propamocarb, *N*-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb, expressed as propamocarb (ruminants, pigs); Sum of propamocarb and *N*-desmethyl propamocarb, expressed as propamocarb (poultry)	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion/ comments	**Plant commodities**: The residue definition set for enforcement and risk assessment by JMPR and at EU level are substantially the same **Animal commodities**: The residue definition set for enforcement and risk assessment by JMPR and at EU level EU are quite different EFSA proposed to limit the residue definition for enforcement to the best marker compound, identified as *N*-oxide propamocarb in tissues of ruminants (and pigs) and in milks and as *N*-desmethyl propamocarb in poultry tissues and eggs (details are reported below as background information) For risk assessment, the EU residue definition is more comprehensive and includes the major plant and animal metabolites. Based on metabolism studies, tentative conversion factors for risk assessment were proposed during the MRL review (4.25 for milk; 2.2 for ruminant kidney, 1.7 for ruminant liver and muscle; 1 for ruminant fat; 1.3 for all poultry tissues and eggs) Overall, the residue definitions for animal products derived at EU level and by JMPR are not compatible Both assessments concluded residues in products of animal origin are not fat soluble According to the MRL review, in ruminants, metabolite *N*-oxide propamocarb was the predominant metabolite of the total residues found in kidney (41% TRR – 0.044 mg/kg), liver (49% TRR – 0.203 mg/kg), muscle (40.5% TRR – 0.008 mg/kg) and also in milk (21% TRR – 0.012 mg/kg). Oxazolidine-2-one propamocarb occurred in significant amounts in kidney, liver and milk (14–23% TRR; 0.014–0.09 mg/kg). 2-hydroxy propamocarb was the major metabolite of the total residues in milk (37.5% TRR – 0.022 mg/kg) but was also identified at a lower level in liver (5% TRR) and kidney (13% TRR). Parent propamocarb accounted for 24.6% TRR in muscle (0.005 mg/kg), 23.5% TRR in kidney (0.025 mg/kg), 6.2% TRR in liver (0.026 mg/kg) and 6.0% TRR in milk (0.003 mg/kg) In poultry, the predominant compound of the total residues was the *N*-desmethyl propamocarb in eggs (45% TRR), liver (22% TRR), muscle (29% TRR) and to a minor extend in fat (6% TRR) while the parent compound occurred at a lower level in all matrices (2–12% TRR). Bis desmethyl propamocarb and *N*-oxide propamocarb accounted for less than 10% TRR. It is noted that a significant fraction of the radioactive residues remained uncharacterised in liver and muscle (32% and 41% TRR, respectively)			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; TRR: total radioactive residues.

5.4.4. Codex MRL proposals

Table 17: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (Mammalian)	**1.5**	Edible offal, liver from – ruminants, equine, others: 0.2 –swine: 0.1 Kidney from – ruminants, equine, others: 0.05 – swine: 0.2	In 2014, JMPR calculated the maximum dietary burden using the OECD diets listed in the 2009 Edition of the FAO manual. The maximum and mean dietary burden was identified for Australian Dairy cattle (31.55 ppm DM and 10.7 ppm DM; the dietary burden is expressed as free base) In 2018, JMPR assessed a new feeding study with dairy cows administered propamocarb-HCl with feed levels equivalent to 13.6, 26.3 and 138 ppm propamocarb equivalents in feed The Codex MRL proposal refers to propamocarb residues only Conclusion: The proposed Codex MRL is not acceptable because it is not compatible with the EU residue definition for enforcement
Mammalian fats (except milk fats)	**0.03**	0.01 (ft)	See comment on mammalian edible offal Conclusion: The proposed Codex MRL is not acceptable because derived according to a different residue definition

Commodity	Codex MRL proposal	EU MRL	Comment
Meat from mammals (other than marine mammals)	**0.03**	0.01 (ft)	See comment on mammalian edible offal Although Codex MRL proposal refers to meat, samples of muscle tissue were analysed Conclusion: The proposed Codex MRL is not acceptable because derived according to a different residue definition
Milks	0.01*	0.01 (ft)	See comment on mammalian edible offal Conclusion: The proposed Codex MRL is not acceptable because derived according to a different residue definition
General comments	The proposed Codex MRLs for tissues and milks cannot be taken over in EU legislation because of incompatible residue definitions In 2014, the proposed Codex MRLs for cabbages, head and kale were retained on step 4, awaiting the livestock feeding study In 2014, JMPR also recommended withdrawal of the CXLs for animal products that were derived by Codex in 2007, (once the CXLs are replaced with new Codex MRL proposals)		

MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; DM: dry matter; CXL: Codex Maximum Residue Limit.

*: Indicates that the input value is proposed at the limit of quantification. Ft: EFSA identified some information on analytical methods and a feeding study as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 22 March 2016 or, if that information is not submitted by that date, lack of it.

5.4.5. Consumer risk assessment

Considering that the residue definitions are not compatible, and currently reliable conversion factors could not be derived, EFSA did not perform a dietary risk assessment for the proposed Codex MRLs.

5.5. Propiconazole (160) R

5.5.1. Background information

Table 18: Background information

		Comments, references
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 (oranges, mandarins, lemons/limes, pumelo/grapefruit, peach, cherries, plums, pineapple); due to toxicological concerns with certain metabolites. (2018 JMPR followed up on 1)
RMS	FI	
Approval status	Not approved	Commission Implementing Regulation (EU) No 2018/1865[(a)]
EFSA conclusion	Yes, see comments	EFSA (2017e); EFSA (2018m) conclusion confirmatory data on TDMs
MRL review	Yes, see comments	EFSA (2015b)
MRL applications	No	UK is evaluating an import tolerance application from USA on behalf Finland (agreed at PAFF June 2018 meeting). The application concerns the following crops: barley, wheat, pineapple and peanuts
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B	Yes	Harmonised classification and labelling for CMR – Annex VI: Toxic for reproduction cat. 1B EU Peer Review proposal for CMR: Toxic for reproduction cat. 1B ED assessment according to ECHA/EFSA guidance (2018) and

		Comments, references
• Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential		scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level; TDMs: triazole-derivative metabolites.

(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.

(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.

5.5.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.07 mg/kg bw per day	JMPR (2015)	0.04 mg/kg bw per day	EFSA (2017e) (chronic rat study with uncertainty factor of 100)	No
ARfD	0.3 mg/kg bw	JMPR (2015)	0.1 mg/kg bw	EFSA (2017e) (developmental study in rat with uncertainty factor of 300)	No
Conclusion/ comment	In the framework of the renewal of the approval (EFSA, 2017e), EFSA proposed to lower the ARfD; the new value is not yet formally adopted. The ADI has been confirmed Propiconazole is proposed to be classified as toxic for reproduction category 1B by the Risk Assessment Committee of ECHA (2016), in accordance with the provisions of Regulation (EC) No 1272/2008, and toxic effects on the endocrine organs have been observed in the available data Due to classification (ECHA, 2016), a non-approval decision was taken in 2018				

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

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	Propiconazole	EU Reg. 2017/626 and EFSA (2017e): Propiconazole (sum of isomers)	Yes
	Animal products	Propiconazole The residue is fat soluble	EU Reg. 2017/626: Propiconazole (sum of isomers) Peer review (EFSA, 2017e): CGA91305 (free and conjugated) ((1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl) ethanol) The residue is fat soluble	Yes
RD-RA	Plant products	Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoic acid,	MRL review(EFSA, 2015b): Propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers) Peer review (EFSA, 2017e): 1) Propiconazole (sum of isomers);	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		expressed as propiconazole	2) CGA 118244 (3,5-dideoxy-1,2-O-[(1*RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-yl) ethylidene]-D,L-pentitol) free and glucoside conjugated Whether the parent compound and CGA 118244 have to be considered together or separately is pending upon the submission of toxicological data to address the toxicity profile on CGA118244) 3) TDMs (EFSA, 2018m)	
	Animal products	Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoic acid, expressed as propiconazole	MRL review (EFSA, 2015b): Parent propiconazole and all the metabolites convertible to the 2,4-dichlorobenzoic acid, expressed as propiconazole (sum of isomers) Peer review (EFSA, 2017e): 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) TDMs (EFSA, 2018m)	Yes
Conclusion/ comments	The enforcement RD for plants established in Reg. 2017/626 is comparable with the RD of JMPR. For the risk assessment residue definitions, JMPR covers the common moiety (2,4-dichlorobenzoic acid); in the MRL review, the same risk assessment residue definitions were derived In the framework of the peer review, data gaps on the genotoxicity potential and toxicological profile of metabolite CGA118244 and CGA91305 were identified JMPR did not set specific residue definitions for the TDMs (TAA and TA). Due to the different risk assessment residue definitions for plant commodities and the open questions as regards the toxicological properties of some of the metabolites, only a tentative risk assessment can be performed			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; TDMs: triazole-derivative metabolites.

5.5.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Cherries, Subgroup of (including all commodities in this subgroup)	**3Po**	0.01*	Critical GAP: US post-harvest GAP: 1 × 12.9 g a.s./100 L (in-line dip/drench) Number of trials: 5 Sufficiently supported by data: Cherries are a major crop according the JMPR and at EU level. Thus, additional residue trials would be required. Last year, the EU did not make a formal reservation on the lack of residue trials The recalculation of the MRL using mean residue + 4 SD resulted in the same MRL proposal as suggested last year Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
Lemons and limes (including citron) Subgroup of (including all	**10Po**	5 (ft)	Critical GAP: US post-harvest GAP: 2 × 52.7 g a.s./100 L (dip/drench) Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: See assessment for the subgroup of oranges Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed

Commodity	Codex MRL proposal	EU MRL	Comment
commodities in this subgroup)			to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
Mandarins (including mandarin-like hybrids) subgroup of (including all commodities in this subgroup)	**10Po**	5 (ft)	Critical GAP: US post-harvest GAP: 2 × 52.7 g a.s./100 L (dip/drench) Number of trials: 16 Sufficiently supported by data: Yes Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
Orange oil	1850		A single-processing study is available (PF 185). In the EU, no MRLs are set for processed products
Oranges, Sweet, Sour (including orange-like hybrids) Subgroup of (including all commodities in this subgroup)	**10Po**	9	Critical GAP: USA, post-harvest GAP: 2 × 52.7 g a.s./100 L (dip/drench), Number of trials: 16 (8 trials on oranges, 4 trials on mandarins and 4 trials on lemons) Sufficiently supported by data: Yes Specific comments/observations: The CF for risk assessment was derived from residue trials in cherries. The validity of this extrapolation is not questionable, but formally the EU did not make a reservation on that point Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
Peach	0.7Po	5	Critical GAP: US post-harvest GAP: 1 × 0.54 g a.s./1,000 kg (in-line aqueous/fruit-coating spray) Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Peaches are a category 3 crop for JMPR; therefore, at least 5 trials would be required. Last year, the EU did not make a formal reservation on the lack of residue trials Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480. Furthermore, a acute intake concern was identified for peaches
Pineapple	**2Po**	0.02*	Critical GAP: US post-harvest GAP: 1 × 25.8 g a.s./100 L (drench) + 1 × 25.8 g a.s./100 L (directed peduncle spray) Number of trials: 4 Specific comments/observations: According the JMPR, pineapples are a category 3 crop, thus, at least 5 residue trials would be required. Last year, the EU did not make a formal reservation on the lack of residue trials UK is evaluating an import tolerance application from USA on behalf Finland (agreed at PAFF June 2018 meeting). The application concerns also pineapples. The GAP and residue data for pineapple seems to be the same as the ones considered by JMPR Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
Plums, Subgroup of (includes all commodities in this subgroup)	0.4Po	0.01*	Critical GAP: US post-harvest GAP: 1 9 0.54 g a.s./1,000 kg (in-line aqueous/fruit-coating spray) Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Sufficient number of trials according to JMPR rules, but at EU level 8 trials would be required

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
Pumelo and grapefruit (including Shaddock-like hybrids) Subgroup of (including all commodities in this subgroup)	4Po	5 (ft)	Critical GAP: US post-harvest GAP: 2 9 52.7 g a.s./100 L (dip/drench) Number of trials: 4 Sufficiently supported by data: Yes Conclusion: It is recommended to discuss with MSs whether the proposed Codex MRL is acceptable considering the fact that propiconazole is proposed to be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480
General comments	2018 CCPR Meeting agreed that more refined maximum residue levels are possible for the post-harvest uses considered by the 2017 JMPR using the mean + 4 SD. The residue data assessed by the 2017 JMPR for post-harvest uses are suitable for estimating maximum residue levels, and for estimating STMR and HR for long-term and acute dietary exposure assessments. The Meeting recommended the following maximum residue levels based on the mean + 4 SD for the post-harvest uses of propiconazole on the crops considered in the 2017 Meeting In the light of the recent decision on non-approval of the a.s. and the lowering of the ARfD in 2017, the existing EU MRLs should be reviewed. Finland has screened the existing EU MRLs in the light of the new toxicological reference values. The assessment was based on the existing RD for RA. STMR, HR and CFs were taken from the previous EFSA assessment on the complete MRL review (EFSA, 2015b) and JMPR reports. Calculations by PRIMO rev. 3 resulted in the ARfD exceedance for the following crops: oranges, peaches, grapefruits, mandarins, lemons and tomatoes. In all cases, the GAPs are based on post-harvest uses (consequently, a CF of 1 was used in the assessment). MRLs for orange, peach and tomatoes are based on CXLs, implemented in the EU legislation. The results of the screening exercise will be presented to the PAFF-Residues meeting February 2019 (ft) In the framework of the MRL review, certain information was considered for lemons, lime, mandarins and grapefruit; deadline for submission of the missing data: 30 March 2018. Finland received an MRL application concerning Art. 12 confirmatory data. The submission included studies on the toxicological properties of the metabolites convertible to 2,4-dichlorobenzoic acid and new residue trials on barley, wheat, maize and sugar beet; and a processing study on cereals. Studies on magnitude of residues were also requested to confirm MRLs for grapefruits, lemon, limes, mandarins, apples, apricots, grapes, bananas and rice, but not submitted. Evaluation of residue data has not been started yet, but the tox. part is going to be finalised during spring and can be submitted earlier, if needed		

GAP: Good Agricultural Practice; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; MS: Member State; a.s.: active substance; CF: conversion factor; STMR: supervised trials median residue; HR: highest residue; ARfD: acute reference dose; RD: residue definition; RA: risk assessment; PRIMo: (EFSA) Pesticide Residues Intake Model; CXL: Codex Maximum Residue Limit.
*: Indicates that the input value 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: The short-term dietary risk assessment was performed for crops under consideration in 2018 JMPR The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015b) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for rape seed	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
A tentative short-term dietary risk assessment was performed for parent propiconazole for citrus fruits with exception of grapefruits, cherries, peaches, plums and pineapples using the HR pulp value for citrus fruit, the HR whole fruit for peaches, cherries and plums and the HR-P for pineapple. For grapefruits, the STMR and HR derived by JMPR for the post-harvest use were included, because they were higher than the previously derived EU input values The risk assessment is considered tentative, because of the difference of residue definitions established at EU level and by JMPR. Additional uncertainties in the risk assessment are resulting from the lack of data on the residue concentration compliant with the residue definition for risk assessment for citrus and the lack of information on the possible impact of plant and livestock metabolism on the isomer ratio of propiconazole Risk management decision required how to proceed with active substances that are not approved in the EU due non-compliance with cut-off criteria	The most recent long-term risk assessment for parent propiconazole (EFSA, 2015b) was updated using the approach as outlined in Section 'Assessment', including the STMR pulp values derived by JMPR for citrus fruits, the STMR whole fruit cherries, peaches, plums and the STMR-P for pineapple The EU ADI was used The risk assessment is considered tentative, because of the difference of residue definitions established at EU level and by JMPR	
Results: A short-term exposure concern was identified (209% of the ARfD for peaches Furthermore, an acute intake concern was identified for the EU MRL for tomatoes due to the use of PRIMo 3	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 21% of the ADI (NL toddler). The contribution of apples and maize corn to the exposure was 3% each of the ADI	**Results:** Long-term exposure: 21% of the ADI (NL toddler) Short-term exposure: 209% of the ARfD for peaches 57% of the ARfD for oranges

ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue; HR: highest residue; ADI: acceptable daily intake; MRL: maximum residue level; RA: risk assessment; PRIMo: (EFSA) Pesticide Residues Intake Model.

5.6. Profenofos (171) R

5.6.1. Background information

Table 23: Background information

		Comments, references
Type of JMPR evaluation	New use	Last periodic review 2008
RMS	–	RMS Germany: toxicological evaluation in the framework of setting MRLs
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[(a)]
EFSA conclusion	No	
MRL review	No	
MRL applications	No	
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B	Not met ED: No information	Harmonised classification and labelling for CMR – Annex VI: none

		Comments, references
• Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	available as not approved in EU	

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

5.6.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.03 mg/kg bw per day	JMPR (2007) (dog: 90 days, 6 months and 1 year studies)	0.0002 mg/kg bw per day	German evaluation of 2001 (dog 1-year study. Toxicological evaluation at EU level performed in the framework of setting MRLs under Council Directive 90/642/EEC[(a)])	No
ARfD	1 mg/kg bw	JMPR (2007) (rat acute neurotoxicity)	0.005 mg/kg bw		No
Conclusion/ comment	The German ADI is based on the LOAEL 1 mg/kg bw per day with an UF of 200 The ARfD is based on the NOAEL for the inhibition of brain cholinesterase activity Due to the limited details available in the JMPR Report and the German evaluation, a final conclusion on the acceptability of the toxicological reference values derived by the two bodies cannot be made				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; LOAEL: lowest observed adverse effect level; NOAEL: no observed adverse effect level; RMS: rapporteur Member State; MRL: maximum residue level; UF: uncertainty factor.
(a): Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables. OJ L 350, 14.12.1990, p. 71–79.

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	Profenofos	EU Reg. 2017/978: Profenofos	Yes
	Animal products	Profenofos The residue is not fat soluble	EU Reg. 2017/978: Profenofos The residue is fat soluble	Yes
RD-RA	Plant products	Profenofos	EU Reg. 2017/978: Profenofos	Yes
	Animal products			Yes
Conclusion/ comments	The JMPR defines the residues as not fat soluble, whereas the EU residue definition defines the residues as fat soluble			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

5.6.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Coffee bean	0.04	0.05*	Critical GAP: Brazil, 2 × 400 g/ha, 30-day interval, PHI 7 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: According to the JMPR criteria, the number of trials is not sufficient because coffee beans are classified as a major crop and a minimum of 8 trials are normally required. The number of trials is not sufficient according to the EU data requirements. The limited number of trials is of low relevance since the Codex MRL proposal is lower than the current EU MRL at the LOQ of 0.05 mg/kg. Further consideration may be required in case the LOQ is in future lowered Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. The long-term risk assessment indicated a potential consumer health risk in the scenario where the toxicological reference value (ADI) derived by the EU evaluation was used
General comments	Monitoring data carried out between 2012 and 2015 show that residues of profenofos occur in herbs and rose petals and Commission Regulation (EU) 2017/978 extend the validity of EU MRLs for these commodities		

PHI: preharvest interval; MRL: maximum residue limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GAP: Good Agricultural Practice; LOQ: limit of quantification; ADI: acceptable daily intake.
*: Indicates that the input value 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: The short-term dietary risk assessment was performed for coffee beans using STMR derived by JMPR for coffee beans. EFSA calculated two scenarios because a conclusion on the acceptability of the toxicological reference values (ARfD) derived by the JMPR and the EU evaluation cannot be made on the basis of the available information. Scenario 1: The EU evaluation ARfD was used (German evaluation of 2001). Scenario 2: The JMPR ARfD was used	**RA assumptions:** An indicative long-term risk assessment was performed using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for coffee beans, as well as the STMR values previously derived by JMPR for mango, mangosteen (EU classification 0163040 papayas), tomato, anise seeds, star anise seeds (EU classification 0820040 cardamom), caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries, nutmeg, mace, cardamom (higher STMR value for star anise seeds used) and grains of paradise (EU classification 0820060 peppercorn). For chili peppers, the existing EU MRL was used for the EU classification of sweet peppers/bell peppers considering the low contribution expected from the specific use on chili peppers. For other commodities, EFSA applied the MRLs established in the EU legislation according to the Corrigendum to Commission Regulation (EU) 2017/978 except for where the EU MRL is set at the LOQ (no use expected) and for animal commodities (contamination of imported feed items is not expected). EFSA calculated two scenarios because a conclusion on the acceptability of the toxicological reference values (ADI) derived by the JMPR and the EU evaluation cannot be made on the basis of the available information Scenario 1: The EU evaluation ADI was used (German evaluation of 2001) Scenario 2: The JMPR ADI was used	**Specific comments:** None

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure concern was identified Scenario 1, EU evaluation ARfD: The estimated short-term exposure from coffee beans accounted for < 0.3% of the ARfD Scenario 2, JMPR ARfD: The estimated short-term exposure from coffee beans accounted for < 0.01% of the ARfD	**Results:** The long-term risk assessment indicated a potential consumer health risk in the scenario where the toxicological reference value (ADI) derived by the EU evaluation was used. No long-term consumer health risk was identified in the scenario where the toxicological reference value (ADI) derived by the JMPR was used Scenario 1, EU evaluation ADI: The overall chronic exposure accounted for 2,800% of the ADI (GEMS/Food G06). The diet with the highest contribution of coffee beans to the chronic exposure was 56% of the ADI for the FI adult diet. The main contributor to the exposure is tomatoes (2,327%) Scenario 2, JMPR ADI: The overall chronic exposure accounted for 19% of the ADI (GEMS/Food G06). The diet with the highest contribution of coffee beans to the chronic exposure was 0.37% of the ADI for the FI adult diet	**Results:** Long-term exposure: 0–20% of the ADI Short-term exposure: 0% of the ARfD

RA: risk assessment; STMR: supervised trials median residue; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; LOQ: limit of quantification; ADI: acceptable daily intake.

5.7. Bentazone (172) R

5.7.1. Background information

Table 28: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Renewal of the approval	Commission Decision 2000/68/EC[(a)] amended by Commission Implementing Regulation (EU) 2018/660[(b)]
EFSA conclusion	Yes, see comments	EFSA (2015i)
MRL review	Yes, see comments	EFSA (2012c)
MRL applications	Yes, see comments	EFSA (2011b) (legume vegetables and fresh herbs) In sweet corn (EFSA, 2010b) Confirmatory data following Art.12 under-finalisation Art. 10 MRLs in various commodities under-consideration
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: Toxic for reproduction cat. 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(c)]): not finalised

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

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

(b): Commission Implementing Regulation (EU) 2018/660 of 26 April 2018 renewing the approval of the active substance bentazone 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 110, 30.4.2018, p. 122–126.

(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.

5.7.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.09 mg/kg bw per day	JMPR (2016)	0.09 mg/kg bw per day	EFSA (2015i) (rat, 2-year study with an UF of 100) conformed in European Commission (2018c)	Yes
ARfD	0.5 mg/kg bw	JMPR (2016)	1 mg/kg bw	EFSA (2015i) (rat developmental toxicity study, 100 UF) conformed in European Commission (2018c)	No
Conclusion/ comment	Regarding the setting of the ADI, both the JMPR and EU assessments are based on the same NOAEL of 9 mg/kg bw per day from the same two-year toxicity study in rats and applying an uncertainty factor of 100 The ARfD established by the JMPR is based on an acute neurotoxicity study in rats that was not available to the EU peer review; this study should be reviewed in the EU peer review to re-visit the established ARfD In the opinion of the EU peer review, the toxicological reference values of the parent, bentazone, are applicable to the metabolite 8-hydroxy-bentazone, however according to the EFSA conclusion, insufficient toxicological information is available to establish reference values for metabolite 6-hydroxy-bentazone In the Review report for the active substance bentazone finalised in the Standing Committee, the following statement for the bentazone metabolites (6-OH and 8-OH bentazone) was made: *According to the JMPR review of bentazone (Bentazone 31-98, JMPR 2012) the 8-hydroxy and 6-hydroxy metabolites of bentazone are of comparable toxicity by the oral route of administration and are both less toxic than the parent compound. In addition the RMS informed that even if 6-OH bentazone would not be regarded as toxicologically equivalent to 8-OH-bentazone, the consumer exposure falls below 1.5 μg/kg bw/day (TTC Cramer Class III for non-genotoxic substances). The TTC approach was recommended in the Scientific Opinion (EFSA, 2012c)* According to the RMS NL, the EU Commission Review Report (2018c) closed the EFSA data gap. The reference values of the parent should also be applicable to 6-hydroxy-bentazone For the 8-hydroxy-bentazone, the peer review concluded that it is less toxic than parent compound and the reference values of parent can be applied to this metabolite. The peer review did not consider this metabolite relevant for the inclusion in the residue definitions. Actual levels of this metabolite in plants are low Following the setting of an ARfD by JMPR in 2016, JMPR re-assessed the previously derived CXLs as regards possible acute intake concerns				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; TTC: threshold of toxicological concern; RMS: rapporteur Member State; CXL: Codex Maximum Residue Limit.

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	Bentazone The residue is not fat soluble	MRL review 2012c and Reg. (EC) No 1146/2014: Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone Peer review (2015i) proposal: Bentazone	No
	Animal products		MRL review 2012c and Reg. (EC) No 1146/2014: Sum of bentazone, its salts and 6-hydroxy (free and conjugated), expressed as bentazone	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			Not fat soluble Peer review (2015i) (provisional): 6-hydroxy-bentazone, expressed as bentazone (all animal commodities, except milk) 6-hydroxy-bentazone (sulphate) conjugates, expressed as bentazone (milk only)	
RD-RA	Plant products		MRL review (2012c): same as RD for enforcement Peer review (2015i): Sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone (provisional)	No
	Animal products			No
Conclusion/ comments	The EU and JMPR residue definitions for bentazone are not comparable. The metabolite 6-hydroxy-bentazone is included in the currently applicable enforcement and risk assessment residue definitions in the EU. For plant commodities, additionally, the 8-hydroxy-metabolite is included in the enforcement and risk assessment residue definitions. Thus, as long as the EU residue definitions are not modified, the Codex MRL proposals are not compatible with the EU enforcement residue definitions. Furthermore, a common understanding regarding the data gap on toxicological information for metabolite 6-hydroxy-bentazone should be derived (see Conclusion/comments on toxicological reference values) The enforcement residue definition for plant commodities as proposed by the peer review (not yet enforced) complies with the residue definition derived by the JMPR, but this residue definition is not yet implemented			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.7.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Beans (dry)	W 0.04	0.1	Withdrawal on the basis of new CXL as extrapolated from dry peas (see comment below)
Dry beans, subgroup of (includes all commodities in this subgroup)	**0.5**	0.1 Soya beans: 0.03*	Critical GAP: USA, foliar, 2 × 1.12 kg/ha, PHI 30 days Number of trials: 8 Sufficiently supported by data: No Specific comments/observations: Extrapolation from peas. The Codex MRL proposal would also cover soya beans; residue trials on soybeans would be also required Conclusion: The proposed Codex MRL is not acceptable because the Codex residue definition is not compatible with the EU residue definition (occurrence of 6-hydroxy and 8-hydroxy-bentazone has not been investigated)
Dry peas, subgroup of (includes all commodities in this subgroup)	0.5	1	Critical GAP: USA, foliar, 2 × 1.12 kg/ha, PHI 30 days Number of trials: 8 Sufficiently supported by data: Yes Specific observations: The CXL derived in 1997 has been taken over in the EU. 2013 JMPR recommended withdrawal of this old CXL; since JMPR derived a new MRL proposal, the CXL for Field peas (dry) VD0561) should be withdrawn Conclusion: The proposed Codex MRL is not acceptable because the Codex residue definition is not compatible with the EU residue definition (occurrence of 6-hydroxy and 8-hydroxy-bentazone has not been investigated). Risk managers to discuss the replacement of the existing EU MRL, considering that the previous CXL will be withdrawn
Edible offal (Mammalian)	0.04	1 (ft) except swine	The Codex MRL proposal is based on the maximum dietary burden calculated by 2013 JMPR based on the OECD feeding tables of 2009, and the new cow feeding study submitted for the current meeting. The CXL for edible offal

Commodity	Codex MRL proposal	EU MRL	Comment
		with 0.15 (ft)	derived on the basis of estimated residues in kidney at the calculated DB The new use on beans/peas does not have an impact on the DB The existing EU MRL is currently assessed for the Article 12 confirmatory data. The same cow feeding study was provided in the EU assessment for the Article 12 confirmatory data gap/EU peer review data gap Considering the different residue definitions, the proposed Codex MRL would not be compatible with the EU legislation
Mammalian fats (except milk fats)	0.01*	1 (ft) except swine 0.15 (ft)	See comments on edible offal (mammalian)
Meat (from mammals other than marine mammals)	0.01*	0.02* (ft)	See comments on edible offal (mammalian)
Milks	0.01*	0.02* (ft)	The CXL proposal is based on the maximum dietary burden calculated for Australian dairy cattle by the 2013 JMPR, and the new cow feeding study submitted for the current meeting. The new use on beans/peas does not have an impact on the DB The existing EU MRL is currently assessed for the Article 12 confirmatory data. The same cow feeding study was submitted for EU assessment. Considering the different residue definitions, the proposed Codex MRL would not be compatible with the EU legislation
Soya bean	W 0.01*	0.03*	See comments on dry beans, subgroup of (includes all commodities in this subgroup)
General comments	The Codex MRL proposals are not compatible with the EU residue definitions; in the residue trials assessed by JMPR the metabolites included in the EU residue definition are not reported/analysed		

CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; PHI: preharvest interval; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; OECD: Organisation for Economic Co-operation and Development; DB: Dietary Burden.

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: The short-term dietary risk assessment was performed using PRIMo rev.3, considering all commodities for which the authorised uses were reported for the Article 12 MRL review and for which the MRL proposal was enforced in the Regulation (EU) No 1146/2014 The crops for which no uses were reported under Article 12 MRL review were excluded from the calculation. The Codex MRL proposal for dry beans and soya beans was included for an indicative calculation, noting that the RD of JMPR does not cover the metabolites included in the EU	**RA assumptions:** The long-term dietary risk assessment was performed using PRIMo rev.3, considering all commodities for which the authorised uses were reported for the Article 12 MRL review and for which the MRL proposal was enforced in the Regulation (EU) No 1146/2014 The crops for which no uses were reported under Article 12 MRL review were excluded from the calculation The Codex MRL proposal for dry beans and soya beans was included for an indicative calculation, noting that the RD of JMPR does not cover	**Specific comments:** The occurrence of 6-hydroxy and 8-hydroxy bentazone was not investigated by the JMPR. The exposure assessment was performed for the parent bentazone only The ARfD set by the JMPR for bentazone is lower (0.05 mg/kg bw) than the value established in the EU (1 mg/kg bw)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RD The EU ARfD was used for the calculation	the metabolites included in the EU RD The EU ADI was used	
Results: No short-term exposure concern was identified	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for a maximum of 3% of the ADI	**Results:** Long-term exposure: 1% of the ADI Short-term exposure: 0% of the ARfD

RA: risk assessment; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; RD: residue definition; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

5.8. Abamectin (177) R

5.8.1. Background information

Table 33: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) No 2017/438[(a)]
EFSA conclusion	Yes, see comments	EFSA (2008b) (acaricide use) EFSA (2016d) (nematicide use) EFSA conclusions ongoing (AIR IV)
MRL review	Yes, see comments	EFSA (2014h)
MRL applications	Yes, see comments	EFSA (2015l) (various crop) EFSA (2017k) (banana) EFSA (2018g) (citrus fruits) Celery and fennel (ongoing, currently on clock-stop) Confirmatory data Art. 12 and Art 10 application on a number of crops (certain nuts, pomefruit, berries, papaya, radish, leafy vegetables, legume vegetables) (ongoing)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: Toxic for reproduction cat. 2 EU Peer Review proposal for CMR: Toxic for reproduction cat. 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): no conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): 2017/438/EU: Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance abamectin. OJ L 67, 14.3.2017, p. 67–69.
(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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.001 mg/kg bw per day	JMPR (2015)	0.0025 mg/kg bw per day	EFSA (2008b); European Commission (2008) (18- and 53-week dog study, UF 100)	No
ARfD	0.003 mg/kg bw	JMPR (2015)	0.005 mg/kg bw	EFSA (2008b); European Commission (2008) (acute neurotoxicity rat, UF 100)	No
Conclusion/ comment	The toxicological reference values derived by JMPR are lower than the ones derived at EU level. It is noted that the ADI/ARfD of JMPR applies also to the 8,9-Z-isomer and the 24-hydroxymethyl metabolite of abamectin The developmental neurotoxicity study in rats was not peer reviewed by EFSA (2008b). EFSA would consider appropriate to use this study as a point of departure for setting the ADI. The use of the dog studies for setting the ARfD would be also consider appropriate since the effects described by JMPR were observed during the first week of treatment Regarding metabolites, EFSA (2008b) also concluded that 8,9-*Z*-isomer showed a similar profile to abamectin. EFSA (2008b) did not discuss the toxicological profile of 24-hydroxymethyl metabolite of abamectin; however, being a major rat metabolite as described by JMPR, EFSA would support the view that it could be considered covered by parent and then the reference values of abamectin would apply to this metabolite				

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

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	Avermectin B1a	EU Reg. 2018/1514: Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9-isomer of avermectin B1a, expressed as avermectin B1a)	No
	Animal products	Avermectin B1a The residue is fat soluble	EU Reg. 2018/1514: Avermectin B1a (except honey; for honey, see plant RD) The residue is fat soluble	Yes
RD-RA	Plant products	Avermectin B1a	Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)	No
	Animal products	Avermectin B1a	Abamectin (sum of avermectin B1a and avermectin B1b, expressed as avermectin B1a)	No
Conclusion/ comments	**Plant commodities:** The residue definitions set for enforcement and risk assessment by JMPR and at EU level in plant commodities are not comparable In the EU, the residue definitions are more comprehensive. Beside the minor abamectin component avermectin B1b (≤ 20% of abamectin mixture), the photodegradate (8,9-*Z*-isomer, identified also as delta-8,9-isomer or NOA427011) of avermectin B1a was included, since it is found in plant metabolism studies in concentrations three times higher than avermectin B1a. The three compounds can be determined with the enforcement analytical method simultaneously. In addition, the formation of the photodegradate during the sample analysis cannot be excluded as well Overall, the enforcement residue definitions established by JMPR and at EU level are not compatible			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal commodities: The residue definition set for enforcement by JMPR and at EU level are comparable. NB: The residue definition for enforcement reported in EU Reg. 2018/1514 was taken over from the legislation on veterinary medicinal products (marker substance avermectin B1a). The current uses of abamectin as pesticide does not lead to residues in animal products. Both assessments concluded that residues in products of animal origin are fat soluble			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

5.8.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Blackberries	0.05 (W)		The previous CXL was withdrawn. It will be covered by the proposed CXL for the subgroup of cane barriers
Cane berries, subgroup of includes all commodities in this subgroup)	**0.2**	0.08 (blackberries, raspberries) 0.01* (dewberries, other cane berries)	Critical GAP: USA, 2 × 0.0213 kg/ha, interval 7 days, PHI 7 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: Trials conducted on blackberry and raspberry, all with 3 instead of 2 applications. Based on decline trials results, JMPR concluded that number of applications do not had an impact on the final residue concentrations of avermectin B1a. Information on the magnitude and the decline behaviour of avermectin B1b and of the delta-8,9-isomer of avermectin B1a in cane berries not reported. The Codex MRL proposal refers to avermectin B1a residues only and would cover blackberries, raspberries and dewberries Conclusion: The proposed Codex MRL for cane fruits is not acceptable because residue definitions for enforcement are not compatible
Chives, dried	0.08	–	Critical GAP: not reported in the summary report Number of trials: 1 Sufficiently supported by data: No Specific comments/observations: PF of 5 refers to avermectin B1a residues only. It is noted that in the EU the MRL is set for the fresh product, but not for dried chives
Dried grape (= currants, raisins and sultanas)	0.1		Critical GAP: information assessed by JECFA in 2015 Number of trials: 3 Sufficiently supported by data: Yes Specific comments/observations: median PF of 2.8 refers to avermectin B1a residues only. It is noted that in the EU the MRL is set for the fresh product, but not for dried grapes
Grape juice	0.05	–	Critical GAP: information assessed by JECFA in 2015 Number of trials: 3 Sufficiently supported by data: Yes Specific comments/observations: best estimate of 1.4 refers to avermectin B1a residues only. It is noted that in the EU the MRL is set for the fresh product, but not for grape juice
Grapes	**0.03**	0.01* (table grapes, wine grapes)	Critical GAP: Brazil, 2 × 0.0108 kg/ha, interval 7 days, PHI 7 days Number of trials: 6 Sufficiently supported by data: No

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: all trials overdosed (0.0144 or 0.018 kg/ha) and with higher number of applications (3-5), proportionally scaled to the GAP rate (scaling factor: 0.75 or 0.60). Based on decline trials results, JMPR concluded that number of applications does not have an impact on the final residue concentrations of avermectin B1a. Information on the magnitude and the decline behaviour of avermectin B1b and of the delta-8,9-isomer of avermectin B1a in crops not reported in the JMPR report. Considering the decline (half-lives of abamectin in grape were 2.1–3.7 days), the higher number of applications is unlikely to affect significantly the final residues at harvest Grapes are major crop both for JMPR and EU and a minimum of 8 trials is required. The Codex MRL proposal refers to avermectin B1a residues only Conclusion: The proposed Codex MRL for grapes is not acceptable because (1) number of trials not sufficient to derive an MRL proposal; (2) residue definitions for enforcement are not compatible; and (3) the proportionality approach should not be applied when more than one parameter is deviating from critical GAP (3)
Green onions, subgroup of (includes all commodities in this subgroup)	**0.01**	0.01* (spring/green/ welsh onion) 0.01* (leeks) 2 (Chives, leaves and bulbs)	Critical GAP: USA, 2 × 0.0213 kg/ha, interval 7 days, PHI 7 days Number of trials: 6 trials in spring onions; additional 3 trials in chives (not used to calculate the MR proposal) Sufficiently supported by data: Yes Specific comments/observations: all trials on spring onions conducted with 4 instead of 2 applications. Based on two decline trials on onions, JMPR concluded that number of applications do not had an impact on the final residue concentrations of avermectin B1a. Information on the magnitude and the decline behaviour of avermectin B1b and of the delta-8,9-isomer of avermectin B1a in spring onions not reported. The Codex MRL proposal refers to avermectin B1a residues only Conclusion: The proposed Codex MRL may be acceptable, despite the incompatibility of the residue definitions, considering the level of the MRL. The proposed Codex MRL would also cover leeks. See also general comments
Herbs, subgroup of, except mint	0.015	2 (herbs and edible flowers, except celery leaves) 0.09 (ft) (celery leaves)	Critical GAP: USA, 2 × 0.0213 kg/ha, interval 7 days, PHI 14 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Trial on basil (3) and mint (2) with 3 instead of 2 applications. For the extrapolation to the whole group (which includes mint in the basil subgroup), a minimum of 6 trials would be required in the EU. However, for JMPR, 5 trials are sufficient. None of the trials designed as decline. Based on decline trials results from other crops, JMPR concluded that number of applications do not had an impact on the final residue concentrations of avermectin B1a. Information on the magnitude and the decline behaviour of avermectin B1b and of the delta-8,9-isomer of avermectin B1a in herbs not reported The Codex MRL proposal refers to avermectin B1a residues only

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL for herbs and edible flowers is not acceptable because the residue definitions are not compatible
Leek	0.005 (W)		The previous CXL was withdrawn. It will be covered by the proposed CXL for the Subgroup of green onions
Orange oil	0.1	–	Critical GAP: not reported in the summary report Number of trials: 3 Sufficiently supported by data: Yes Specific comments/observations: median PF 5.5 refers to avermectin B1a residues only. It is noted that in the EU the MRL is set for the fresh product, but not for orange oil
Pineapple	0.002*	0.01*	Critical GAP: USA, 2 × 0.0261 kg/ha, interval 7 days, PHI 112 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: Residues of avermectin B1a < LOQ of 0.002 mg/kg in all 6 trials. Number of trials is in line with JMPR rules The Codex MRL proposal refers to avermectin B1a residues only, but avermectin B1b and of the delta-8,9-isomer of avermectin B1a are not expected to be found in the edible part of the fruit at the long PHI of the cGAP Conclusion: The proposed Codex MRL is acceptable, despite the incompatibility of the residue definitions, considering the level of the MRL. See also general comments
Raspberries, Red, Black	0.05 (W)		The previous CXL was withdrawn. It will be covered by the proposed CXL for the Subgroup of cane barriers
Soya bean (dry)	0.002*	0.01*	Critical GAP: USA, 2 × 0.0213 kg/ha (foliar application), interval 6 days, PHI 28 days Number of trials: 19 Sufficiently supported by data: Yes Specific comments/observations: Trails conducted with a seed treatment followed by 2 foliar applications with residues of avermectin B1a < LOQ of 0.002 mg/kg. The Codex MRL proposal refers to avermectin B1a residues only, but avermectin B1b and of the delta-8,9 isomer of avermectin B1a are not expected to be found in the seed at the long PHI of the cGAP Conclusion: The proposed Codex MRL is acceptable, despite the incompatibility of the residue definitions, considering the level of the MRL. See also general comments
Succulent beans without pods, subgroup of (includes all commodities in this subgroup)	0.002*	0.01* (beans w/out pod)	Critical GAP: USA, 2 × 0.0213 kg/ha, interval 6 days, PHI 7 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: All trials on beans w/out pods with 3 or 4 instead of 2 applications with residues of avermectin B1a < 0.002 mg/kg. Based on decline trials results from other crops, JMPR concluded that number of applications do not had an impact on the final residue concentrations of avermectin B1a. Information on the magnitude and the decline behaviour of avermectin B1b and of the delta-8,9 isomer of avermectin B1a in beans not reported. The Codex MRL proposal refers to avermectin B1a residues only

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is acceptable, despite the incompatibility of the residue definitions, considering the level of the MRL. See also general comments
Sweet corns	0.002*	0.01*	Critical GAP: USA, 2 × 0.0213 kg/ha, interval 7 days, PHI 7 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: GAP-compliant trials with residues of avermectin B1a < LOQ of 0.002 mg/kg. Information on the magnitude of avermectin B1b and of the delta-8,9 isomer of avermectin B1a in sweet corns not reported. The Codex MRL proposal refers to avermectin B1a residues only Conclusion: The proposed Codex MRL is acceptable, despite the incompatibility of the residue definitions, considering the level of the MRL. See also general comments
General comments	Overall, the residue definitions for plant products derived at EU level and by JMPR are not compatible Risk managers to discuss whether this is a sufficient reason: to make a reservation for all crops or whether a reservation is only justified for crops with MRL proposals higher than the existing EU MRL or a reservation is appropriate only for crops with MRL proposals > LOQ		

CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; PHI: preharvest interval; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue limit; PF: processing factor; JECFA: Joint FAO/WHO Expert Committee on Food Additives; LOQ: limit of quantification

*: Indicates that the input value is proposed at the limit of quantification. Ft: Under the MRL review, some information on residue trials were missing and were requested as confirmatory data. The assessment of the data submitted by the manufacturer in response to the identified data gaps is currently ongoing.

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: An indicative short-term dietary risk assessment was performed with the products of plant origin for which Codex proposed higher MRLs compared to the existing EU MRLs. The HRs derived for raw agricultural commodities by JMPR refer to the avermectin B1a component only and were used if higher in absolute value (cane fruits, grapes) compared to the HRs derived based on the EU use according with the EU residue definition for risk assessment The risk assessment is indicative because information on the residue concentration in accordance with the EU risk assessment residue definition is not available for the crops assessed by JMPR The EU ARfD was used	**RA assumptions:** An indicative long-term risk assessment was performed with the products of plant origin for which Codex proposed higher MRLs compared to the existing EU MRLs, and the existing MRL values in Reg 396/2005 The STMRs derived for raw agricultural commodities by JMPR refer to the avermectin B1a component only and were used if higher in absolute value (grapes) compared to the STMRs derived based on the EU use according with the EU residue definition for risk assessment. A conversion factor for risk assessment of 1.25 was used for the MRLs on products of animal origin set in the regulation above the LOQ The risk assessment is indicative because information on the residue concentration in accordance with the EU risk assessment residue definition is not available for the crops assessed by JMPR The EU ADI was used	**Specific comments:** Consumer exposure considering residues of avermectin B1a only

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: The consumer risk assessment is indicative No short-term exposure concern was identified (maximum 24% of the ARfD for blackberries)	**Results:** The consumer risk assessment is indicative No long-term exposure concern was identified (maximum 74% of the ADI)	**Results:** Long-term exposure: 1-6% of the JMPR ADI Short-term exposure: Max. 40% of the JMPR ARfD

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

5.9. Fenpyroximate (193) R

5.9.1. Background information

Table 38: Background information

		Comments, references
Type of JMPR evaluation	Follow-up evaluation	First evaluation of the crops under assessment in 2017 JMPR; due to intake concerns in dried tomatoes, Codex MRL proposal was not advanced
RMS	AT	
Approval status	Approved	Commission Directive 2008/107/EC[(a)] (approval) Commission Regulation (EU) 2016/183[(b)] (renewal)
EFSA conclusion	Yes, see comments	EFSA (2008c) EFSA (2013j) (amendment approval and confirmatory data) EFSA conclusion ongoing (AIR IV)
MRL review	Yes, see comments	EFSA (2015c)
MRL applications	Yes, see comments	Art. 10 celery (currently on clock-stop additional data request)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	No concluded	Harmonised classification and labelling for CMR – Annex VI: no classification ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(c)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): 2008/107/EC: Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances. OJ L 316, 26.11.2008, p. 4–11.
(b): 2016/187/EC: Commission Implementing Regulation (EU) 2016/183 of 11 February 2016 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest (Text with EEA relevance). OJ L 37, 12.2.2016, p. 44–55.
(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.

5.9.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.01 mg/kg bw per day	JMPR (2017) Rat, 2-year study	0.01 mg/kg bw per day	EFSA (2013j) Rat, 2-year study	Yes
ARfD	0.01 mg/kg bw		0.02 mg/kg bw		No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
		JMPR (2017) Dog, 1-day and 13-week studies		EFSA (2013j) Dog, 1- and 5-day study	
Conclusion/ comment	For the derivation of the ADI, the JMPR considered the NOAEL of 1 mg/kg bw per day in the 2-year rat study, applying an uncertainty factor (UF) of 100. The same derivation was adopted at EU level In 2017, the JMPR withdrew the ARfD of 0.02 mg/kg bw from 2008 and established an ARfD of 0.01 mg/kg bw on the basis of the LOAEL of 2 mg/kg bw for the induction of diarrhoea seen in a newly submitted single bolus gavage study and 13-week study of toxicity in dogs. A safety factor of 200 was used since no NOAEL was identified In the EU assessment, an ARfD of 0.02 mg/kg bw was established in 2008 on the same basis as conclusion reached by the JMPR in 2007 (1- and 5-day toxicity study in dogs presenting a NOAEL of 2 mg/kg bw per day for the occurrence of diarrhoea, applying an UF of 100) It appears that the JMPR had access to a new acute toxicity study in dogs in 2017 resulting in a LOAEL at 2 mg/kg bw The RMS informed EFSA that for the renewal of fenpyroximate an additional single dose study in dogs has been submitted, which was not available for the first approval. In this study, dogs showed diarrhoea already after acute exposure to 2 mg/kg bw. No NOAEL could be determined and the LOAEL of the study is set at 2 mg/kg bw. The RMS will propose to lower the ARfD from 0.02 mg/kg bw to 0.01 mg/kg bw, on the basis of the LOAEL of 2 mg/kg bw from the single oral dose study in dogs and application of a uncertainty factor of 200 (for LOAEL) For the metabolites, the JMPR concluded that M-1, M-3, M-5, M-21, M-22 and Fen-OH would be covered by the reference values of the parent compound since these metabolites were also detected in rats at significant levels During the EU evaluation, the metabolites M-1 and M-12 were concluded of equal or lower acute toxicity than the parent compound				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; LOAEL: lowest observed adverse effect level; RMS: rapporteur Member State.

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	Fenpyroximate	EU Reg. 2019/552: Fenpyroximate Peer review (2013l): Fenpyroximate (fruit crops, pulses and oilseeds, only)	Yes
	Animal products	Sum of fenpyroximate, 2-hydroxymethyl-2-propyl (*E*)-4-[(1,3-dimethyl-5- phenoxypyrazol-4-yl)-methylenaminooxymethyl]benzoate (Fen-OH), and (*E*)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl) methyleneaminooxymethyl]benzoic acid (M-3), expressed as fenpyroximate The residue is fat soluble	EU Reg. 2019/552: Fenpyroximate for all animal products, except liver and kidney of ruminants: Liver and kidney of ruminants: metabolite M-3 Peer review (2013l): Metabolite M-3 expressed as fenpyroximate The residue is fat soluble	No
RD-RA	Plant products	Sum of parent fenpyroximate and *tert*-butyl (*Z*)-α-(1,3- dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-*p*-toluate	(EFSA, 2015c) Sum of fenpyroximate and its *Z*-isomer, expressed as	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		(its *Z*-isomer M-1), expressed as fenpyroximate	fenpyroximate (fruit crops, pulses and oilseeds, only)	
	Animal products	Sum of fenpyroximate, 2-hydroxymethyl-2-propyl (*E*)-4-[(1,3-dimethyl-5- phenoxypyrazol-4-yl)-methylenaminooxymethyl]benzoate (Fen-OH), and (*E*)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl) methyleneaminooxymethyl]benzoic acid (M-3), expressed as fenpyroximate	(EFSA, 2015c) Sum of fenpyroximate, Fen-OH, M-3 and their *Z*-isomers (M-1), expressed as fenpyroximate	No
Conclusion/ comments	**Plant:** Residue definitions for enforcement and risk assessment in plant commodities are comparable. Additional metabolism studies with fenpyroximate following foliar application to citrus, apples, grapes, snaps beans, cotton and Swiss chard were evaluated by the JMPR. These studies allowed deriving a general residue definition **Animal:** RD enf: Fen-OH is not included in the residue definition for enforcement established at EU level. However, according to the results of the metabolism and livestock-feeding studies, at the calculated dietary burden, residues in livestock consist mainly of metabolite M-3 (liver and kidney) and fenpyroximate (fat). Therefore, the difference in the residue definitions for enforcement in animal commodities can be considered as minor RD-RA: In 2018, JMPR revised the definition for risk assessment considering that M-5 and its conjugates were only detected in liver and kidney and only below or equal to 10% TRR. Thus, these metabolites were excluded In the EU residue definition, the *Z*-isomers of parent fenpyroximate, Fen-OH and M-3 are also included in the residue definition. JMPR considered not necessary to include them in the residue definition since there was no evidence in the goat metabolism study of significant levels of *Z*-isomers The process on the renewal of the approval is currently ongoing; the RMS informed EFSA that the RD enf animal might be revised (M-3 expressed as fenpyroximate)			

RD: residue definition; RA: risk assessment; RMS: rapporteur Member State; TRR: total radioactive residues.

5.9.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Cherry tomato	**W 0.3**	0.2 (ft) (tomato)	The previous MRL is replaced by the MRL proposal for tomatoes, subgroup
Edible offal (mammalian)	**0.5**	0.09 except swine with 0.01*	Max dietary burden: 3.503 mg/kg DM (Australian diet after refinement excluding bean forage) The feeding study covered the max DB Sufficiently supported by data: Yes Specific comments/observations: MRL proposal reflects the residue definition of JMPR which is different than the EU RD Conclusion: The proposed Codex MRL is not fully compatible with the EU residue definition
Mammalian fats (except milk fats)	**0.1**	0.01*	Max dietary burden: 3.503 mg/kg DM (Australia diet after refinement excluding bean forage) Number of trials: 1 feeding study with highest dose level (10 ppm) covering the max DB Sufficiently supported by data: Yes Specific comments/observations: MRL proposal reflects the residue definition of JMPR which is different than the EU RD. HR in fat is 0.089 mg/kg; thus, a MRL proposal of 0.09 mg/kg should be enough

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is not fully compatible with the EU residue definition
Meat (from mammals other than marine mammals)	**0.1(fat)**	0.01*	Since the residue definition is fat soluble, according to the Codex rules, an MRL proposal was derived for fat only Considering the result of the feeding study assessed by JMPR, the existing EU MRL for muscle may not be sufficient, since at the expected dietary burden, the maximum residues measured in muscle are 0.02 mg/kg
Milks	0.01	0.01*	Max dietary burden: 3.503 mg/kg DM (Australia diet after refinement excluding bean forage) 1 feeding study with highest dose level (10 ppm) covering the max DB Sufficiently supported by data: Yes Specific comments/observations: See comments on residue definitions Conclusion: The proposed Codex MRL is acceptable, despite the difference in the RD, considering the level
Tomato	**W 0.3**		The previous MRL is replaced by the MRL proposal for tomatoes, subgroup
Tomatoes, subgroup of (includes all commodities in this subgroup)	**0.3**	0.2 (ft) (tomato)	Critical GAP: 2 × 117 g a.i./ha; PHI 1 day Number of trials: 19 trials on tomatoes conducted in the USA Sufficiently supported by data: Yes Specific comments/observations: As residues in cherry tomato is normally higher than that in tomato, the Meeting estimated a maximum residue level, STMR and HR of 0.3, 0.10 and 0.17 mg/kg, respectively, for cherry tomato and tomato Conclusion: The proposed Codex MRL is acceptable
General comments	Considering that the JMPR residue definition for animal products (enforcement) is more comprehensive than the EU residue definition, the proposed MRLs for animal commodities may be slightly higher than required according to the EU residue definition. However, it is not expected that this difference has a major impact on the MRL The RMS informed EFSA that in the framework of the renewal of the approval for fenpyroximate some EU MRLs will be modified, but since the EU MRL assessment is not related to crops/commodities assessed by JMPR, the future modification of existing EU MRLs does not affect the EU position for CCPR		

MRL: maximum residue limit; DM: dry matter; RD: residue definition; HR: highest residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GAP: Good Agricultural Practice; STMR: supervised trials median residue; RMS: rapporteur Member State; DB: Dietary Burden.
*: Indicates that the input value 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: The short-term dietary risk assessment was performed for all commodities for which uses were assessed in the Art. 12 review, including HR/STMR values derived by JMPR for tomatoes and animal commodities The risk assessment for animal commodities is indicative since the EU RD covers the *Z*-isomers which are not included in the JMPR risk assessment values The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015c) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for tomatoes and animal commodities The risk assessment for animal commodities is indicative since the EU RD covers the *Z*-isomers which are not included in the JMPR risk assessment values	**Specific comments and Results:** The Meeting concluded that the exceedance of the ARfD identified by JMPR in 2017 based on residues in dried tomatoes is now unlikely since a consumption figure was recently amended. For tomatoes (including dried tomatoes), the IESTI represents 2–20% of the ARfD for the general population and 5–60% for children. The Meeting concluded that the acute dietary exposure to residues of fenpyroximate in food commodities in the subgroup of tomatoes when used in

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: For the Codex MRL proposals no short-term exposure concern was identified (maximum for tomatoes 49% of EU ARfD)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 25% of the ADI	ways that have been considered by the JMPR, is unlikely to present a public health concern

RA: risk assessment; HR: highest residue; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; ARfD: acute reference dose RD: residue definition; ADI: acceptable daily intake; IESTI: international estimated of short-term intake.

5.10. Kresoxim-methyl (199) R,T

5.10.1. Background information

Table 43: Background information

		Comments, references
Type of JMPR evaluation	Periodic review	
RMS	SE	
Approval status	Renewal of the approval	Commission Implementing Regulation (EU) No 810/2011[(a)]
EFSA conclusion	Yes, see comments	EFSA (2010c)
MRL review	Yes, see comments	EFSA (2014b)
MRL applications	Yes, see comments	EFSA (2015m) (leeks) EFSA (2018s) Confirmatory data assessment following Art. 12
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification for CMR – Annex VI: Carcinogen Cat. 2 EU Peer Review proposal for CMR: Carcinogen. Cat. 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(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.
(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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.3 mg/kg bw per day	JMPR (2018) (2-year chronic toxicity and carcinogenicity study in rats)	0.4 mg/kg bw per day	EFSA (2010c) (2-yr oral rat with a uncertainty factor of 100) European Commission (2014)	No
ARfD	Unnecessary	JMPR (2018)	Not allocated	Not necessary	Yes
Conclusion/ comment	The ADI in the EU and JMPR are based on a 2-year rat studies. Whereas in the EU assessment the point of departure was the NOAEL for systemic toxicity of 36 mg/kg bw per day, JMPR derived a benchmark dose for a 10% response ($BMDL_{10}$) for liver tumours in female rats of 29.1 mg/kg bw				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	per day. The use of a BMD is an alternative approach to the NOAEL that it is also considered acceptable and give a very similar value that the NOAEL. During the peer review, it was considered unlikely that metabolites BF 490-1, BF 490-2 and BF 490-9 are more toxic than kresoxim-methyl, and therefore the reference values of the parent are applicable in case a consumer risk assessment is needed				

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

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	Kresoxim-methyl	EU Reg. 2016/486: Kresoxim-methyl	Yes
	Animal products	Sum of 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) expressed as kresoxim-methyl The residue is not fat soluble	EU Reg. 2016/486: Milk: 490M9, expressed as kresoxim-methyl Other animal products: 490M1, expressed as kresoxim-methyl The residue is not fat soluble	No
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): 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-[(2-methylphenoxy)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): Sum of metabolites BF 490-1, BF 490-2 (490M2) and BF 490-9 (490M9), expressed as parent Peer-review (EFSA, 2010c): Ruminant matrices, milk: Sum of BF 490-1 (490M1), BF 490-2 (490M2) and BF 490-9 (490M9); No residue definition is proposed for poultry matrices	No
Conclusion/comments		The metabolite codes BF 490-1, BF 490-2 and BF 490-9, which were at some occasions used in the EU residue definitions, correspond to metabolites with codes 490M1, 490M2 and 490M9 (used by JMPR), respectively The EU risk assessment RD for plant products is different from the one of JMPR. JMPR did not include metabolite BF 490-2. BF 490-2 (490M2) was found as a major residue in the metabolism studies in grapes (unconjugated and conjugated, up to 14% TRR), but was not present in significant amounts in apple, wheat and sugar beet metabolism studies. BF 490-2 was found at significant levels in field residue trials (fruit crops). Thus, the risk assessment values derived by JMPR are		

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		likely to underestimate the exposure RD for processed products: Considering that kresoxim-methyl is significantly hydrolysed to kresoxim acid (BF 490-1), the RD for processed products (enforcement) was defined as the sum of kresoxim-methyl and BF 490-1, expressed as kresoxim; RD for risk assessment of processed products: sum of kresoxim-methyl, BF 490-1 (490M1), BF 490-2 (490M2) and BF 490-9 (490M9), free and conjugated, expressed as parent (EFSA, 2014b) For animal products, the residue definitions are not fully compatible. The EU residue definition for enforcement is restricted to the most relevant metabolite for the respective matrix, while JMPR established a comprehensive residue definition that covers all metabolites observed in animal products Thus, the residue definitions for animal products proposed by JMPR differ from the current EU residue definitions, both for enforcement and for risk assessment		

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRR: total radioactive residues.

5.10.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Barley	W 0.1	0.1	JMPR proposes to withdraw the MRL for barley and replace it with an MRL of 0.15 for the whole barley grain subgroup (see below)
Barley, subgroup of (includes all commodities in this subgroup)	**0.15**	0.1 (barley and oats) 0.01* (buckwheat)	Critical GAP: UK, 2 foliar applications at 125 g a.i./ha (RTI not given) PHI not needed (last application up to BBCH 59) Number of trials: 10 The proposed Codex MRL would be also applicable to oats and buckwheat. At EU level, the extrapolation of residue trials in barley to buckwheat would not be acceptable Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Beet root	0.05*	0.05*	Critical GAP: German GAP for beet root in Germany allows two foliar applications of kresoxim-methyl at 125 g a.i./ha with a RTI of 10 days and a PHI of 28 days Number of trials: 10 trials in sugar beet Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Cucumber	W 0.05*	0.05*	JMPR proposes to replace existing CXL by a MRL for the whole group of fruiting vegetables (including edible and non-edible peel) (see below)
Currants, Black, Red, White	0.9	0.9	Critical GAP: UK, 3 × 100 g a.i./ha, RTI of 10 days, PHI of 14 days, foliar use Number of trials: 5 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Dried grapes (= currants, raisins and sultanas)	**3**	1	PF of 1.6, based on 3 trials. It is noted that in the EU MRLs are set only for the fresh product, but not for dried grapes
Edible offal (Mammalian)	0.05	0.05*	JMPR calculated the dietary burden, including the feed items sufficiently supported by data. Maximum dietary burden in Australia 3.2 ppm Feeding studies (7, 21 and 77 ppm) on lactating cow, corrected for maximum dietary burden of 3.2 ppm

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The maximum residue expected in kidney is 0.02 mg/kg. The proposed Codex MRL was derived by rounding up; according to EFSA a lower MRL of 0.02 mg/kg would be sufficient. Further discussion with MS recommended, whether the proposed MRL is acceptable, taking into account that the residue definitions are not fully compatible
Eggs	0.02*	0.05*	JMPR calculated the dietary burden, including the feed items sufficiently supported by data. Maximum dietary burden in EU (0.33 ppm) No feeding study available; MRL proposal were derived from metabolism study which is about 500 times overdosed compared to the expected maximum dietary burden Conclusion: The proposed Codex MRL is acceptable; a MRL of 0.01 mg/kg would be sufficient. Considering the proposed level of the MRL, the difference of the residue definition may not be relevant
Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)	**0.5**	cucurbits with edible peel: 0.05*; cucurbits with inedible peel: 0.3	Critical GAP: Cucumber, summer squash, melon: USA: 4 × 168 g a.i./ha, RTI 7 days, PHI 0 days Number of trials: 8 cucumber, 5 summer squash and 5 melon Sufficiently supported by data: No; according to EFSA's interpretation of the JMPR rules, additional 3 trials on melons (major crop in Codex classification) would be required to derive a group MRL for cucurbits Specific comments/observations: JMPR proposes an MRL for the whole group of fruiting vegetables (including edible and non-edible peel). According to the agreement on extrapolation, trials on cucumbers and summer squash and/or gourd and melon would be required. Since this condition is not fulfilled, and the number of trials for melons is not sufficient, it would be possible to derive a group MRL for the subgroup fruiting vegetables, cucurbits- cucumber and summer squashes (0.3 mg/kg) For melons, the number of trials is insufficient (melons are classified as major crop) Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Garlic	0.01	0.3	Critical GAP: BR GAP: 4 × 70 g a.i./ha, RTI 10 days, 7 days PHI Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: The existing EU MRL is based on a more critical GAP (DE, NL, 3 × 200 g/ha, 7 days PHI) Conclusion: The proposed Codex MRL is acceptable
Grape	**1.5**	1	Critical GAP: USA, 4 × 224 g a.i./ha, RTI 7 days, PHI of 14 days, foliar Number of trials: 18 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Grapefruit	W 0.5	0.5	The existing CXL was proposed to be withdrawn since insufficient data were provided to support the GAPs reported to JMPR The existing EU MRL was derived from the CXL; in the framework of the MRL review, no EU GAPs were reported for citrus Conclusion: It is recommended to discuss with MS to revise the existing EU MRL
Leek	10	10	Critical GAP: NL GAP: 3 × 375 g a.i./ha, RTI 10 days, PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: The existing EU MRL was derived from the same data and on the basis of the same cGAP Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Mammalian fats (except milk fats)	0.02*	0.05*	See comments on edible offal (mammalian) At the expected maximum dietary burden, the residues in fat were < 0.01 mg/kg Conclusion: The proposed Codex MRL is acceptable. Considering the proposed level of the MRL, the difference of the residue definition may not be relevant
Mango	**0.1**	0.01*	Critical GAP: BR, 2 × 120 g a.i./ha, RTI 15 days, PHI 7 days Number of trials: 5 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Meat (from mammals other than marine mammals)	0.02*	0.05*	See comments on edible offal (mammalian) At the expected maximum dietary burden, the residues in muscle were < 0.01 mg/kg Conclusion: The proposed Codex MRL is acceptable; a MRL of 0.01 mg/kg would be sufficient. Considering the proposed level of the MRL, the difference of the residue definition may not be relevant
Milks	0.02*	0.01*	See comments on edible offal (mammalian) At the expected maximum dietary burden, the residues in milk were < 0.002 mg/kg Conclusion: The proposed Codex MRL is acceptable; a MRL of 0.01 mg/kg would be sufficient. Considering the proposed level of the MRL, the difference of the residue definition may not be relevant
Olive oil, Virgin	1		The MRL proposal for olive oil was derived from the MRL proposal for olives, applying a processing factor of 4.5 (derived from one processing study) and rounding up to the next MRL class. It is noted that in the EU MRLs are set only for the fresh product, but not for olive oil
Olives for oil production	0.2	0.2	Critical GAP: France, 3 × 100 g a.i./ha, PHI of 30 days Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: Since olives for oil production are a major crop (in the EU and in Codex), at least 8 trials are required. In the MR review, the same cGAP was assessed which was sufficiently supported by data. Thus, additional trials were available in the EU which were not made available to JMPR Conclusion: To discuss with RMS, whether the proposed Codex MRL is acceptable
Oranges, Sweet, Sour (including Orange-like hybrids):several cultivars	W0.5	0.5	The existing CXL was proposed to be withdrawn since insufficient data were provided to support the GAPs reported to JMPR The existing EU MRL was derived from the CXL; in the framework of the MRL review, no EU GAPs were reported for citrus Conclusion: It is recommended to discuss with MS to revise the existing EU MRL
Peach	**1.5**	0.01*	Critical GAP: Japan, 3 × 25 g a.i./hL, PHI of 1 day, RTI not specified, foliar use. Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: According to Codex classification, peaches are a crop for which at least 5 trials are required to derive a MRL proposal. At EU level, 8 trials would be required Conclusion: The proposed Codex MRL is acceptable
Pecan nuts	0.05*	0.05*	Critical GAP: USA, 3 × 168 g a.i./ha, RTI 14 days, PHI 45 days. Number of trials: 6 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
			Specific comments/observations: The same USA cGAP and trial data had been considered in the framework of the EU MRL review; the same MRL was derived as proposed by JMPR Conclusion: The proposed Codex MRL is acceptable
Peppers, sweet	0.3	0.8	Critical GAP: BR, 4 × 100 g a.i./ha, RTI 10 days, PHI 3 days. Number of trials: 4 according GAP + 2 overdosed proportionality corrected (0.4 scaling factor) Sufficiently supported by data: No Specific comments/observations: For peppers, at least 8 trials would be required, since it is classified as a major crop in Codex The EU MRL was derived from a more critical GAP (ES, CY, 4 × 250 g/ha, 3 d PHI). The EU GAP was not reported the JMPR Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Furthermore it should be highlighted that data for a more critical EU GAP are available that have not been notified to JMPR
Pome fruits	W0.2 (apple)	0.2	The existing CXL was proposed to be withdrawn since insufficient data were provided to support the GAPs reported to JMPR The existing EU MRL was derived from the CXL; in the framework of the MRL review, EU GAPs were reported for pome fruits (apples, pears, quinces, medlar, loquat) and an MRL of 0.15 mg/kg was proposed for the EU uses Conclusion: It is recommended to discuss with MS to ask for maintaining the current CXL under the 4-years rule and to encourage the applicant to provide the EU GAPs and EU residue data to JMPR for evaluation
Poultry fats	0.02*	0.05*	See comments on eggs
Poultry meat	0.02*	0.05*	See comments on eggs
Poultry, Edible offal of	0.02*	0.05*	See comments on eggs
Straw and fodder (dry) of cereal grains	3(DM)	–	United Kingdom GAP for wheat and barley: Number of trials: 22 Sufficiently supported by data: Yes It is noted that in the EU no MRLs are set for feed products
Sugar beet	0.05*	0.05*	Critical GAP: Germany, 1 × 125 g a.i./ha, PHI of 28 days. Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Table olives	0.2	0.2	Critical GAP: France 3 × 100 g a.i./ha, PHI 30 days Number of trials: 5 Sufficiently supported by data: No Specific comments/observations: According to JMPR criteria, table olives are considered a major crop and therefore at least 8 trials would be required. In the EU, table olives are a minor crop and therefore 5 trials would be sufficient Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that at EU level the number of trials would be sufficient and that the MRL proposal relates to a EU GAP
Turnip	0.05*	0.05*	MRL proposal was derived by extrapolation from sugar beets (see comments on sugar beets) Conclusion: The proposed Codex MRL is acceptable
Wheat	W 0.05*	0.08	JMPR proposed to withdraw the MRL of 0.05 for wheat and replace it with an MRL of 0.05 applicable to the whole subgroup of wheat grain (see below)

Commodity	Codex MRL proposal	EU MRL	Comment
Wheat, subgroup of (includes all commodities in this subgroup)	0.05	0.08	Critical GAP: UK: GAP for wheat, rye and triticale, 2 × 125 g a.i./ha, no PHI (last application up to BBCH 65) Number of trials: 12 Sufficiently supported by data: Yes The proposed Codex MRL would be also applicable to rye. Conclusion: The proposed Codex MRL is acceptable
General comments	–		

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; PHI: preharvest interval; BBCH: growth stages of mono- and dicotyledonous plants; PF: processing factor; RTI: re-treatment interval.
*: Indicates that the input value is proposed at the limit of quantification.

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: Not relevant since no ARfD was allocated	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2018s) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for crops where the Codex MRL proposal is higher than the EU MRL The risk assessment is indicative, because for the proposed Codex MRLs the STMRs do not cover BF 490-2; instead BF 490-1 is covered which is not included in the EU RD The risk assessment was performed with the EU ADI	**Specific comments**
Results: –	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 1% of the ADI Among the crops under consideration. wine grapes were identified as the main contributor, accounting for up to 0.23% of the ADI	**Results:** Long-term exposure: 0–0.4% of the ADI

RA: risk assessment; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; RD: residue definition; ADI: acceptable daily intake.

5.11. Pyriproxyfen (200) R

5.11.1. Background information

Table 48: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	NL	
Approval status	Approved	Commission Directive 2008/69/EC[(a)]
EFSA conclusion	Yes, see comments	EFSA (2009b) Renewal ongoing
MRL review	Ongoing	On hold pending renewal process
MRL applications	Yes, see comments	EFSA (2013i) (stone fruits and tea) EFSA (2015e) (bananas)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B	Not met	Harmonised classification and labelling for CMR – Annex VI: no entry for CMR EU Peer Review proposal: none for CMR

		Comments, references
• Toxic for reproduction cat. 1A or 1B • Endocrine disrupter (ED) potential		ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): negative

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

5.11.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.1 mg/kg bw per day	JMPR (1999) (1-year dog, safety factor 100)	0.1 mg/kg bw per day	EFSA (2009b) (1-year, dog with a safety factor of 100) Confirmed in European Commission (2010b)	Yes
ARfD	Unnecessary	JMPR (1999)	Was not set, not appropriate	EFSA (2009b) confirmed in European Commission (2010b)	Yes
Conclusion/ comment	In the framework of the EU peer review for renewal (expert meeting January, 2019), the TRV for pyriproxyfen were proposed to be changed: – the ADI was lowered to 0.05 mg/kg bw per day based on the LOAEL of 16.4 mg/kg bw per day from the 18-month mouse study and applying an uncertainty factor of 300; – an ARfD was set at 1 mg/kg bw based on an increased incidence of malformations in the developmental rabbit study, applying an uncertainty factor of 100. In relationship with the ADI, the EU peer review reconsidered the assessment of the 18-month mouse study in which the decreased survival in males at the low dose was considered to be an adverse effect. JMPR has not considered this dose-related increase in mortality rate relevant at the low-dose level In relationship with the ARfD, the EU peer review reconsidered the assessment of one developmental rabbit study in which multiple visceral malformations in one animal and single visceral malformation in 2 animals at 300 mg/kg bw per day were concluded to be treatment-related and adverse, leading to a lower NOAEL of 100 mg/kg bw per day				

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

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	Pyriproxyfen	EU Reg. 2016/1902: Pyriproxyfen	Yes
	Animal products	Pyriproxyfen The residue is fat soluble	EU Reg. 2016/1902: Pyriproxyfen Peer-review (EFSA, 2009b): Not relevant for notified uses. (No significant intake; no accumulation of residues in edible	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			animal products expected) The residue is fat soluble	
RD-RA	Plant products	Pyriproxyfen	Peer-review (EFSA, 2009b): Pyriproxyfen	Yes
	Animal products	Pyriproxyfen	Peer-review (EFSA, 2009b): Not relevant for notified uses. (No significant intake; no accumulation of residues in edible animal products expected)	Yes
Conclusion/ comments	In the framework of the peer-review process, no investigation of the residues of pyriproxyfen in animal origin commodities has been performed (representative use on tomatoes and cotton seed – residues in cotton seeds at LOQ) In succeeding MRL applications, no need for setting MRLs in animal commodities was identified (intended uses on fruits and tea) JMPR 1999 assessed animal commodities and derived the residue definition for animal products which covers only parent compound Residue definitions for plant commodities identical			

RD: residue definition; RA: risk assessment; LOQ: limit of quantification; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

5.11.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Cucumbers	0.04	0.1	Critical GAP: Europe (Italy, Greece, France, Spain) 2 × 0.12 kg a.s./ha, RTI 14 days, PHI 3 days Number of trials: 8 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Eggplant	0.6	1	Critical GAP: Europe (Italy), 2 × 0.12, RTI 14 days, PHI 3 days Number of trials: 8 trials in peppers were used to derive MRL proposal by extrapolation At EU level an extrapolation from peppers to eggplants would not be appropriate. However, this extrapolation was proposed by JMPR in the general considerations Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Gherkins	0.04	0.1	Critical GAP: Europe (Italy, Greece, France, Spain) 2 × 0.12 kg a.s./ha, RTI 14 days, PHI 3 days Number of trials: 8 residue trials in cucumbers, used to derive MRL proposal by extrapolation Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Melons, except Watermelon	**0.07**	0.05*	Critical GAP: USA, 2 × 0.075 kg a.i./ha, RTI 14 days, PHI 7 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: Since melons are classified as a major crop in Codex and at EU level, a minimum of 8 residue trials would be required Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the fact that 1 additional trial would be required
Papaya	**0.3**	0.05*	Critical GAP: Philippines, 2 × 0.1 kg a.s./ha, RTI 14 days, PHI 1 day Number of trials: 6 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Peppers	0.6	1	Critical GAP: Europe (Italy), 2 × 0.12, RTI 14 days, PHI 3 days Number of trials: 8 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Peppers chili, dried	**6**		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, but not for processed chili peppers
Pineapple	0.01	0.05*	Critical GAP: USA, 2 × 0.06 kg a.s./ha, RTI 21 days, PHI 1 day Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: Although for pineapples a minimum of 8 residue trials would be required in the EU, according to Codex classification, 5 trials are sufficient to derive a Codex MRL Conclusion: The proposed Codex MRL is acceptable
Summer squash	0.04	0.05*	Critical GAP: Europe (Italy, Greece, France, Spain) 2x 0.12 kg a.s./ ha, RTI 14 days, PHI 3 days Number of trials: 8 residue trials in cucumbers, used to derive MRL proposal by extrapolation Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Tomato	0.4	1	Critical GAP: Italy, 2 × 0.12 kg a.s./ha, RTI 14 days, PHI 3 days Number of trials: 8 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Canned pepper			PF (best estimate or mean): 0.08 Individual processing factors: 0.08, 0.08 Number of studies to derive the PF: 2
Canned tomato			PF (best estimate or mean): < 0.18 Individual processing factors: < 0.17, < 0.2 Number of studies to derive the PF: 2
Tomato Juice			PF (best estimate or mean): < 0.18 Individual processing factors: < 0.17, < 0.2 Number of studies to derive the PF: 2
Tomato Puree			PF (best estimate or mean): 1.2 Individual processing factors: 0.67, 1.8 Number of studies to derive the PF: 2
Ketchup			PF (best estimate or mean):0.67 Individual processing factors: 0.67 Number of studies to derive the PF would not be sufficient in the EU
General comments	According to the information reported, pyriproxyfen is stable under standard hydrolysis studies. This was also concluded by EFSA in the framework of the peer-review process Additionally, the processing factors for tomato processed commodities in the JMPR report are the same that the ones assessed by EFSA during the peer-review process		

GAP: Good Agricultural Practice; PHI: preharvest interval; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; a.s.: active substance; PF: processing factor; RTI: re-treatment interval.
*: Indicates that the input value 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: An indicative short-term exposure calculation	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015e) was updated using the approach as outlined in	**Specific comments:** No further comments

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
was performed for papayas and melons, using the proposed ARfD derived in the ongoing renewal process. For the other commodities no acute risk assessment was performed, since the existing EU MRL is higher than the proposed Codex MRLs	Section 'Assessment', including the STMR values derived by JMPR for papaya since it is the only commodity for which the CXL proposal is higher than the EU MRL Tentatively the Codex MRL proposal for melons has been considered in the exposure calculation; although the MRL proposal is not fully compliant with EU policies The MRL proposal for dried peppers was not included in the PRIMO since consumption data for dried peppers is not included in the PRIMO rev 3.1. For the commodities where the MRL was lower than the existing MRL, the STMR values derived from the EU uses were used for exposure calculations Since the review of the EU existing uses is pending of finalisation, EU MRLs established by Reg (EU). 2016/1902 were used for exposure calculations in chronic exposure scenario The calculations were performed with the currently approved ADI and in an indicative calculation with the ADI proposal derived recently in the framework of the renewal	
Results: No exceedance of the recently proposed ARfD (1 mg/kg bw) was identified for papaya and melons (exposure calculation with the proposed MRL) For other crops, no calculations were considered necessary	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 15% of the ADI, being the diet for Dutch toddlers the most critical one The contribution of the proposed Codex is considered low, accounting for less than 0.1% With the proposed new ADI, no intake concern is expected either	**Results:** Long-term exposure: 15% of the ADI Review of existing EU uses ongoing. Exposure estimates must be considered in tentative basis Short-term exposure: not calculate since no ARfD is available

RA: risk assessment; ARfD: acute reference dose; MRL: maximum residue level; CXL: Codex Maximum Residue Limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake.

5.12. Cyprodinil (207) R

5.12.1. Background information

Table 53: Background information

		Comments, references
Type of JMPR evaluation	Follow-up evaluation due to concern form	In 2018 CCPR, the EU made a reservation: – regarding the MRL proposals for post-harvest uses, calculated according to a wrong methodology leading to MRLs higher than necessary (CF*3 Mean); – regarding the cyprodinil metabolism data that did not reflect post-harvest applications (studies with foliar applications only) 2018 JMPR revised the MRL proposals for post-harvest uses (mean + 4SD); regarding the metabolism studies JMPR concluded that the residue definitions are also appropriate for post-harvest uses, considering that less extensive metabolism is expected
RMS	FR	
Approval status	Approved	Commission Implementing Regulation (EU) No 678/2014[(a)]
EFSA conclusion	Yes, see comments	EFSA (2006a) EFSA conclusions ongoing (AIR III)

		Comments, references
MRL review	Yes, see comments	EFSA (2013h)
MRL applications	Yes, see comments	EFSA (2015g) (celery) EFSA (2019e) (Florence fennel)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification for CMR – Annex VI: none EU peer review proposal for CMR: none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not finalised

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

5.12.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.03 mg/kg bw per day	JMPR (2003) (2-year rat, SF 100)	0.03 mg/kg bw per day	EFSA (2006a) (2-year rat, UF 100)	Yes
ARfD	Unnecessary	JMPR (2003)	Not necessary/[(b)]	EFSA (2006a)	see comments under footnote (b)
Conclusion/ comment	[(a)] Confirmed for the renewal of the approval (not yet finalised in an EFSA conclusion) [(b)] In the French RAR, an ARfD was proposed (1.5 mg/kg bw); in the expert meeting, the ARfD was agreed to be set at a level of 2 mg/kg bw. The conclusion is not yet published During the EU peer review meeting (September 2018), several metabolites were discussed: – **NOA422054**: not concluded since genotoxicity potential could not be concluded due to lack of data and repeat-dose toxicity had not been investigated – **CGA232449**: not concluded since genotoxicity potential could not be concluded due to lack of data and repeat-dose toxicity had not been investigated – **CGA249287**: ADI is 0.08 mg/kg bw per day based on the 90-day rat study, applying an uncertainty factor of 1000 to take into account the limited data package. – **CGA263208**: ADI is 0.02 mg/kg bw per day based on the 90-day rat study, applying an uncertainty factor of 1000 to take into account the limited data package. – **CGA304075**: the ADI and ARfD of cyprodinil can be applied to this major rat metabolite. – **CGA304076**: not concluded since genotoxicity potential could not be concluded due to lack of data and repeat-dose toxicity had not been investigated – **I13C** and **I13b**: not concluded since genotoxicity potential could not be concluded due to lack of data and repeat-dose toxicity had not been investigated – **CGA275535**: no genotoxic potential, use of TTC value (Cramer class III) was proposed – **CGA321915**: no genotoxic potential, use of TTC value (Cramer class III) was proposed For the TTC approach, the sum of the exposure for all non-toxicological characterised metabolite should be compared to the TTC. It is noted that currently the TTC is not used at European Level for assessing residues metabolites since there is no agreement yet on how this tool should be used			

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; RAR: renewal assessment report; TTC: threshold of toxicological concern.

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	Cyprodinil The residue is fat soluble	EU Reg. 2019/552: Cyprodinil	Yes
	Animal products		EU Reg. 2019/552: Milk: Cyprodinil (sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil) Other animal products: Cyprodinil (sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil) The residue is fat soluble	No
RD-RA	Plant products	Cyprodinil	Cyprodinil	Yes
	Animal products		Milk: Cyprodinil (sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil) Other animal products: Cyprodinil (sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil)	No
Conclusion/ comments	Plant products: The residue definition for enforcement and risk assessment derived by the JMPR and at EU level is identical Animal products: For animal products, the EU residue definition for enforcement and risk assessment is wider as comprises the metabolite CGA304075 (4-[(4-cyclopropyl-6-methylpyrimidin-2-yl)amino)]phenol) for tissues. In the framework of the MRL review also, the conjugates of CGA 304075 were also included in the residue definition for milk. However, this difference is of no relevance for the current MRL proposal The RMS informed EFSA that in the framework of the renewal of the approval, residue definitions may be revised (e.g. residue definition for animal products (risk assessment and enforcement): sum of cyprodinil and CGA 304075 (free form and glucuronide), expressed as cyprodinil; residue definition for plant products (risk assessment) – fruit crops: cyprodinil and CGA232449 (free and conjugated) (pending submission of toxicity data on CGA232449 to be decided whether a separate residue definition for the metabolite would be more appropriate); cereals: cyprodinil by default (cereal) (provisional); rotational crops: NOA422054 (free and conjugated) (provisional) However, since the modification of new residue definitions has not yet been implemented, the ongoing discussions at EU level do not affect the conclusions on Codex MRL proposals			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.

5.12.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Pomegranate	**5Po**	0.02*	Critical GAP: US post-harvest (dip/drench) GAP, 1 × 54 g/hL before storage + 1 × 54 g/hL before trading, PHI 0 days Number of trials: 1 storage facility, 4 trials at different dates Sufficiently supported by data: to be discussed with MS. AT EU level the trials would not be considered independent Specific comments/observations: Residue data were submitted for the 2017 JMPR, who proposed a CXL of 10 mg/kg The EU made a reservation due to uncertainty over the relevance of the foliar metabolism study used to support the post-harvest treatments and because for post-harvest use the MRL should be

Commodity	Codex MRL proposal	EU MRL	Comment
			calculated using mean + 4SD instead of CF × 3 Mean. The CXL proposal for pomegranates was maintained at step 4 2018 JMPR derived a revised MRL proposal calculated as proposed by the EU (5 mg/kg instead of 10 mg/kg) 2018 JMPR confirmed the metabolism studies are appropriate since post-harvest treatment is unlikely to result in a more extensive metabolism than observed from foliar treatments As regards question on the independence of residue trials and the lack of clarity of the GAP raised last year by the EU (see EFSA report on preparing EU position for the 50th CCPR), new information was not provided to 2018 JMPR A risk management decision to be taken on the acceptability of the CXL proposal The proposed Codex MRL is supported by the RMS
General comments	Further comments on residue trials can be found in EFSA, 2018n (50th Session of CCPR), and JMPR 2018 Report (FAO, 2017)		

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

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: Currently, no ARfD is established formally for cyprodinil. Thus, an acute risk assessment would not be required However, considering that in the framework of the renewal of the approval ARfD values were proposed/ agreed in expert meetings, EFSA calculated an indicative acute risk assessment using the ARfD proposed in the RAR/agreed in the expert meeting (scenario 1/scenario 2) for pomegranates	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2019e), which was performed with EFSA PRIMo rev.3 was updated, including the CXL proposal of 5 mg/kg for pomegranates	**Specific comments:**
Results: No short-term exposure concern was identified; exposure to residues from pomegranate accounted for a maximum of 12.5% of the ARfD (scenario 1); 9% of the ARfD (scenario 2)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 55% of the ADI The contribution of pomegranate to the exposure was 1.7% of the ADI	**Results:** Long-term exposure: 8–70% of the ADI Acute exposure not necessary (ARfD not set)

RA: risk assessment; ARfD: acute reference dose; RAR: renewal assessment report; CXL: Codex Maximum Residue Limit; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake.

5.13. Pyraclostrobin (210) R,T

5.13.1. Background information

Table 58: Background information

		Comments, references
Type of JMPR evaluation	New use	Additional toxicological studies on parent and a number of metabolites were provided and assessed by JMPR; a new ARfD has been derived and the previous ARfD has been withdrawn
RMS	DE	
Approval status	Approved	Commission Directive 2004/30/EC[(a)] amended by Commission Regulation (EU) No 823/2012[(b)] and Commission Implementing Regulation (EU) 2016/2016[(c)]
EFSA conclusion	Ongoing	Peer-review ongoing
MRL review	Yes, see comments	EFSA (2011e)
MRL applications	Yes, see comments	EFSA (2011a) (oranges) EFSA (2012b) (crops) EFSA (2013a) (Jerusalem artichokes) EFSA (2014d) (chicory roots) EFSA (2014i) (swedes and turnips) EFSA (2016g) (beet leaves) EFSA (2017a) (various crops) EFSA (2018p) (confirmatory data) EFSA (2018q) (rice) EFSA (2018r) (various crops & import tolerances) EFSA (2018u) (soya bean)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: none EU Peer Review proposal for CMR: Toxic for reproduction cat. 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(d)]): not finalised

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

(a): Commission Directive 2004/30/EC of 10 March 2004 amending Council Directive 91/414/EEC to include benzoic acid, flazasulfuron and pyraclostrobin as active substances. OJ L 77, 13.3.2004, p. 50–53.

(b): Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide. OJ L 250, 15.9.2012, p. 13–14.

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

(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.

5.13.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
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 Report 2019 (FAO, 2018), 90-day and 1-year feeding studies in dogs, uncertainty factor of 8	0.03 mg/kg bw	European Commission (2004) (Rabbit developmental study, with an uncertainty factor of 100	No
Conclusion/ comment	JMPR assessment: The previous ARfD of 0.05 mg/kg bw (JMPR, 2003), based on embryo and fetal toxicity in a developmental toxicity study in rabbits (SF 100), has been withdrawn. 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-yr 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 Additional toxicological information on certain metabolites/degradation products was assessed by JMPR, e.g. degradation product formed under high temperature conditions, (see olives for oil production). The conclusions were: – for **500M04**: No evidence of genotoxicity, oral LD_{50} > 2,000 mg/kg bw (rats), 3-month oral toxicity study NOAEL 100 mg/kg bw per day (rats), – for **500M49**: no evidence of genotoxicity *in vitro* EU peer review assessment: Peer review for the renewal is ongoing – The same toxicological reference values established during the first assessment (European Commission, 2004) are proposed by the RMS. To be discussed at the experts' meeting The agreed ARfD of the first peer review was based on maternal toxicity (body weight losses) during the initial phase of the treatment in the rabbit developmental toxicity studies				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; LD_{50}: lethal dose, median; RMS: rapporteur Member State.

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	Pyraclostrobin	EU Reg. 2017/1016: Pyraclostrobin	Yes
	Animal products	Pyraclostrobin The residue is fat soluble	EU Reg. 2017/1016: Pyraclostrobin The residue is fat soluble	Yes
RD-RA	Plant products	Pyraclostrobin	Art.12 (EFSA, 2011e): Pyraclostrobin	Yes
	Animal products	Pyraclostrobin	Art.12 (EFSA, 2011e): Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1*H*-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazole	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
			moiety, expressed as pyraclostrobin Conversion factor of 4 for ruminant liver Conversion factor of 6.8 for milk	
Conclusion/ comments	The residue definitions for enforcement are compatible The difference in the residue definition for animal products (risk assessment) can be compensated by using the conversion factors derived in the EU			

RD: residue definition; RA: risk assessment.

5.13.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Apple	W 0.5		The existing CXL is proposed to be withdrawn and replaced by the group MRL for pome fruit
Asparagus	0.01*	0.02*	Critical GAP: Germany, 2 foliar applications (BBCH > 69, after harvest of spears) at 0.1 kg a.i./ha, PHI not specified Number of trials: 7 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Avocado	**0.2**	0.02*	Critical GAP: USA, 2 foliar applications of 0.166 kg a.i./ha, PHI 0 days Number of trials: 4 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Beans with pods, subgroup of, except common beans (poroto)	0.3	0.6	Critical GAP: USA (for whole subgroup of beans with pods), 3 applications of 0.16 kg a.i./ha, PHI 7 days Number of trials: 7 trials with 2 × 0.23 kg/ha, PHI 7 days; trials were scaled (scaling factor 0.7). Scaling was considered acceptable, considering that decline trials demonstrated that the first application does not significantly contribute to the final residues Sufficiently supported by data: Yes Specific comments/observations: EFSA proposes to set only one MRL for beans with pods, subgroup (VP2060) at the level of 0.6 mg/kg derived from the EU trials (see below) Conclusion: The proposed Codex MRL is acceptable. However, preferably only one MRL for the whole subgroup should be set. The proposed Codex MRL of 0.6 mg/kg derived for common beans (poroto) would be the appropriate level for the code VP 2060
Broad beans without pods (succulent seeds)	0.01	0.02*	Critical GAP: France, 2 applications of 0.1 kg a.i./ha and PHI 7 days Number of trials: 8 (all at 0.01*) Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL refers to the code VP 0523 (*Vicia faba*). A separate MRL proposal of 0.3 mg/kg was derived for *Phaseolus* beans (common beans without pods (succulent seeds, VP 2845) Conclusion: The proposed Codex MRL is acceptable. See comments below on common beans without pods (succulent seeds)
Cacao beans	0.01	0.1*	Critical GAP: Brazil, 3 foliar applications of 0.2 kg a.i./ha, PHI 14 days Number of trials: 3 Sufficiently supported by data: No Specific comments/observations: Cocoa beans are a crop of consumption category 2; thus at least 4 trials would be required. At EU level 8 trials would be requested (if residues < LOQ, 4 trials would be sufficient) Conclusion: It is recommended to discuss with MS whether the proposed

Commodity	Codex MRL proposal	EU MRL	Comment
			Codex MRL is acceptable, considering the level of the MRL proposal. If the proposed Codex MRL is found acceptable, it should be proposed to label it with an asterisk, indicating that the MRL is at the LOQ
Carrot	W 0.5		Existing CXL to be replaced by new MRL for Root and tuber vegetables
Celery	1.5	1.5	Critical GAP: Poland, 2 foliar applications at 0.1 kg a.i./ha, PHI 14 days Number of trials: 9 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Common bean (poroto)	0.6	0.6	Critical GAP: France, 2 applications of 0.1 kg a.i./ha, PHI 7 days Number of trials: 17 trials Sufficiently supported by data: Yes Specific comments/observations: NEU and SEU residue trials were merged. The proposed Codex MRL refers to code VP2060 (*Vicia faba*) Conclusion: The proposed Codex MRL is acceptable. However, it would be preferable to set the MRL for the whole subgroup of beans with pods (VP2060) at this level. (See also comments on Beans with pods, subgroup of, except common beans (poroto)
Common beans (succulent seeds)	0.3	0.02*	Critical GAP: France, 2 applications of 0.1 kg a.i./ha and PHI = 7 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL refers to the code VP 2845 (*Phaseolus vulgaris*). A separate MRL proposal of 0.01 mg/kg was derived for fava beans (Broad beans without pods (succulent seeds, VP 0523) Conclusion: Since in the EU, the two commodities (*Phaseolus* beans and fava beans (codex code VP) are covered by the same code (260020), the MRL proposal of 0.3 mg/kg would be relevant. It is sufficiently supported by data and therefore acceptable. See also comments on broad beans without pods (succulent seeds)
Dry peas, Subgroup of (includes all commodities in this subgroup)	0.3	0.3 dry peas, 0.5 dry lentils	Critical GAP: Canada, 2 foliar applications at 0.15 kg a.i./ha, PHI 30 days Number of trials: 9 overdose trials, scaled down (scaling factor of 0.67) and 5 trials in lentils Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL covers peas and lentils Conclusion: The proposed Codex MRL is acceptable
Edible offal (Mammalian)	**0.05**	0.05*	See comments on meat (for mammals other than marine mammals)
Lettuce, head	**40**	2	Critical GAP: in USA of 0.23 kg a.i./ha and PHI = 0 Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: Although at EU level, 8 trials would be required, the number of trials is acceptable at Codex level, since lettuce is not a major crop 2006 JMPR assessed the same trials, but due to an exceedance of the ARfD, the MRL proposal was not advanced. With the higher ARfD value established by 2018 JMPR, the proposed MRL did not exceed the TRV JMPR withdrew previous recommendation of MRL of 2 mg/kg in head lettuce Conclusion: The proposed Codex MRL is not acceptable because of acute intake concerns identified at EU level (see below)
Meat (from mammals	**0.5 (fat)**	0.05*	No feeding study was available. The MRL proposals were derived from metabolism study in lactating goats. At EU level, MRLs are set for

Commodity	Codex MRL proposal	EU MRL	Comment
other than marine mammals)			muscle. The residue concentration in muscle at the calculated dietary burden of 29 ppm (EU diet) is expected to be between 0.05 and 0.06 mg/kg Conclusion: The proposed Codex MRL is not acceptable; considering the significant dietary burden, a feeding study would be required to derive a reliable MRL for animal products
Mammalian fats (except milk fats)	**0.5**	0.05*	See comments on meat (for mammals other than marine mammals)
Mango	**0.6**	0.05	Critical GAP: Brazil, 4 foliar applications at 0.133 kg a.i./ha, PHI 7 days Number of trials: 6 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Milks	**0.03**	0.01*	See comments on meat (for mammals other than marine mammals)
Olives for oil production	0.01*	0.02*	Critical GAP: See table olives is proposed Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Extrapolation from table olives. In the framework of an Art. 10 application, additional toxicological data were requested for certain degradation products formed under conditions representative for frying and raffination (metabolite 500M04 and 500M49). The application was withdrawn JMPR assessed data on 500M04 and 500M49 (see comments on toxicological reference values) Conclusion: The proposed Codex MRL is acceptable
Olive oil, Virgin	**0.07**		Proposed PF for olive oil: 6.24 It is noted that in the EU MRLs are set only for unprocessed olives, but not for olive oil
Peas with pods, Subgroup of	0.3	0.6	Critical GAP: Spain, 2 applications of 0.1 kg a.i./ha, PHI 7 days Number of trials: 5 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Peas (pods and succulent= immature seeds)	0.02* W		The existing CXL is replaced by the new proposal for the subgroup of peas with pods
Passion fruit	**0.2**	0.02*	Critical GAP: Brazil, 4 foliar applications of 0.15 kg a.i./ha, PHI 7 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
Pineapple	**0.3**	0.02*	Critical GAP: Brazil, 4 foliar applications of 0.15 kg a.i./ha, PHI 3 days. Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: In 4 residue trials, residue concentration was measured in the pulp as well. At EU level, a peeling factor of 0.27 was proposed Conclusion: The proposed Codex MRL is acceptable
Pome fruits	**0.7**	0.5 pome fruit, 0.02* kaki, 3 azaroles	Critical GAP: Germany, 4 foliar application of 0.1 kg a.i./ha, PHI 7 days Number of trials: 33 (25 in apples + 8 in pears) Sufficiently supported by data: Yes Specific comments/observations: extrapolation to the entire pome fruits group (apples, pears, quinces, medlar and loquats/Japanese medlars) but also including azarole (0154070) and kaki (Japanese persimmon) (0131060)

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is sufficiently supported by data, but since an acute intake concern was identified for apples, pears and kakis the proposed MRL is not acceptable
Potato	0.02* W		The existing CXL is replaced with the new proposal for tuberous and corm vegetables
Radish	0.5 W		The existing CXL is replaced with the new proposal for root vegetables
Rice	1.5		Critical GAP: see rice, husked
Rice, Husked	**0.09**	0.02	Critical GAP: Indonesia, 2 foliar applications at 0.1 kg a.i./ha and BBCH 65 (last application at mid-flowering), PHI not defined. Number of trials: 16 (results for brown rice) Sufficiently supported by data: Yes Specific comments/observations: Residue trials conducted in Asian countries, Italy and Spain. Conclusion: The proposed Codex MRL is acceptable
Rice, Polished	0.03		PF 0.2 (from brown rice to polished rice); no MRL is set for polished rice in the EU
Rice straw and fodder, dry	5(dw)		No MRLs are set for feed items in the EU
Root vegetables, Subgroup of this subgroup)	0.5	0.06 for Jerusalem artichokes, 0.09 for swedes and turnips; 0.1 beetroots, parsley roots, salsifies; 0.3 for parsnips and horseradish; 0.5 for radishes, carrots, celeriacs	Critical GAP: in USA for 3 foliar applications at 0.234 kg a.i./ha and PHI 0 Number of trials: 5 trials in radishes (minor crop), 6 in carrots (major crop) Sufficiently supported by data: No Specific comments/observations: The number of trials is not sufficient to derive a MRL proposal for the subgroup of root vegetables; furthermore, following the agreed policy on also trials on sugar beet or beetroots would be required Conclusion: The proposed Codex MRL is not acceptable because the residue trials are not sufficient
Spinach	**1.5**	0.6	Critical GAP: Germany and Italy, 2 applications of 0.1 kg a.i./ha, PHI 14 days, RTI 8 days (DE), 7 days (IT) Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: Trials were conducted in Germany, France and Italy. JMPR merged the NEU and SEU trials to derive the MRL proposal. The EU MRL was derived from residue trials reflecting the NEU use. The trial with the highest residue (0.91 mg/kg) that is driving the MRL calculation was not available in the EU data package. Most likely this result is not correctly reflecting the trial results (the total residue (sum of parent plus metabolite is 0.1 mg/kg, while the parent alone was reported as 0.91 mg/kg; the results at a shorter PHI of 7 days were lower than at PHI 14 days) Conclusion: JMPR should be asked to verify the results for the residue trial leading to the highest result. Most likely the value of 0.91 mg/kg is a typo
Succulent peas without pods Subgroup of (includes all	0.08	0.15 peas 0.02* lentils	Critical GAP: Spain, 2 applications of 0.1 kg a.i./ha, PHI 7 days Number of trials: 16 trials in peas Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL covers also

Commodity	Codex MRL proposal	EU MRL	Comment
commodities of this subgroup)			fresh lentils. At EU level, the residue trials in peas would not be acceptable to set an MRL for lentils Conclusion: The proposed Codex MRL is acceptable
Sugar cane	**0.08**	0.02*	Critical GAP: Brazil, single application in-furrow at 0.133 kg a.i./ha, followed by 5 foliar applications of 0.13 kg a.i./ha with PHI 30 days Number of trials: 4 + 8 overdosed trails (scaled down to match the GAP) Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Table olives	0.01*	0.02*	Critical GAP: Greece, foliar application, 2 × 0.1 kg a.i./ha, last application no later than BBCH 71; PHI not specified Number of trials: 8 Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Tea, Green, Black (black, fermented and dried)	**6**	0.1*	Critical GAP: Japan, 2 applications of 0.003 kg a.i./hL, PHI 7 days Number of trials: 6 overdosed trials, scaled down to match the GAP Sufficiently supported by data: No Specific comments/observations: Tea is a major crop and according to EFSA's understanding 8 trials would be required Conclusion: The proposed Codex MRL is not acceptable because the number of trials is insufficient. To discuss with MS if EFSA'S view is shared
Tuberous and corm vegetables, commodities in this subgroup)	0.02*	0.02*	Critical GAP: USA for 6 foliar applications at 0.22 kg a.i./ha and PHI 3 days Number of trials: 19 trials, probably in potatoes, not specified in which crops the trials were performed Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL covers arrowroots, cassava, potatoes, sweet potatoes, yams Conclusion: The proposed Codex MRL is acceptable
Witloof chicory (leaves/ sprouts)	0.09	0.09	Critical GAP: France, 1 application of 0.42 g a.i./m^2 tray area, PHI 21 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
General comments	–		

CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; PHI: preharvest interval; MRL: maximum residue level; LOQ: limit of quantification; NEU: northern European Union; SEU: southern European Union; TRV: toxicological reference values; PF: processing factor; BBCH: growth stages of mono- and dicotyledonous plants; RTI: re-treatment interval.
*: Indicates that the input value is proposed at the limit of quantification.

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: The short-term dietary risk assessment was performed for all crops under assessment for which Codex MRL proposals were higher than the existing EU MRLs. The calculations were	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2018u) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the	**Specific comments:** New ARfD derived of 0.7

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
performed using PRIMo ver. 3.1 The EU ARfD of 0.03 mg/kg bw was used For animal commodities conversion factors were used for milk and liver to accommodate for the additional metabolites included in the EU residue definition for risk assessment	crops/commodities, for which the proposed Codex MRLs were higher than the existing EU MRLs	
Results: The risk assessment identified potential consumer risks for: Lettuce (2,500% of the ARfD) pears (319% of the ARfD) apples (247.90% of the ARfD) kaki/Japanese (107.07% of the ARfD)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 29% of the ADI The highest contributor is milk	**Results:** Long-term exposure: 1–7% of the ADI Short-term exposure: 0–60% of the ARfD for children to 0–30% for the general population

RA: risk assessment; ARfD: acute reference dose; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake.

5.14. Fludioxonil (211) R

5.14.1. Background information

Table 63: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	FR	Co-RMS: ES
Approval status	Approval process ongoing	Commission Directive 2007/76/EC[(a)] amended by Commission Implementing Regulation (EU) 2018/1262[(b)]
EFSA conclusion	Yes, see comments	EFSA (2007) Renewal ongoing
MRL review	Yes, see comments	EFSA (2011d)
MRL applications	Yes, see comments	EFSA (2016b) Art.10 in fennel (ongoing) Assessment of confirmatory data (ongoing, combined with renewal)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI EU Peer Review proposal for CMR: no proposal for CMR properties ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(c)]): not conducted

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

(a): Commission Directive 2007/76/EC of 20 December 2007 amending Council Directive 91/414/EEC to include fludioxonil, clomazone and prosulfocarb as active substances. OJ L 337, 21.12.2007, p. 100–104.

(b): Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron. OJ L 238, 21.9.2018, p. 62–64.

(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.

5.14.2. 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 (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.4 mg/kg bw per day	JMPR (2004)	0.37 mg/kg bw per day	EFSA (2007) (2-y rat with an uncertainty factor of 100) confirmed in European Commission (2007b)	Yes
ARfD	Unnecessary	JMPR (2004)	Not applicable	Not allocated – not necessary (EFSA, 2007)	Yes
Conclusion/ comment	During the previous peer review at EU level (EFSA, 2007), the ADI was based on the NOAEL of 37 mg/kg bw per day in the 2-year rat study; the same basis than the JMPR in 2004. The differences are because different policy in rounding. During the EU assessment, no assessment was done on whether metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155) could be covered by the parent compound In the framework of the renewal process in the EU, the RMS proposed 0.1 mg/kg bw per day for both the ADI and ARfD, whereas the proposal of the co-RMS was 0.37 mg/kg bw per day for both reference values. (Discussion at Expert meeting foreseen in April 2019). The toxicological profile of metabolites including CGA 192155 will be also discussed during Expert meeting foreseen in April, 2019				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; RMS: rapporteur Member State.

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	Fludioxonil	EU Reg. 2016/1902: Fludioxonil EFSA (2007, 2011d) (Peer-review, Art.12 MRL Review): Fludioxonil	Yes
	Animal products	Fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid and expressed as fludioxonil The residue is fat soluble	EU Reg. 2016/1902: Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid The residue is fat soluble	Yes
RD-RA	Plant products	Fludioxonil	EFSA (2007, 2011d): Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo [1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil	No
	Animal products	Fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid and expressed as fludioxonil	EFSA (2007, 2011d): Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo [1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion/ comments	For cereals (seed treatment), fruits and leafy vegetables, pulses and oilseeds, the conversion factor (CF) of 1 between residue definitions for enforcement and risk assessment was derived which reflects the fact that no significant concentrations of metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety are expected. For root vegetables after foliar application the conversion factor of 2.8 (derived from the metabolism study on spring onions) from enforcement to risk assessment residue definition is proposed (EFSA, 2007, 2011d) For the commodities for which Codex MRLs were proposed by JMPR, the different residue definition is not expected to have a major impact as for root vegetables a CF derived from metabolism studies can be used in risk assessment to account for the presence metabolites measured as CGA 192155 (CF 2.8); for the other commodities similarly as in the MRL review a CF of 1 can be used, assuming that the metabolites is not present in significant concentrations. The dietary risk assessment may need to be reviewed pending the conclusion of the ongoing renewal			

RD: residue definition; RA: risk assessment; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues

5.14.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Avocado	**1.5**	0.4	Critical GAP: Australia post-harvest dip/drench/flood spray application at a rate of 60 g a.i./hL Number of trials: 8 (dip treatment) + 2 (flood spray); trials combined Sufficiently supported by data: Yes Specific comments/observations: JMPR agreed to use the STMR of 0.01 mg/kg derived from the combined residues in the flesh. However, as information is not available on the time of sampling (whether samples analysed after a realistic storage period, allowing for penetration of residues in edible part of the fruit, as fludioxonil is fat soluble) the STMR relevant for the whole fruit was used in the exposure calculation Conclusion: The proposed Codex MRL is acceptable
Blueberries	2	2	Critical GAP: Canada: 3 × 244 g a.i./ha, RTI 7 days, PHI 1 days Number of trials: 8 trials (JMPR, 2004); 2 new trials compliant with the Canadian GAP Sufficiently supported by data: Yes Specific comments/observations: JMPR concluded that the existing CXL derived in 2004 for the US GAP (4 × 250 g a.i./ha PHI: 0 day) covers the Canadian GAP Conclusion: No change to the current Codex MRL is foreseen
Bulb onions, Subgroup of (includes all commodities in this subgroup)	0.5	onions: 0.5 garlic and shallots: 0.02	Critical GAP: US, 4 × 245 g a.i./ha, PHI 7 days Number of trials: 16 (13 assessed by JMPR in 2004) Sufficiently supported by data: Yes Specific comments/observations: JMPR proposed to set a group tolerance which covers also garlic (0220010), and shallots (0220030). It should be verified whether the US GAP applies to the whole group of bulb onions Conclusion: The proposed Codex MRL is acceptable, provided US GAP for the subgroup exists
Cabbages, head	2	2	Critical GAP: US, 4 × 250 g a.i./ha, PHI 7 days. Number of trials: 6 (JMPR 2004) + 5 new trials Sufficiently supported by data: Yes Specific comments/observations: The previous MRL and STMR recommendations were maintained Conclusion: No change necessary

Commodity	Codex MRL proposal	EU MRL	Comment
Carrot	1	1	Critical GAP: EU (DE), 3 × 250 g a.i./ha, RTI and PHI 7 days Number of trials: 15 Sufficiently supported by data: Yes Specific comments/observations: The RTI in the trials were 14 days, but was considered acceptable based on decline studies showing limited degradation. In the EU, a CF of 2.8 is proposed Conclusion: The proposed Codex MRL is acceptable
Celery	**15**	1.5 (stem vegetable)	Critical GAP: USA, 4 × 245 g a.i./ha, RTI 7 days, PHI 0 days Number of trials: 8 (±25% GAP)Sufficiently supported by data: Yes Specific comments/observations: Pending on the setting of the ARfD an acute risk may occur (if ARfD is set at 0.1 mg/kg bw per day; no concern if set at 0.37 mg/kg) Conclusion: The proposed Codex MRL is acceptable
Chick-pea (dry)	0.3	0.4	Critical GAP: Canada, 3 × 244 g a.i./ha foliar; PHI 7 days Number of trials: 7 Sufficiently supported by data: No Specific comments/observations: In the EU food classification, chick peas are classified under peas (dry): 8 trials would be required for peas. However, considering that the EU MRL is higher than the proposed Codex MRL, the lack of 1 study may not be of relevance Conclusion: The proposed Codex MRL is acceptable
Currants, Black, Red, White	**3**	2	Critical GAP: Ireland 3 × 250 g a.i./ha, 10 days interval between 1st and 2nd applications and 28 days interval between 2nd and 3rd application, PHI 7 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Same GAP assessed by EFSA (2011d). In the MRL review, the MRL was based on 9 GAP compliant residue trials on blueberries (0.15; 0.31; 0.31; 0.37) and currants (0.26; 0.6; 0.62; 0.63; 1.44) combined. The trials on currants are the same Conclusion: The proposed Codex MRL is acceptable
Edible offal (Mammalian)	**0.1**	Swine liver, kidney, edible offals: 0.05* Liver, kidney of other species: 0.2 (ft)	Critical GAP: Australian animal burden – dairy cattle (max dietary burden 23 ppm/mean dietary burden 6.4 ppm); since the dietary burden calculation was not presented in Annex 6 of the JMPR report, the calculations cannot be checked Sufficiently supported by data: Yes, a new feeding study was provided that covered the calculated dietary burden Specific comments/observations: In the EU, a livestock feeding study was requested as confirmatory data (deadline 30 January 2016). Confirmatory data assessment currently ongoing Conclusion: The proposed Codex MRL is acceptable
Eggs	0.02	0.05*	Critical GAP: EU, laying hen (maximum dietary burden calculation 1.9 ppm/mean dietary burden 0.86 ppm) Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Green onion, Subgroup of (includes all commodities in this subgroup) VA 2032	**0.8**	Spring onions: 5 Leek: 0.01* Chives: 20	Critical GAP: EU (Italy), 3 × 250 g a.i./ha, RTI 10 days and PHI 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – The MRL proposal would also cover leeks and chives which are classified in the subgroup of green onions Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Guava	**0.5**	0.01*	Critical GAP: USA, 4 × 245 g a.i./ha; RTI 7 days, PHI 0 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Leaves of Brassicaceae, subgroup of (includes all commodities in this subgroup) Subgroup 013B, Brassica leafy vegetable	**15**	0.3 Chinese cabbage: 10 land cress: 20, Kale: 0.01* Broccoli (covering chinese broccoli): 0.7 Rucola: 20	Critical GAP: US, 4 × 240 g a.i./ha, PHI 7 days Number of trials: 9 trials in mustard greens and water cress (assessed in 2004 JMPR) + 1 new trial in mustard greens Sufficiently supported by data: Yes Specific comments/observations: JMPR proposed to extrapolate to the whole subgroup of leaves of Brassicaceae. This crop group covers several crops that are classified differently in the EU food classification (e.g. Chinese cabbage, cress, kale, Chinese broccoli and rucola). It is noted that the higher MRL derived compared to the existing MRL is due to change in the method of calculation (OECD calculator, 2015) This approach is acceptable, however it needs to be confirmed that a US GAP refers to the whole group of Brassica. Based on the preliminary acute exposure calculation if the ARfD will be set at 0.1 mg/kg, a concern is foreseen for kales, broccoli and Chinese cabbage. No concern is expected if the ARfD is set at 0.37 mg/kg bw per day. Conclusion: The proposed Codex MRL is acceptable, provided the US GAP covers the whole group; an acute intake concern may be expected if the ARfD is lowered as proposed by the RMS
Lentils	**0.3**	0.05	Critical GAP: Canada, 3 × 244 g a.i./ha foliar; PHI 7 days Number of trials: 7 on dry peas Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	0.02	swine fat: 0.05* other species: 0.2(ft)	See edible offal (Mammalians); In the EU a metabolism study was requested as confirmatory data Conclusion: The proposed Codex MRL is acceptable
Meat (from mammals other than marine mammals)	0.02(fat)	swine muscle: 0.01* other species: 0.04 (ft)	See edible offal (Mammalians) In the EU, a metabolism study was requested as confirmatory data Conclusion: The proposed Codex MRL is acceptable. The respective MRL for muscle would be 0.01 or 0.02 mg/kg
Milks	**0.04**	0.01*	Critical GAP: Australian animal burden – dairy cattle (maximum dietary burden 23 ppm/mean dietary burden 6.4 ppm) Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Mustard greens	W 10	10	JMPR proposed to withdraw the existing CXL for mustard greens and to replace it with the new MRL for Subgroup of Leaves of Brassicaceae
Onion, bulb	W 0.5	0.5	Existing CXL is proposed to be withdrawn, and replaced by a CXL applicable to the whole subgroup
Pineapple	5Po	7	Critical GAP: USA, one drench treatment and one spray treatment at a rate of 60 g a.i./hL Number of trials: 4 Sufficiently supported by data: To be discussed with MS. Specific comments/observations: According to the JMPR crop classification, at least 5 trials are required for pineapples. However, for the post-harvest use 4 trials may be considered sufficient. In an US import tolerance application, EFSA derived the MRL proposal currently implemented in the EU legislation. In addition, pending on the ARfD to be set an acute risk may occur Conclusion: The proposed Codex MRL may not acceptable if MS

Commodity	Codex MRL proposal	EU MRL	Comment
			agree that the number of trials is insufficient. Nonetheless, in Europe a higher MRL is in place for pineapples
Pomegranate	3Po	3	Critical GAP: USA two post-harvest dip applications at a rate of 36 g a.i./hL Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: The current CXL for fludioxonil is 2 mg/kg. This change in CXL has no implications on the current EU MRL Conclusion: The proposed Codex MRL is acceptable
Poultry fats	0.01*	0.05*	See eggs Conclusion: The proposed Codex MRL is acceptable
Poultry meat	0.01*	0.01*	See eggs Conclusion: The proposed Codex MRL is acceptable. For muscle the corresponding MRL would be 0.01* mg/kg
Poultry, edible offal of	**0.1**	0.05*	See eggs Conclusion: The proposed Codex MRL is acceptable
Soya bean (dry)	**0.2**	0.01*	Critical GAP: Brazil, foliar, 2 × 250 g a.i./ha, RTI 7 days, PHI 30 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Carrots (canned)			JMPR derived a PF of 0.14, based on 4 processing studies
Carrots (cooked)			JMPR derived a PF of 0.12, based on 4 processing studies
Carrots (pasteurised)			JMPR derived a PF of 0.18, based on 4 processing studies
General comments	–		

GAP: Good Agricultural Practice; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue; PHI: preharvest interval; CXL: Codex Maximum Residue Limit; MRL: maximum residue level; CF: conversion factor; OECD: Organisation for Economic Co-operation and Development; RMS: rapporteur Member State; PF: processing factor; RTI: re-treatment interval.
*: Indicates that the input value is proposed at the limit of quantification.

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: The short-term dietary risk assessment was not performed as an EU ARfD was not yet established. Within the scope of the renewal an ARfD will be set. An indicative risk assessment was carried out for the commodities where a new CXL was proposed using both reference values proposed by the RMS and co-RMS (0.1 and 0.37 mg/kg bw per day) Since the EU residue definition for risk assessment in plants is wider, a CF of 2.8 was applied for bulb vegetables to account for the additional metabolites (see comments on residue definition)	**RA assumptions:** The most recent long-term risk assessment (ongoing application for fennel) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the RACs having a higher Codex MRL proposed compared to the existing EU MRLs and using a CF of 2.8 for garlic and shallots The risk assessment is indicative	**Specific comments:**

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified when the ARfD of 0.37 mg/kg bw was used However, if the ARfD proposed by FR will be accepted (ARfD of 0.1 mg/kg bw), short-term intake concerns are expected for kales, broccoli, celery, pineapples, Chinese cabbage, spring onions and pomegranate	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 20% of the existing ADI; if the ADI will be lowered as proposed by FR, the exposure accounts for 75%	**Results:** Long-term exposure: Up to: 6% of the ADI

RA: risk assessment; ARfD: acute reference dose; CXL: Codex Maximum Residue Limit; RMS: rapporteur Member State; CF: conversion factor; STMR: STMR: supervised trials median residue; RAC: raw agricultural commodity; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; bw: body weight; ADI: acceptable daily intake.

5.15. Mandipropamid (231) T/R

5.15.1. Background information

Table 68: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) No 188/2013[(a)]
EFSA conclusion	Yes, see comments	EFSA (2012d)
MRL review	Yes, see comments	EFSA (2018i)
MRL applications	Yes, see comments	EFSA (2018t) (cocoa bean import tolerance) EFSA (2019c) (beetroot, Brussels sprouts, cauliflower, globe artichoke, peas, radish, witloof, Belgian endive)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: no entry for CMR EU Peer review proposal for CMR: none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): Commission Implementing Regulation (EU) No 188/2013 of 5 March 2013 approving the active substance mandipropamid, 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 62, 6.3.2013, 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.

5.15.2. 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 (source, study)	Value	Comments (source, study)	
ADI	0.2 mg/kg bw per day	JMPR (2008)	0.15 mg/kg bw per day	Rat, 2-year with an uncertainty factor of 100	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
				(EFSA, 2012d, 2018i) confirmed in European Commission (2018a)	
ARfD	Unnecessary	JMPR (2008)	Not necessary	(EFSA, 2012d, 2018i) confirmed in European Commission (2018a)	Yes
Conclusion/ comment	The different ADI values derived by JMPR and at EU level are the result of different policy on rounding (same study, same NOAEL) For the metabolite **SYN500003**, more acutely toxic than mandipropamid, JMPR concluded that it was unlikely to be genotoxic based on genotoxicity studies not available for the EU peer review. Nevertheless, both JMPR and EU review concluded that the ADI for mandipropamid is not applicable to the metabolite SYN500003, and no specific ADI or ARfD can be established				

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

5.15.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Mandipropamid	EU Reg. 2015/845: Mandipropamid	Yes
	Animal products	Mandipropamid The residue is not fat soluble	EU Reg. 2015/845: Mandipropamid The residue is not fat soluble	Yes
RD-RA	Plant products	Mandipropamid	Art.12 (EFSA, 2018i): Fruits and leafy vegetables: mandipropamid (any ratio of constituent isomers) Root crops: Sum of mandipropamid and SYN 500003 [tentative, pending on the submission of toxicological information on SYN 500003] Peer-review (EFSA, 2012d): Mandipropamid except for root/tuber crops where the definition is provisionally proposed as 'mandipropamid and SYN 500003', pending the submission of toxicological information on SYN 500003	No for root crops; yes for fruits and leafy vegetables
	Animal products	Mandipropamid	Art.12 (EFSA, 2018i): not required Peer-review (EFSA, 2012d): Mandipropamid	Yes
Conclusion/ comments	The JMPR and EU residue definitions for enforcement and risk assessment for plant and animal commodities are comparable except for the risk assessment residue definition for root/tuber crops, where the EU residue definition is provisionally proposed as 'mandipropamid and SYN 500003', pending the submission of toxicological information on SYN 500003 The JMPR plant risk assessment residue definition, in contrast to the EU definition for root/tuber crops, does not include the plant metabolite SYN 500003 The residue definition for enforcement proposed in the Peer Review and the MRL Review are equivalent to the residue definition set in Regulation (EC) No 396/2005, although they			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	specifically detail that it covers any ratio of constituent isomers The different risk assessment residue definition for root crops (due to the inclusion of SYN 500003), is a relevant issue in the risk assessment only with regard to the Codex MRL proposal for potatoes The RMS informed EFSA that for renewal of the active, the notifier plans to fully address the toxicological properties of metabolite SYN500003			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.

5.15.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Beans with pods, subgroup of (includes all commodities in this subgroup)	**1**	0.01*	Critical GAP: Canada, 4 × 150 g/ha, RTI not reported, PHI 1 days Number of trials: 10 Sufficiently supported by data: Yes Specific comments/observations: Trials on snap beans. The available plant metabolism studies conducted on leafy crops and fruit crops are sufficient to address the metabolic behaviour for the specific use on beans (with pods). Conclusion: The proposed Codex MRL is acceptable
Cacao bean	**0.06**	0.02* (0.06 proposed EU MRL; EFSA, 2018i)	Critical GAP: Cameroon, 6 × 90 g/ha, retreatment interval not reported, PHI 14 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residue trials on cacao beans assessed previously in an EU import tolerance application (EFSA, 2018i). The available plant metabolism studies conducted on leafy crops and fruit crops are sufficient to address the metabolic behaviour for the specific use on cocoa Conclusion: The proposed Codex MRL is acceptable
Edible offal (mammalian)	0.01*	0.02*	The dietary burden was calculated, including cabbage head, grape pomace, potato by-products Since a feeding study is not available, the Codex MRL proposals were derived from the available lactating goat metabolism study Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Eggs	0.01*	0.02*	The dietary burden was calculated, including the cabbage head and potato by-products. No animal feeding studies on poultry are available and Codex MRL proposals were derived for poultry from the poultry metabolism study. The highest dose level covers the max DB Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Mammalian fats (except milk fats)	0.01*	0.02*	See comments on edible offal (mammalian) Conclusion: The proposed Codex MRL is acceptable
Meat (from mammals other than marine mammals)	0.01*	0.02*	See comments on edible offal (mammalian) Conclusion: The proposed Codex MRL is acceptable
Milks	0.01*	0.02*	See comments on edible offal (mammalian) Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Potato	**0.1**	0.01*	Critical GAP: Canada and USA, seed treatment at 1 × 100 g/t seed potato followed by foliar treatment at 3 × 146 g/ha, retreatment interval not reported, PHI 14 days Number of trials: 18 Sufficiently supported by data: Yes Specific comments/observations: The metabolite SYN500003 was identified in potato tubers at levels up to 0.013 mg/kg with an estimated median reside of 0.005 mg/kg for SYN500003. No ADI or ARfD established for the metabolite SYN500003. The JMPR applied the threshold of toxicological concern (TTC) approach for the metabolite SYN500003 (the chronic exposure based on the median residue accounted for 0.027 μg/kg bw; an acute exposure was not calculated by JMPR; in the EU, this approach was not accepted to address the EU data requirements Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Toxicological reference vales (ADI or ARfD) are not available for the metabolite SYN500003 which was identified in potato tubers at levels above 0.01 mg/kg The RMS proposed to accept the proposed Codex MRLs, considering that individual residue levels of the metabolite are expected to be low (in all trials provided levels were below 0.01 mg/kg with the exception of 2, for which residues in potatoes were 0.01 mg/kg and 0.013 mg/kg). The use of TTC concept is according to the RMS acceptable. NL supported this view
Poultry edible offal	0.01*	0.02*	See comments on eggs Conclusion: The proposed Codex MRL is acceptable
Poultry fats	0.01*	0.02*	See comments on eggs Conclusion: The proposed Codex MRL is acceptable
Poultry meat	0.01*	0.02*	See comments on eggs Sufficiently supported by data: Yes Conclusion: The proposed Codex MRL is acceptable
Cocoa butter	–	–	A reduction of residues in cocoa butter occurs and a PF of 0.53 was derived from two processing studies
Cocoa powder	–	–	A reduction of residues in cocoa powder occurs and a PF of 0.48 was derived from two processing studies
General comments	EU MRLs established by Regulation (EU) 2015/845		

GAP: Good Agricultural Practice; PHI: preharvest interval; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ADI: acceptable daily intake; ARfD: acute reference dose; RMS: rapporteur Member State; DB: Dietary Burden; RTI: re-treatment interval.
*: Indicates that the input value is proposed at the limit of quantification.

5.15.5. Consumer risk assessment

Table 72: 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 required for the parent mandipropamid because an acute reference dose (ARfD) was not applicable for the active substance considering the toxicological profile. A short-term dietary risk assessment may be required for the metabolite SYN500003 for the proposed Codex	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2019c) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for beans with pods and cacao beans (mandipropamid only), and potato (sum of mandipropamid and SYN500003). The long-term risk assessment is indicative because a	**Specific comments:** Toxicological reference values (ADI or ARfD) are not available for the metabolite SYN500003. The JMPR. The JMPR applied the threshold of toxicological concern (TTC) approach for the metabolite SYN500003 based on the estimated the chronic exposure for potatoes

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
MRL on potatoes, pending on the toxicological profile of this metabolite	toxicological reference value (ADI) is not available for the metabolite SYN500003 and was performed based on the assumption that SYN500003 is of similar chronic toxicity as the parent mandipropamid. The indicative calculation did not indicate a risk to consumers although the overall risk might be underestimated if the metabolite SYN500003 possesses a higher chronic toxicity than the parent mandipropamid (relevant for uses on root/tuber crops: potatoes, onions and spring onions) The EU ADI for mandipropamid was used The risk assessment was performed disregarding the possible impact of enantiomer ratio due to plant or livestock metabolism	
Results: No short-term dietary risk assessment was performed	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 5% of the ADI (NL toddler). From the commodities under consideration, the contribution to the total exposure was the highest for residues in beans with pods (0.12% of the ADI)	**Results:** Long-term exposure: 0–6% of the ADI No short-term dietary risk assessment was performed

RA: risk assessment; MRL: maximum residue level; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ADI: acceptable daily intake.

5.16. Fluopyram (243) R

5.16.1. Background information

Table 73: Background information

		Comments, references
Type of JMPR evaluation	Follow-up assessment	In 2017 JMPR MRL proposals were derived only for tomatoes; JMPR did not consider it appropriate to derive a MRL proposal for the whole subgroup. Following comments in the CCPR meeting, JMPR reconsidered its policy for extrapolation to the whole subgroup
RMS	DE	
Approval status	Approved	Commission Implementing Regulation (EU) 802/2013[(a)]
EFSA conclusion	Yes, see comments	EFSA (2013b) EFSA (2018a) (confirmatory data)
MRL review	No	Ongoing
MRL applications	Yes, see comments	EFSA (2017j) (purslanes) EFSA (2019d)

		Comments, references
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not met. ED: not concluded	Harmonised classification and labelling for CMR – Annex VI: none EU Peer Review proposal (2013b): R40: Limited evidence of a carcinogenic effect (Carc. Cat. 3) ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): 802/2013/EU: Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 225, 23.8.2013, p. 13–16.
(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 74: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.01 mg/kg bw per day	JMPR (2010)	0.012 mg/kg bw per day	EFSA (2013b) (2-yr, rat, uncertainty factor 100) confirmed in European Commission (2013a)	Yes
ARfD	0.5 mg/kg bw	JMPR (2010)	0.5 mg/kg bw	EFSA (2013b) (acute neurotoxicity, rat, uncertainty factor 100) confirmed in European Commission (2013a)	Yes
Conclusion/ comment	The agreed EU ADI is 0.012 mg/kg bw per day based on the NOAEL of the 2-year study applying an uncertainty factor of 100. The EU ARfD is 0.5 mg/kg bw based on the acute neurotoxicity NOAEL with an uncertainty factor of 100 The slightly different ADI values are probably the result of a different policy on rounding				

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

5.16.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fluopyram	Fluopyram	Yes
	Animal products	Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram The residue is not fat soluble	Sum fluopyram and fluopyram-benzamide (M25), expressed as fluopyram The residue is not fat soluble	Yes
RD-RA	Plant products	Fluopyram	Sum fluopyram, fluopyram-benzamide (M25), fluopyram-E/Z-olefine (M02/M03), expressed as fluopyram	No
	Animal products	Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of *N*-{(*E*)-2-[3-chloro-5-	Sum of fluopyram, fluopyram-benzamide (M25), expressed as fluopyram	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
		(trifluoromethyl)pyridin-2-yl] ethenyl}-2-trifluoromethyl) benzamide and *N*-{(*Z*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram		
Conclusion/ comments	The residue definitions for enforcement (plant and animal commodities) derived by JMPR and applicable in the EU are identical. Thus, the Codex MRLs are compatible with the EU legal framework As regards the residue definition for risk assessment for plants, the EU residue definition is wider It is noted that metabolite M25 was observed at important proportions in the metabolism study in beans. At EU level, a conversion factor was derived for fruit crops (1.1), peas without pods (1.5), peas/beans with pods, oilseeds, stem vegetables (1.2) The lack of conversion factors introduces an uncertainty in the exposure calculations and the consumer risk assessment should be considered as tentative and may underestimate the actual exposure for plant products for which JMPR derived MRL proposals that are higher than the existing EU MRLs Rotational crop studies in cereals, leafy vegetables and roots were assessed in the peer review (EFSA, 2013b). Fluopyram and the metabolites resulting from the cleavage of the parent (fluopyram-benzamide (M25) and fluopyram-PCA (M43)) major components of the residues in rotational crops. 7-hydroxy metabolites observed in higher proportions than in primary crops. Residues in rotational crops cannot be excluded. (Default MRL proposals have been made for root/tuber and leafy crops (0.1 mg/kg), cereals, oilseeds and perennial crops (0.01*))		

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.16.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Cherry Tomato	W 0.4	0.9 (tomato)	JMPR proposed to withdraw the existing CXL for cherry tomato and to replace it with the new MRL for Subgroup of Tomatoes At EU level, the MRL established for tomatoes is also applicable to cherry tomatoes
Rice, husked	**1.5**	0.01*	Critical GAP: Thailand 2 × 0.024 kg/hL (up to BBCH 59) Number of trials: 8 trials in rice grain; 1 processing study (JMPR, 2017) Sufficiently supported by data: No Specific comments/observations: The Codex MRL proposal of 4 mg/kg derived by JMPR in 2017 referred to cereal grain (GC 0649). The MRL proposal for husked rice of 1.5 mg/kg (MRL relevant for rice, according to Annex I of Reg (EU) 2018/62) was derived by applying the processing factor of 0.29 (JMPR, 2017). Since only one processing study is available, the proposed MRL is not sufficiently supported. Conclusion: The proposed Codex MRL is not acceptable because the number of processing studies is insufficient
Rice, polished	**0.5**	–	Critical GAP: Thailand 2 × 0.024 kg/hL (up to BBCH 59) Number of trials: 8 trials in rice grain; 1 processing study (JMPR, 2017) Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL proposal of 4 mg/kg by JMPR in 2017 referred to cereal grain (GC 0649). The MRL proposal for polished rice of 0.5 mg/kg was derived by applying the processing factor of 0.11 JMPR (2017)

Commodity	Codex MRL proposal	EU MRL	Comment
			Conclusion: The proposed Codex MRL is acceptable, noting that in the EU the relevant commodity is husked rice
Tomato	W 0.5	0.9	JMPR proposed to withdraw the existing CXL for tomato and to replace it with the new MRL for subgroup of Tomatoes
Tomatoes, subgroup of (includes all commodities in this subgroup)	0.5	0.9 (tomato)	Critical GAP: USA, 2 × 0.25 kg a.i./ha, PHI 0 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: revised from 2017 to accommodate comments by EU and Canada. MRL extrapolated from tomato to the whole group of tomato (no change, in the EU classification tomatoes cover the whole subgroup) Conclusion: The proposed Codex MRL is acceptable
General comments	The changes are based on studies assessed by JMPR in 2017		

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

5.16.5. Consumer risk assessment

Table 77: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An indicative short-term dietary risk assessment was performed for rice for which the Codex MRL proposal is higher than the existing EU MRLs were derived, as outlined in Section 2 STMR residue value was used for the exposure calculation The residues conversion from enforcement to risk assessment residue definitions has not been done due to the lack of reliable CF. Therefore, the risk assessment needs to be considered in indicative The EU ARfD was used	**RA assumptions:** An indicative long-term dietary risk assessment was performed with PRIMo rev. 3.1. The calculation is based input values derived in the framework of the most recent MRL application (broccoli). Considering that following the completeness check performed for the MRL review under Art. 12, EFSA expects that the livestock dietary burden calculation might result in lower livestock exposure and consequently lower residues in animal products, and considering that milk is a major driver for the long-term intake calculation and inaccurate input values have a major effect on the outcome of the calculation, EFSA did not include the previously derived STMR value for milk. Thus, risk assessment is therefore considered as indicative; a more accurate risk assessment taking into account the available data submitted in support of the existing MRLs will be presented in the framework of the Art. 12 MRL review For rice, the STMR value derived by JMPR for husked rice was included in the calculation. A conversion factor to accommodate for the wider EU residue definition was not available The EU ADI was used	**Specific comments:** The commodities were assessed in the previous assessment (JMPR, 2017)
Results: No short-term exposure concern was identified (4% of the ARfD for rice)	**Results:** The indicative long-term exposure assessment (without milk) accounted for 99% of the ADI The contribution of rice was max. 2% of the ADI Risk managers to discuss whether the existing MRL for rice should be amended before the MRL review is completed, considering that currently a comprehensive risk assessment cannot be performed	**Results:** No consumer risk identified in previous assessment related to rice (JMPR, 2017)

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

5.17. Sulfoxaflor (252) R

5.17.1. Background information

Table 78: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	IE	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/1295[(a)]
EFSA conclusion	Yes	EFSA (2014e) EFSA (2019f)
MRL review	Yes, see comments	EFSA (2017d) (statement; no MRL review required since MRLs were set in the framework of the first approval of the a.s.)
MRL applications	Yes	EFSA (2017n) (grape leaves, artichoke) EFSA (2019b) (various crop)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling-entry into Annex VI: no entry in Annex VI for CMR properties EU Peer Review proposal for CMR: no proposal for CMR properties ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level; a.s.: active substance.

(a): Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, 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 199, 29.7.2015, p. 8–11.

(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.

5.17.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR (2011)	0.04 mg/kg bw per day	EFSA (2014e); European Commission (2015b) (Rat, 2-year study, UF 100)	No
ARfD	0.3 mg/kg bw	JMPR (2011)	0.25 mg/kg bw	EFSA (2014e); European Commission (2015b) (Rat, acute Neurotoxicity, UF 100)	No
Conclusion/ comment	The slight difference in the toxicological reference values are probably resulting from a different policy on rounding (ARfD) or conversion from ppm to mg/kg bw per day (ADI). During the EU peer review, it was agreed that references values of sulfoxaflor can apply to metabolite X11719474				

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

5.17.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sulfoxaflor	EU Reg. 2018/832: Sulfoxaflor (sum of isomers)	Yes
	Animal products	Sulfoxaflor The residue is not fat soluble	EU Reg. 2018/832: Sulfoxaflor (sum of isomers) The residue is not fat soluble	Yes
RD-RA	Plant products	Sulfoxaflor	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor	No
	Animal products	Sulfoxaflor	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor	No
Conclusion/ comments	**Plant and animal commodities**: The residue definitions for enforcement set by JMPR and at EU level are substantially identical. Since the routine analytical method could not separate the two diastereomeric pairs of enantiomers in sulfoxaflor, the residue definitions apply to the sum of all isomers At EU level, the residue definition for risk assessment in plant and animal commodities is more comprehensive and includes the metabolite X11719474. X11719474 is a plant and soil metabolite, which has shown to be preferentially taken up by the roots of the plants and to be present (> LOQ) in the leafy parts of the crops in rotation crops, particularly in feed items. However, its inclusion in the residue definition for risk assessment of plant and animal products is provisional. It was agreed that if the metabolite X11719474 is shown to be significantly less toxic than sulfoxaflor, then the residue definitions for risk assessment will be restricted to parent sulfoxaflor only For several crops, including crops previously assessed by JMPR (JMPR evaluation 2011) and recently assessed by EFSA (2019f), results for X11719474 were reported separately. At the uses and PHIs assessed, concentrations of this metabolite were at or close to the LOQ of 0.01 mg/kg, except in cereal straw (up to 0.034 mg/kg). Considering the low concentrations and its toxicological profile, the differences between the two risk assessment residue definitions is of low practical implication Both assessments concluded residues in products of animal origin are not fat soluble			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; LOQ: limit of quantification; PHI: preharvest interval.

5.17.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Edible offal (Mammalian)	**1**	0.6 (edible offal, liver, kidney from farmed terrestrial animals, except poultry)	New maximum dietary burden of sulfoxaflor was calculated from the Australian diet for beef cattle. The Codex MRL proposal is based on estimates from previously assessed feeding studies Conclusion: The proposed Codex MRL is acceptable
Maize	0.01*	0.01*	Critical GAP: Canada, 2 × 36 g/ha, interval 7 days PHI 14 days (restriction max 72 g/ha per season) Number of trials: 14 Sufficiently supported by data: Yes Specific comments/observations: All trials overdosed (50 g/ha) with residues < LOQ (12) and at LOQ (2) proportionally scaled to derive STMR of 0.007 mg/kg, scaling factor 0.7. However, it is not a good practice to scale down overdosed trials with residues below the LOQ Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Maize fodder (dry)	0.6	–	Critical GAP: Canada, 2 × 36 g/ha, interval 7 days, PHI 14 days (restriction max 72 g/ha per season) Number of trials: 15 Sufficiently supported by data: Yes No MRLs are set for feed items at EU level
Mammalian fats	**0.2**	0.1 (farmed terrestrial animals, except poultry)	See comments on mammalian edible offal Conclusion: The proposed Codex MRL is acceptable
Meat (mammalian except marine mammals)	**0.4**	0.3 (farmed terrestrial animals, except poultry)	See comments on mammalian edible offal The Codex MRL proposal refers to meat; for muscle the same MRL proposal would be derived Conclusion: The proposed Codex MRL is acceptable
Milks	**0.3**	0.2	New maximum dietary burden of sulfoxaflor was calculated from the Australian diet for dairy cattle. The Codex MRL proposal is based on estimates from previously assessed feeding studies. It was derived according to the residue definition set by JMPR, which includes parent compound only Conclusion: The proposed Codex MRL is acceptable
Poultry meat	**0.7**	0.1	New maximum dietary burden of sulfoxaflor was calculated from the Australian diet for broilers. The Codex MRL proposal was derived from a previously assessed feeding studies (JMPR 2011). The Codex MRL proposal refers to meat; for muscle the same MRL proposal would be derived Conclusion: The proposed Codex MRL is acceptable
Poultry edible offal	No modification proposed (existing CXL 0.3)	0.3 (edible offal, liver, kidney)	See comments on poultry meat Conclusion: The proposed Codex MRL is acceptable
Poultry fats	No modification proposed (existing CXL 0.03)	0.03	See comments on poultry meat Conclusion: The proposed Codex MRL is acceptable
Eggs	No modification proposed (existing CXL 0.1)	0.1	New maximum dietary burden of sulfoxaflor was calculated from the Australian diet for laying hens. The revised dietary burden calculation required a modification of the STMR and HR values for eggs, but did not lead to a modification of the existing CXL which is set at the level of 0.1 mg/kg
Rice	7	–	Critical GAP: Indonesia, 4 × 100 g/ha, interval 7 days, PHI 10 days (restriction 400 g/ha season) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Trials conducted in Philippines and Australia. The Codex MRL proposal was derived from residues of sulfoxaflor in paddy rice Conclusion: The proposed Codex MRL is not acceptable because it refers to paddy rice, which is not the commodity to which the EU MRL applies
Rice, polished	1	–	Critical GAP: not reported in the Summary report Number of trials: 3 Sufficiently supported by data: Yes Specific comments/observations: median PF of 0.14

Commodity	Codex MRL proposal	EU MRL	Comment
Rice, husked	**1.5**	0.01*	Critical GAP: not reported in the Summary report Number of trials: 8 residue trials in paddy rice, 3 processing studies Sufficiently supported by data: Yes Specific comments/observations: The MRL proposal was derived by applying the median PF of 0.2 on the MRL proposal derived for rice Conclusion: The proposed Codex MRL is acceptable; it refers to the commodity which is included in the EU MRL legislation
Rice straw and fodder (dry)	20		Critical GAP: Indonesia, 4 × 100 g/ha, interval 7 days, PHI 10 days (restriction 400 g/ha season) Number of trials: 8 Sufficiently supported by data: Yes No MRLs are set in the EU for feed items
Sorghum	**0.2**	0.01*	Critical GAP: Canada, 2 × 36 g/ha, interval 7 days, PHI 14 days (restriction max 72 g/ha per season) Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: All trials overdosed (50 g/ha) proportionally scaled, scaling factor 0.7 Conclusion: The proposed Codex MRL is acceptable
Sorghum straw and fodder (dry)	0.7	–	Critical GAP: Critical GAP: Canada, 2 × 36 g/ha, interval 7 days, PHI 14 days Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: All trials overdosed (50 g/ha) proportionally scaled, scaling factor 0.7 No MRLs are set in the EU for feed items
Sweet corn (corn-on-the-cob) kernels plus cobs with husks removed)	0.01*	0.01*	Critical GAP: Canadian, 2 × 36 g/ha, interval 7 days, PHI 7 days (restriction max 72 g/ha per season) Number of trials: 9 Sufficiently supported by data: Yes Specific comments/observations: All trials overdosed (50 g/ha) with residues < LOQ (9) Conclusion: The proposed Codex MRL is acceptable
Tree nuts	**0.03**	0.02*	Critical GAP: USA, 4 × 101 g/ha, interval 7 days, PHI 7 days (restriction max 298 g/ha per season) Number of trials: 10 trials conducted on almonds (5) and pecans (5) with 3 × 100 g/ha Sufficiently supported by data: Yes Specific comments/observations: Residues < LOQ except in one trial (0.02 mg/kg). The previously derived MRL proposal of 0.015 mg/kg (step 4) should be withdrawn Conclusion: The proposed Codex MRL is acceptable
General comments	Information on the concentrations of the metabolite X11719474, currently included in the EU residue definitions for risk assessment, in the products of plant and animal origin under assessment are not available. It is expected that this deviation does not have a practical implication for the consumer risk assessment **Typos** (summary report) STMR for maize fodder (dry) 0.16 mg/kg instead of 0.6 mg/kg		

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; LOQ: limit of quantification; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; CXL: Codex Maximum Residue Limit: HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.

5.17.5. Consumer risk assessment

Table 82: 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 performed for the products of plant and animal origin for which higher Codex MRLs were proposed, compared to the existing EU MRLs The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2019f) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the products of plant and animal origin which higher Codex MRLs were proposed, compared with the existing EU MRLs STMR related to the Codex MRLs refer to parent compound only, except citrus different than limes, where a conversion factor for risk assessment of 1.16 was used	**Specific comments:** –
Results: No short-term exposure concern was identified (maximum 7% of the ARfD for milk) In the framework of the EFSA conclusion, a theoretical factor of 2 was applied to the risk assessment in order to accommodate for the lack of information on the ratio of the enantiomers present in the individual diastereomers of sulfoxaflor and X11719474 (EFSA, 2014e). Following this approach, the margin of safety of the exposure calculation is still sufficiently large to conclude that the assessed uses are unlikely to present a consumer health concern	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 34% of the ADI In the framework of the EFSA conclusion, a theoretical factor of 2 was applied to the risk assessment in order to accommodate for the lack of information on the ratio of the enantiomers present in the individual diastereomers of sulfoxaflor and X11719474 (EFSA, 2014e). Following this approach, the margin of safety of the exposure calculation is still sufficiently large to conclude that the assessed uses are unlikely to present a consumer health concern	**Results:** Long-term exposure: 2–9% of the JMPR ADI Short-term exposure: Max. 20% of the ARfD

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

5.18. Chlorfenapyr (254) T/R

5.18.1. Background information

Table 83: Background information

		Comments, references
Type of JMPR evaluation	New use	In 2012 and 2013, JMPR assessed the active substance, however could not conclude on residue definitions and therefore did not propose Codex MRLs
RMS	ES	
Approval status	Not approved	Commission Decision No 2001/697/EC[(a)]
EFSA conclusion	No	
MRL review	No	
MRL applications	No	
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	**Chlorfenapyr** is approved for use as a biocide in the EEA and/or Switzerland for wood preservation Harmonized classification and labelling for CMR – Annex VI: No classification ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): Commission Decision of 5 September 2001 concerning the non-inclusion of chlorfenapyr in Annex I to Council Directive 91/414/EEC (2001/697/EC). OJ L 249, 19.9.2001. pp. 19-20.
(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 84: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.03 mg/kg bw per day	JMPR (2012)	0.015 mg/kg bw per day	ECCO (99)	No
ARfD	0.03 mg/kg bw	JMPR (2012)	0.015 mg/kg bw	ECCO (99)	No
Conclusion/ comment	Parent compound: No recent toxicological assessment available for the a.s. used as a pesticide The **ADI** established by the JMPR is based on a NOAEL of 2.8 mg/kg bw per day for decreases in body weight gain and vacuolation of the white matter of the brain in an 18-month mouse study and a NOAEL of 2.9 mg/kg bw per day for reduced body weight and body weight gain and increased liver weight associated with hepatocellular enlargement in a 2-year rat study. This was supported by a NOAEL of 2.6 mg/kg bw per day for reversible vacuolar myelopathy, vacuolation and/or myelin sheath swelling of the brain and spinal cord in males in a 1-year neurotoxicity study in rats. An uncertainty factor (UF) of 100 was applied The **ARfD** is based on the NOAEL of 3 mg/kg bw for depression of grooming and reactivity and decreased spontaneous motor activity observed in a pharmacological study in mice and applying an UF of 100 In the framework of the EU biocides assessment, an ADI of 0.028 mg/kg bw per day was derived, based on the same NOAELs from the same studies as the ones used by the JMPR; no ARfD was allocated under Reg. 98/8/EC, however it seems that the biocide assessment may not have had access to the study that was used by the JMPR to establish the ARfD According to JMPR, the metabolite 4-bromo-2-(*p*-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile (tralopyril) which was observed in plant metabolism studies, is more toxic than parent chlorfenapyr and an additional uncertainty factor of 10 was applied with regards to chlorfenapyr toxicological reference values (JMPR, 2013) Details on the studies on genotoxicity are not reported in the JMPR report (it states only that *in vitro* and *in vivo* studies were provided); EFSA could not find evidence on these genotoxicity studies in JMPR Evaluations and therefore a conclusion cannot be derived whether all genotoxicity endpoint have been covered . . .. Six metabolites identified in residue studies were considered toxicologically not relevant at currently estimated dietary exposures using TTC approach (exposure was estimated individually for the 6 metabolites and compared to the TTC threshold of 1.5 μg/kg bw for Cramer Class 3). Toxicological data on these substances are not available to justify the use of the TTC threshold for Cramer Class 3. The calculated exposure for these metabolites ranged from < 0.001 μg/kg bw (CL 152832), to 0.003 μg/kg bw (CL322250, CL151835 and CL325157, respectively), 0.015 μg/kg bw (CL152837) and 0.018 μg/kg bw (CL 325195)				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; NOAEL: no observed adverse effect level; TTC: threshold of toxicological concern.

5.18.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Chlorfenapyr	Reg. 396/2005: Chlorfenapyr	Yes
	Animal products	Chlorfenapyr The residue is fat soluble	Reg. 396/2005: Chlorfenapyr The residue is not labelled as fat soluble	Yes
RD-RA	Plant products	Sum of chlorfenapyr plus 10 × 4-bromo-2-(*p*-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile (tralopyril)	No formally approved RD for RA available	No comparison possible
	Animal products	Sum of chlorfenapyr plus 10 × 4-bromo-2-(*p*-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile (tralopyril)		No comparison possible
Conclusion/ comments	Plant metabolism studies were assessed by the 2012 JMPR. Metabolism studies in oranges, tomatoes, head lettuce, potatoes and cotton are available JMPR recommended that if in future further uses of chlorfenapyr result in an increase in exposure to the metabolites for which no toxicological studies (except genotoxicity data) are available, the residue definition should be reconsidered EU assessment: RMS informed EFSA that in the peer review a residue definition for plants was agreed (residue definition was finally proposed as chlorfenapyr + AC 303268 (= tralopyril) expressed as AC 303268); for animal products the proposed residue definition was finally proposed as chlorfenapyr + CL 303268 (= tralopyril), expressed as CL 303268 (Evaluation table; ECCO, 99)			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State.

5.18.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Chili pepper, dry	**3**	–	The proposed Codex MRL is based on the MRL proposal for peppers, applying the default dehydration factor of 10 No MRLs are set in the EU for processed products
Edible offal (Mammalian)	**0.05**	–	The MRL proposal was derived from a feeding study assessed previously by JMPR (2012), taking into account the updated dietary burden calculation. Since the samples taken in the feeding study were not analysed for tralopyril, JMPR derived conversion factors on the basis of metabolism studies Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable with the EU policy on setting MRLs, considering the approach to derive input values for risk assessment using conversion factors derived from metabolism studies
Eggs	**0.01**	–	The MRL proposal was derived from a metabolism study assessed previously by JMPR (2012), taking into account the updated dietary burden calculation. JMPR should be asked to verify the correctness of the dietary burden calculation: according to Annex 6, p 602 of JMPR report, the maximum dietary burden for EU poultry broiler and layer is 0.008 ppm and 0.007 ppm, while the calculation of the MRL was based on an assumption of a maximum dietary burden of 0.47 ppm

Commodity	Codex MRL proposal	EU MRL	Comment
Garlic	0.01*	0.02*	Critical GAP: BR, 24 g a.i./hL, 1,000 L/ha, PHI 14 days, number of application was not specified (GAP originally reported in 2012 JMPR) Number of trials: 5 trials with 3 × 240 g a.i./ha, PHI 14 days Sufficiently supported by data: If it is confirmed by JMPR/BR that the residue trials reflect an approved GAP, the supporting residue trials are sufficient. See also general comments below
Lemons and Limes, subgroup pf (includes all commodities in this subgroup)	**0.8**	0.01* Kumquats: 0.01*	Critical GAP: BR, 3 × 15 g a.i./hL, PHI 14 days. Water amount per ha are not specified Number of trials: 8 trials with 3 × 15 g/hL, PHI 14 days Sufficiently supported by data: Yes Specific comments/observations: See general comments below Conclusion: The proposed Codex MRL is acceptable
Mammalian fats	**0.6**	–	See edible offal mammalians
Meat (from mammals other than marine mammals)	**0.6(fat)**	–	See edible offal mammalians
Melons, except Watermelon	**0.4**	0.01*	Critical GAP: BR, 12–24 g/ha, PHI 14 days, number of applications and water amount per ha not specified Number of trials: 9 trials, with 3 × 24 g/hL, PHI 14 days; in 5 trials residues in edible part of the crop were measured Before a conclusion on the appropriateness of the MRL proposal and the validity of trials can be taken, further details on the Brazilian GAP need to be reported (i.e. number of applications, water amount/ha). See also general comment
Milks	**0.03**	–	See edible offal mammalians
Onion, bulb	0.01*	0.02*	Critical GAP: BR, 120–180 g/ha, 800–1000 l/ha, PHI 14 days, number of applications not specified Number of trials: 9 trials with 3 × 180 g/ha, PHI 14 days Before a conclusion on the appropriateness of the MRL proposal and the validity of trials can be taken, further details on the Brazilian GAP need to be reported (i.e. number of applications). See also general comment
Oranges, Sweet, Sour, subgroup of (includes all commodities in this subgroup)	**1.5**	0.01*	Critical GAP: BR, 3 × 15 g a.i./hL, PHI 14 days. Water amount per ha not specified Number of trials: 7 trials with 3 × 15 g/hL, PHI 14 days Sufficiently supported by data: No; one additional trial would be required Specific comments/observations: See general comments below Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Papaya	**0.3**	0.01*	Critical GAP: 7.2–12 g/hL, PHI 14 days, number of applications and water amount per application not specified Number of trials: 5 trials with 3 × 12 g/hL, PHI 14 days Before a conclusion on the appropriateness of the MRL proposal and the validity of trials can be taken, further details on the Brazilian GAP need to be reported (i.e. number of applications). See also general comment

Commodity	Codex MRL proposal	EU MRL	Comment
Peppers	**0.3**	0.01*	Critical GAP: BR, 7.2 g/ha, 7-day PHI, number of applications not specified Number of trials: 7 trial with 3 × 7.2 g/ha, 1,000 L/ha, 7-day PHI Sufficiently supported by data: Not fully supported (1 additional trial would be required) Specific comments/observations: From metabolism studies, a conversion factor of 1 was derived. Since in the metabolism study the sampling was 1 day after the last application, the residues are shifted to the unmetabolised parent compound. Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs
Poultry, edible offal of	**0.01**	–	See eggs
Poultry, fats	**0.02**	–	See edible offal mammalians
Poultry, meat	**0.02(fat)**	–	See edible offal mammalians
Potato	0.01*	0.01*	Critical GAP: BR; 180 g a.i./ha, 7-day PHI, number of applications not reported. Number of trials: 9 trial (4 × 180 g a.i./ha, 7-day PHI Sufficiently supported by data: Unclear Before a conclusion on the appropriateness of the MRL proposal, further details on the Brazilian GAP need to be reported (i.e. number of applications, water amount/ha). See also general comment
Soya bean (dry)	**0.08**	0.02*	Critical GAP: BR, 3 × 0.29 kg a.i./ha, PHI 30 days Number of trials: 14 trials representative for the BR GAP Sufficiently supported by data: Yes Specific comments/observations: see general comment
Soya bean fodder	7(DM)	–	No MRLs are set in the EU for feed
Soya bean, crude oil	0.4	–	The proposed Codex MRL is based on the MRL proposal for soya beans, applying the processing factor of 4.5 derived from 3 processing studies No MRLs are set in the EU for processed products
Tomatoes	**0.4**	0.01*	Critical GAP: BR, 12 g a.i./hL, 7 d PHI, number of applications and water amount/ha not specified (JMPR 2012) Number of trials: 8 trials with 5 × 24 g/hL, 1,000 L/ha. The results were adjusted to the GAP using scaling. Sufficiently supported by data: Unclear Before a conclusion on the appropriateness of the MRL proposal and the validity of scaling can be taken, further details on the Brazilian GAP need to be reported (i.e. number of applications, water amount/ha). See also general comment
Tea, Green, Black (black, fermented and dried)	**60**	50	Critical GAP: Japan, 2 × 100 g/ha (5 g/hL), 7-day PHI. Number of trials: 4 trials with 2 × 200 g/ha (5 g/hL), 7-day PHI Sufficiently supported by data: To be discussed with MS. At EU level 8 trials would be required. Number of trials required by JMPR is not clearly specified. Scaling might be appropriate for the residue trials, leading to a lower MRL proposal Conclusion: The proposed Codex MRL is not acceptable because the number of residue trials is probably insufficient, the residue trials are not reflecting the GAP in terms of application rate per hectare and because of the intake concern identified (short-term exposure > EU ARfD) See also general comment

Commodity	Codex MRL proposal	EU MRL	Comment
General comments	In none of the residue trials, tralopyril was analysed. To derive the risk assessment values, JMPR derived conversion factors on the basis of the ratio of parent compound and tralopyril measured in plant metabolism studies representative for the GAP. In the conversion factors the higher toxicity of the metabolite was also taken into account In general, this approach leads to additional uncertainties for the risk assessment, in particular where samples were taken shortly after the last application (i.e. peppers, eggplants, tomatoes), because this is likely to shift the ratio of parent and metabolite in direction of the less toxic parent compound, leading to an underestimation of the risk for consumers. See risk assessment see below The RMS provided detailed information on the GAPs (EU uses) and the residue trials assessed in the DAR; however, since the active substance has not been approved in the EU, the data provided in the EU peer review do not affect the proposed Codex MRL proposals		

MRL: maximum residue level; ARfD: acute reference dose; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ADI: acceptable daily intake; DM: dry matter; DAR: draft assessment factor.

5.18.5. Consumer risk assessment

Table 87: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An indicative short-term dietary risk assessment was performed with PRIMo rev. 3.1 using the HR/STMR values derived by JMPR for the crops for which Codex MRL proposals were higher than the corresponding EU MRL. For the remaining crops, the current EU MRL was used as input value The EU ARfD was used. The risk assessment is indicative, because of additional, non-standard uncertainties, related to the lack of data on the occurrence of the more toxic metabolite tralopyril, which was overcome by JMPR using conversion factors derived from metabolism studies and the relative toxicity. In addition, an indicative peeling factor (0.017) for citrus was derived based on the ration of TRR found in metabolism study in oranges	**RA assumptions:** An indicative long-term dietary risk assessment was performed using the STMR values derived by JMPR for crops for which Codex MRL proposals were higher than the corresponding EU MRL. For the remaining crops, the current EU MRL was used in input value The EU ADI was used The risk assessment is indicative because of additional, non-standard uncertainties, related to the lack of data on the occurrence of the more toxic metabolite tralopyril, which was overcome by JMPR using conversion factors derived from metabolism studies and the relative toxicity	**Specific comments:**
Results: The indicative short-term exposure exceeded the ARfD for tea (122% of the ARfD). Further refinements might be possible, considering the transfer to the tea infusion. However, no appropriate processing factors are available at the moment. For other crops, no short-term intake concerns were identified For the other commodities no exceedance of the ARfD was identified	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 28% of the ADI	**Results:** Long-term exposure: 1-6% of the ADI Short-term exposure: 0-60% of the ARfD

RA: risk assessment; HR: highest residue; STMR: supervised trials median residue; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; ARfD: acute reference dose; ADI: acceptable daily intake; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRR: total radioactive residues.

5.19. Fluxapyroxad (256) T/R

5.19.1. Background information

Table 88: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Approved	Commission Implementing Regulation (EU) No 589/2012[(a)]
EFSA conclusion	Yes, see comments	EFSA (2012a)
MRL review	No	Ongoing
MRL applications	Yes, see comments	EFSA (2017i) (various crops); EFSA (2016a) (various crops); EFSA (2015o) (grapes and potatoes); EFSA (2011c) (various crops)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	EU Peer Review proposal for CMR: Carc 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

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

5.19.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.02 mg/kg bw per day	JMPR (2012)	0.02 mg/kg bw per day	EFSA (2012a) (Rat, 2-year study, UF 100) Same in European Commission (2012)	Yes
ARfD	0.3 mg/kg bw	JMPR (2012)	0.25 mg/kg bw	EFSA (2012a) (Rabbit (developmental effects), and rat (maternal effects) developmental toxicity studies; UF 100) Same in European Commission (2012)	No
Conclusion/ comment	The 2018 JMPR assessed additional *in vitro* studies, which supported the conclusions of 2012 JMPR that high doses of fluxapyroxad cause hepatocellular adenomas and carcinomas in rats. The Meeting concluded that new studies support the existing ADI and have not impact on the ARfD established.				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	The ADI and ARfD established by the JMPR and the EU assessments are based on the same NOAELs from the same studies; the final ARfD value established by the JMPR resulted from rounding. It is noted that such rounding would not be applied at EU level since it represents more than 10% variation between the two values According to the EU assessment, the toxicological reference values of fluxapyroxad are applicable to metabolites **M700F048** and **M700F008** The EU assessment established an ADI of 0.25 mg/kg bw per day for the metabolite **M700F001** based on a developmental toxicity study in rabbits and applying an uncertainty factor (UF) of 1000; no ARfD was allocated to this metabolite as considered unnecessary. The metabolite would not share the carcinogenic potential of the parent. The metabolite **M700F002** would not share the carcinogenic properties of the parent either; the EU peer review established an ADI of 0.3 mg/kg bw per day for this metabolite based on a developmental toxicity study in rabbits and applying an UF of 1,000. No ARfD needs to be established for this metabolite				

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

5.19.3. Residue definitions

Table 90: 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	EC Reg. 2018/685: Fluxapyroxad	Yes
	Animal products	Fluxapyroxad The residue is fat soluble	EC Reg. 2018/685: Fluxapyroxad The residue is fat soluble	Yes
RD-RA	Plant products	Plants: Sum of fluxapyroxad and 3-difluoromethyl)- *N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-1-(ß-D-glucopyranosyl)-*N*-(3′,4′,5′-triflurobipheny-2-yl)-1*H*-pyrzaole-4-carboxamide (M700F048) and expressed as parent equivalents	Plants: Fluxapyroxad	No
	Animal products	Animals: Sum of fluxapyroxad and 3-(difluoromethyl)- *N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide (M700F008) expressed as parent equivalents	Animals: Fluxapyroxad (BAS 700F) and metabolite M700F008 expressed as parent equivalent	Yes
Conclusion/ comments	The plant and animal residue definitions for enforcement are comparable, as both refer to the parent fluxapyroxad only. The risk assessment residue definitions in animal commodities are also comparable For the plant risk assessment residue definition, the JMPR, in contrast to EU, has included two plant metabolites (M700F008 and M700F048). Although the fluxapyroxad metabolites were observed in the primary and rotational crop metabolism studies, they were not included in the EU risk assessment residue definition for plant commodities, since they were never observed at levels above the LOQ in residue trials or rotational crop studies (Comment of RMS: the EU risk assessment residue definition for plants should be reconsidered.)			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	The reside trials submitted for the JMPR assessment indicate that the overall contribution of metabolites is low Using the risk assessment values derived by JMPR will lead to a slightly more conservative result			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; LOQ: limit of quantification.

5.19.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Alfalfa hay	20 (DM)	–	Critical GAP: USA, 2 × 100 g/ha, 14-day interval, PHI 14 days (max 3 annual applications) Number of trials: 10 (CAN/USA) Sufficiently supported by data: Yes Specific comments/observations: The Meeting derived risk assessment values for alfalfa forage and alfalfa hay for the DB calculation. Since the dietary burden did not change significantly compared to the previous JMPR assessment, no modification of MRLs for animal products were derived No MRLs are set in the EU for this crop which is used exclusively as feed items
Citrus fruit, Group of (includes all commodities in this group)	**1**	0.01* except grapefruit and oranges with 0.3	Critical GAP: USA, 4 × 138 g/ha, 10-day interval, PHI 0 days Number of trials: 23 (7 lemons, 5 grapefruit, 1 mandarin, 10 oranges) Sufficiently supported by data: to be discussed with MS According to agreed extrapolation at Codex levels, to derive MRL proposals for citrus fruit the following information is required: lemon or lime; mandarin; orange or pummelo or grapefruit. The minimum number of trials per commodity and the requirement to demonstrate that trials on different commodities belong to the same population are not defined in detail in the agreed extrapolation document (Appendix XI of 2012 CCPR Report) The JMPR combined residue trials for lemons, grapefruit, mandarins and oranges, since the number of trials was considered sufficient to derive a group MRL The CXL would be applicable also to kumquats (classified as miscellaneous fruit, edible peel). The appropriateness of the MRL proposal for kumquat should be addressed by JMPR. No information on the residue distribution between peel and pulp was provided Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering that the number of mandarin trials is very limited (mandarins are a major crop at Codex level) and that the data sets for oranges, lemons and grapefruit are significantly different (Kruskal–Wallis H-test) Instead of deriving a group MRL for citrus, the data would allow to set a MRL for oranges (1.5 mg/kg), lemon/lime/kumquat (1 mg/kg) and grapefruit (0.6 mg/kg)
Citrus oil, edible	**60**	–	The PF of 59 derived from two processing studies

Commodity	Codex MRL proposal	EU MRL	Comment
Coffee beans	**0.15**	0.01*	Critical GAP: Brazil, 3 × 100 g/ha, 45-day interval, PHI 45 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: None Conclusion: The proposed Codex MRL is acceptable
Cotton seed	**0.5**	0.3	Critical GAP: Brazil, 4 × 58.5 g/ha, 12-day interval, PHI 14 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Cotton seed according to EU classification is considered a major crop in the SEU/ World. According to the JMPR criteria 4 trials are sufficient Conclusion: The proposed Codex MRL was derived in accordance with the JMPR policy
Mango	**0.6**	0.5	Critical GAP: Brazil, 4 × 66.8 g/ha, 7-day interval, PHI 7 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: None Conclusion: The proposed Codex MRL is acceptable
Oranges, Sweet, Sour (including Orange-like hybrids)	W 0.3		The existing CXL will be withdrawn; instead the new Codex MRL proposed for citrus fruit (group) will be applicable
Papaya	**1**	0.01*	Critical GAP: Brazil, 4 × 66.8 g/ha, 7-days interval, PHI 7 days Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: None Conclusion: The proposed Codex MRL is acceptable
Potato	0.07	0.1	Critical GAP: Italy, 1 × 240 g/ha (in-furrow), no PHI Number of trials: 16 Sufficiently supported by data: Yes Specific comments/observations: The same GAP and trials were already assessed by EFSA in 2015 with an MRL proposal of 0.07 mg/kg. On the basis of residues in rotational crops an MRL of 0.1 mg/kg was enforced Conclusion: The proposed Codex MRL is acceptable
Tuberous and corm vegetables, except potato, Subgroup of (includes all commodities in this subgroup)	0.03	0.1 tropical root and tuber vegetables; 0.3 Jerusalem artichokes	Critical GAP: USA, 3 × 99 g/ha, 7-day interval, PHI 7 days Number of trials: 19 Sufficiently supported by data: Yes Specific comments/observations: According to the EU classification, the CXL is applicable to a) tropical root and tuber vegetables group; Jerusalem artichoke Conclusion: The proposed Codex MRL is acceptable.
Citrus juice		–	PF 0.12; the reduction of residues in citrus juice occurs; the PF derived from two processing studies
Citrus peel		–	PF 1.9; residues concentrate in the peel; the concentration factor derived from two data points
Citrus marmalade		–	PF 0.042; the reduction of residues in citrus marmalade occurs; the PF derived from two processing studies
Cotton seed refined oil		–	PF 0.045; the processing factors for cotton were derived by 2015 JMPR. Now with new MRL proposal for raw cotton seed, the input values for processed commodities for the risk assessment are updated

Commodity	Codex MRL proposal	EU MRL	Comment
Potato baked tuber (with peel)		–	PF 0.5; the processing factors for potato were derived by 2012 JMPR. Now with new MRL proposal for raw potato, the input values for processed commodities for the risk assessment are updated
Potato boiled tuber (with peel)			
Potato chips			
Potato fried tuber (with peel)			
Potato granules/ flakes			
Potato peeled tuber			
General comments	–		

GAP: Good Agricultural Practice; PHI: preharvest interval; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MS: Member State; CXL: Codex Maximum Residue Limit; PF: processing factor; DM: dry matter; DB: Dietary Burden.
*: Indicates that the input value is proposed at the limit of quantification.

5.19.5. Consumer risk assessment

Table 92: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The acute exposure assessment was performed using EFSA PRIMo rev. 3, considering the existing EU MRLs (Reg. 2018/685) For citrus fruits, kumquats, mango, papaya, coffee beans and cotton seed the HR values derived for parent fluxapyroxad were used as input values The EU ARfD was used	**RA assumptions:** The chronic exposure assessment was performed using EFSA PRIMo rev. 3, considering the existing EU MRLs (Reg. 2018/685) For citrus fruits, kumquats, mango, papaya, coffee beans and cotton seed the STMR values derived for parent fluxapyroxad were used as input values. For several commodities, which contributed most to the chronic exposure, the STMR values related to previously assessed EU uses were included to refine the exposure calculation. Further refinements of the exposure calculation would be possible	**Specific comments:** The risk assessment considers also metabolites of fluxapyroxad (M700F008 and M700F048)
Results: No short-term exposure concern was identified (citrus fruits (5–31% of the ARfD), kumquats (1% of the ARfD), mango (12%), papaya (9%), coffee beans (0%) and cotton seed (no data))	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for a maximum of 89% of the ADI (further refinements would be possible). From the crops under consideration, the contribution to the total exposure was the highest for residues in oranges (6.6% of the ADI)	**Results:** Long-term exposure: 6–20% of the ADI Short-term exposure: 0–10% of the ARfD

RA: risk assessment; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; HR: highest residue; STMR: supervised trials median residue; ARfD: acute reference dose; ADI: acceptable daily intake.

5.20. Benzovindiflupyr (261) R

5.20.1. Background information

Table 93: Background information

		Comments, references
Type of JMPR evaluation	Other evaluation, see comment	Request of manufacturer to set a group MRL for the subgroup of dry peas and the subgroup of dry beans (instead of individual MRLs for dry peas and dry beans)
RMS	NL	
Approval status	Approved	Commission Implementing Regulation (EU) 2016/177[(a)]
EFSA conclusion	Yes, see comments	EFSA (2015f) EFSA (2017b) (E-fate, phys/chem,ecotox)
MRL review	No	Not required
MRL applications	No	EFSA (2016h) Import tolerance
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: No classification ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not finalised

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): (EU) 2016/177: Commission Implementing Regulation (EU) 2016/177 of 10 February 2016 approving the active substance benzovindiflupyr, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. OJ L 35, 11.2.2016, p. 1–5.
(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 94: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR (2013)	0.05 mg/kg bw per day	EFSA (2015f); European Commission (2015a) (Rat, 2-year study, UF 100)	Yes
ARfD	0.1 mg/kg bw	JMPR (2013)	0.1 mg/kg bw	EFSA (2015f); European Commission (2015a) (Rat, acute neurotoxicity Study, UF 100)	Yes
Conclusion/ comment	The toxicological reference values derived at EU level and by JMPR are identical and are based on the same NOAELs from the same studies The JMPR concluded that **SYN546039** and **SYN545720** are less toxic than the parent based on acute oral toxicity studies The EU assessment established an **ADI of 0.3 mg/kg bw per day** for the metabolite **SYN545720** (CSCD465008), based on a developmental toxicity study in rabbits and applying an uncertainty factor (UF) of 1000, **no ARfD** being needed for the metabolite An **ADI of 0.25 mg/kg bw per day** was established for the metabolite **NOA449410** (CSAA798670) based on a developmental toxicity study in rabbits and applying an UF of 1000; **no ARfD** was set, as considered not necessary				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	Insufficient information was provided on metabolite **SYN546039** (CSCD695908) to conclude on its toxicological profile, including its genotoxicity potential				

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

5.20.3. Residue definitions

Table 95: 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	EC Reg. 2018/687: Benzovindiflupyr	Yes
	Animal products	Benzovindiflupyr The residue is fat soluble	EC Reg. 2018/687: Benzovindiflupyr The residue is not fat soluble	Yes
RD RA	Plant products	Benzovindiflupyr	Benzovindiflupyr	Yes
	Animal products	Benzovindiflupyr	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% to 50% TRR in tissues and milk. A conversion factor of 2 was proposed to account for the residue definition for consumer risk assessment for animal commodities. Furthermore, the residues were not considered fat soluble in the EU For the current request, the difference in the residue definitions is not relevant			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRR: total radioactive residues.

5.20.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Beans (dry)	W 0.15		The previous CXL will be replaced by the proposed CXL for the Subgroup of dry beans
Dry beans, subgroup of, except soya bean, dry	0.15	0.2 (beans and lupins)	Critical GAP: Canada, 2 × 0.075 kg/ha, interval 7 days, PHI 15 days Number of trials: 13 Sufficiently supported by data: Yes Specific comments/observations: Residue trials already assessed by JMPR in 2016. Extrapolation of the individual CXL to the subgroup of dry beans possible. The MRL proposal for dry beans covers also lupins At EU level, the same MRL would have been derived for the whole group of dry pulses from the combined data set of residues in beans and peas Conclusion: The proposed Codex MRL is acceptable
Dry peas, subgroup of (includes	0.2	0.2 (peas and lentils)	Critical GAP: 2 × 0.075 kg/ha, interval 7 days, PHI 15 days Number of trials: 11 Sufficiently supported by data: Yes

Commodity	Codex MRL proposal	EU MRL	Comment
all commodities in this subgroup)			Specific comments/observations: Residue trials already assessed by JMPR in 2016. Extrapolation of the individual CXL to the subgroup of dry peas possible. At EU level, a slightly lower MRL of 0.15 mg/kg (OECD calculator) would have been derived for the whole group of dry pulses from the combined data set of residues in beans and peas. The MRL proposal for dry peas covers also lentils Conclusion: The proposed Codex MRL is acceptable
Peas (dry)	W 0.2		The previous CXL will be covered by the proposed CXL for the Subgroup of dry peas
General comments	Upon request from the manufacturer, JMPR decided to expand the CXL in beans (dry) and peas (dry) derived based on the GAP for Canada for pulses (not including soybeans) to the respective subgroups A **typo** was noted in the 2018 publications (both Summary report & Report): the STMR for peas (dry) has been reported as '0.014 mg/kg' instead of '0.011 mg/kg' (please refer to 2016 Summary report & Report, where the residue data were assessed)		

CXL: Codex Maximum Residue Limit; GAP: Good Agricultural Practice; PHI: preharvest interval; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; OECD: Organisation for Economic Co-operation and Development; STMR: supervised trials median residue.

5.20.5. Consumer risk assessment

Table 97: 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 conducted using for pulses the STMR value of 0.011 mg/kg derived by JMPR from studies on dry beans and peas	**RA assumptions:** The long-term risk assessment was conducted using the approach as outlined in Section 'Assessment' and the STMR value of 0.011 mg/kg derived by JMPR from studies on dry beans and peas. MRLs of products of animal origin were multiplied by a conversion factor for risk assessment of 2	**Specific comments:** JMPR did not provide an update of the consumer exposure performed in EFSA (2016h)
Results: No short-term exposure concern was identified for dry beans (0.2% of the ARfD), peas and lentils (0.07% of the ARfD)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 16% of the ADI The maximum contribution of pulses to the exposure was 0.02% of the ADI (dry beans)	**Results:** –

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

5.21. Cyantraniliprole (263) R

5.21.1. Background information

Table 98: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	UK	Co-RMS: FR
Approval status	Approved	Commission Implementing Regulation (EU) 2016/1414[(a)]
EFSA conclusion	Yes, see comments	EFSA (2014g)
MRL review	Yes, see comments	Statement EFSA (2017d)
MRL applications	Yes, see comments	EFSA (2017m) (Raspberries and blackberries) EFSA (2018c) (leeks) 3 MRL applications on various crops: ongoing Table olives and olives for oil production: ongoing
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not met. ED: not concluded	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI EU Peer Review proposal (2014g): none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 approving the active substance cyantraniliprole, 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 230, 25.8.2016, p. 16–19.
(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.

5.21.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.03 mg/kg bw per day	JMPR (2013) (dog studies, SF 100)	0.01 mg/kg bw per day	EFSA (2014g) (1-year dog study, UF 100) European Commission (2016a)	No
ARfD	Unnecessary	JMPR (2013)	Not necessary	EFSA (2014g) European Commission (2016a)	Yes
Conclusion/ comment	The ADI values set by JMPR and EU are not comparable The EU ADI is 0.01 mg/kg bw per day, based on the 1-year dog study and applying an uncertainty factor (UF) of 100. In the 90-day and 1-year dog studies, the agreed NOAEL was 1 mg/kg bw per day based on increased relative liver weights and altered clinical chemistry On the contrary, in the JMPR report of 2013, the NOAEL from the 90-day oral toxicity study was 3.08 mg/kg bw per day (based on increased total protein, albumin and AP levels in males) which is the basis for the ADI				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	Metabolites considered during the EU peer review: The plant metabolite IN-J9Z38, it is covered by the reference values derived for cyantraniliprole. For the metabolites IN-F6L99 and IN-N5M09 (found in processed commodities), an assessment of their toxicological properties is still missing (data gap)				

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

5.21.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyantraniliprole	EU Reg. 2016/486: Cyantraniliprole	Yes
	Animal products	Cyantraniliprole The residue is not fat soluble	EU Reg. 2016/486: Cyantraniliprole The residue is not fat soluble	Yes
RD RA	Plant products	Cyantraniliprole For processed plant commodities: Sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole	Peer review (EFSA, 2014g, 2017m, 2018c): Cyantraniliprole For processed commodities: Sum cyantraniliprole and 2-[3-bromo-1-(3-chloropyridin-2-yl)-1*H*-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile (IN-J9Z38), expressed as cyantraniliprole	Yes
	Animal products	Sum of:-cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazoline-carbonitrile (IN-J9Z38), 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazoline carbonitrile (IN-MLA84), 3-Bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5-carboxamide (IN-N7B69) and 3-Bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2 [[(hydroxymethyl) amino]carbonyl]-6-methylphenyl]-1*H*-pyrazole-5-carboxamide expressed as cyantraniliprole (IN-MYX98)	Peer review (EFSA, 2014g): Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole	No
Conclusion/ comments	The RA RDs for animals are not compatible. The metabolite IN-MYX98 is included (highlighted in green) in the RA RD derived by JMPR, but not in the one derived by EFSA. Since no Codex MRLs are proposed for animal commodities this year, it is not expected that this has an impact on the assessment			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue levels.

5.21.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Cranberries	**0.08**	0.01*	Critical GAP: Canada (3 × 150 g a.i./ha, PHI 14 days) Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: trials compliant with the GAP Conclusion: The proposed Codex MRL is acceptable
Fruiting vegetables, Cucurbits	W 0.3		CXL withdrawn, see below the new proposal
Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)	0.3	cucurbits with edible peel: 0.4; cucurbits with inedible peel: 0.3	Critical GAP: JMPR 2018: USA (3 × 150 g a.i./ha, PHI 0 days, indoor use) 2013: Canada (4 × 0.025–0.15 kg/ha, max. 0.45 kg/ha per season, PHI 1 day, outdoor use) Number of trials: 5 trials for indoor use assessed by 2015 JMPR were found to match the US GAP 10 trials on cucumbers and 9 trials in summer squash for outdoor use (JMPR 2013) Sufficiently supported by data: No for indoor use, Yes for outdoor use In 2013, a MRL proposal of 0.3 mg/kg was derived for fruiting vegetables (cucurbits) based on a sufficient data package. The new data submitted for the indoor use (see GAP mentioned above); since the data were insufficient, the previously derived MRL was maintained Number of trials considered insufficient to derive MRL for major crops. 4 additional trials compliant to Canadian GAP (4 × 100 g a.i./ha, PHI 0 days), also deemed insufficient. Both data set could not be matched using the 'GAP versus trial model' Conclusion: The proposed Codex MRL reflecting the Canadian GAP assessed in 2013 is acceptable
Mango	**0.7**	0.01*	Critical GAP: Cambodia (2 × 180 g a.i./ha, PHI 7 days) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: residue results available for RAC and pulp Conclusion: The proposed Codex MRL is acceptable
Rice, Husked	0.01*	0.01*	Critical GAP: China (2 × 60 g a.i./ha, PHI 21 days) Number of trials: 33 Sufficiently supported by data: Yes Specific comments/observations: Residues in overdosed trials performed to: 2 or 3 × 100 g a.i./ha, PHI 21 days, were all < 0.01 mg/kg (n = 12). Residues in overdosed trials performed to: 2 or 3 × 150 g a.i./ha, PHI 21 days, ranged from < 0.01 (n = 9) to 0.019 mg/kg (n = 12). No residue situation anticipated when applied according to GAP Conclusion: The proposed Codex MRL is acceptable
Rice, polished	0.01*		Estimations from husked rice apply to polish rice At EU level no MRL is set for processed products
Rice straw & fodder (dry)	1.7 (dw)		Critical GAP: China (2 × 60 g a.i./ha, PHI 21 days) Number of trials: 6 No EU MRLs are set for feed items like straw and fodder

Commodity	Codex MRL proposal	EU MRL	Comment
Strawberry	**1.5**	0.05*	Critical GAP: Canada (3 × 150 g a.i./ha, PHI 1 day) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
Winegrapes	1	1.5	Critical GAP: Italy (2 × 112.5 g a.i./ha, PHI 10 days) Number of trials: 27 Sufficiently supported by data: Yes Specific comments/observations: combined data set of trials compliant with the GAP (n = 4) and overdosed (n = 23). Results from overdosed residue trials were scaled down according to the proportionality principle Conclusion: The proposed Codex MRL is acceptable
Grape, juice	–		Median PF: 0.52 Robust (n = 3)
Dried grapes (= currants, raisins and sultanas)	–		Median PF: 0.52 Robust (n = 3)
Grape, wine	–		Median PF: 1.0 Robust (n = 3)
Grape, must	–		Median PF: 1.5 Robust (n = 3)
General comments	General discussion with risk managers how to deal with data gaps identified in the EU peer review for metabolites (metabolites IN-F6L99 and IN-N5M09 (found in processed commodities), see comments on toxicological reference values		

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

5.21.5. Consumer risk assessment

Table 102: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Not relevant for the EU (no ARfD was derived)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2018c) was updated including the STMR values derived by JMPR for cranberries, mangoes and strawberries. The calculations is based on the STMR values; where the MRL was set above the LOQ and no STMR value was available, the MRL was used as input value. Crops with MRLs at the LOQ are not included in the calculation The risk assessment was performed with the EU ADI	**Specific comments:** –
	Results: A long-term consumer health risk was identified The overall chronic exposure accounted for 152% of the ADI The contribution of cranberries, mangoes and strawberries to the exposure was < 0.01, 0.03 and 2.3% of the ADI, respectively The main contributor were the STMR for cattle milk (96% of the ADI, Dutch toddler), apples (20% for German child), and olives for oil production (12%, calculation with MRL, further refinement would be possible)	**Results:** Long-term exposure: 4-40% of the ADI

RA: risk assessment; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; LOQ: limit of quantification; ARfD: acute reference dose; ADI: acceptable daily intake.

5.22. Cyazofamid (281) R

5.22.1. Background information

Table 103: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	FR	
Approval status	Renewal of the approval	Commission Directive 2003/23/EC[(a)] as amended by Commission Implementing Regulation (EU) 2018/917[(b)], A decision on the renewal has not yet been taken
EFSA conclusion	Yes, see comments	EFSA (2016e)
MRL review	Yes, see comments	EFSA (2012e)
MRL applications	Yes, see comments	EFSA (2013g) (grapes) EFSA (2015d) (aubergines) EFSA (2015n) (spring/welsh onions, globe artichoke, leek and hops) Confirmatory data following Art. 12 review ongoing
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	No	Harmonised classification: none for tox. Peer review proposal: none ED: assessed before EU criteria were defined and implemented (2018)

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances OJ L 81, 28.3.2003, p. 39–42.
(b): 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.

5.22.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.2 mg/kg bw per day	JMPR (2015)	0.17 mg/kg bw per day	EFSA (2016e) (rat, 2-year, UF 100) Same in European Commission (2002)	Yes
ARfD	Unnecessary	JMPR (2015)	Not allocated, not necessary	EFSA (2016e) Same in European Commission (2002)	Yes
Conclusion/ comment	Parent compound: The ADI established by JMPR is based on the NOAEL of 17.1 mg/kg bw per day for increase in kidney weight and changes in blood urea nitrogen and urine volume in the 2-year carcinogenicity study in rat and applying an uncertainty factor (UF) of 100 The EU evaluation derived a comparable ADI based on the NOAEL of 17.1 mg/kg bw per day from the same study (2-year carcinogenicity study in the rat) considered by JMPR and applying an UF of 100. The small difference between JMPR and EU assessment is due to different rounding of the values obtained				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
	As regards the ARfD, JMPR and EU came to the same conclusion that no ARfD was necessary Metabolite CCIM: JMPR concluded that the ADI derived for parent compound is also applicable for CCIM. For this metabolite, an ARfD of 0.2 mg/kg bw was agreed by JMPR In the EU Experts' meeting 141, the same ADI was proposed for CCIM. However, as reported in the EFSA Conclusion, considering that a data gap was identified for CCIM with regard to genotoxicity testing (mammalian cell mutation assay, *in vitro* mutation test using mouse lymphoma L518Y cells) EFSA, after the experts' meeting, considered preferable not to set an ARfD for CCIM until its genotoxic potential is clarified				

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

5.22.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyazofamid	Reg. 396/2005: Cyazofamid	Yes
	Animal products	Not defined Fat solubility not specified	Reg. 396/2005: Cyazofamid The residue is fat soluble	Yes
RD RA	Plant products	Long-term dietary intake: Cyazofamid plus CCIM, expressed as cyazofamid short-term dietary intake: CCIM	Peer review and Art. 12 review (EFSA, 2012e, 2016e): Cyazofamid	No
	Animal products	Not defined	Peer review (EFSA, 2016e): Cyazofamid Art. 12 MRL review (EFSA, 2012e): no RD proposed due to expected low dietary burden	Yes
Conclusion/ comments	Primary crops: The JMPR and EU evaluations resulted in the same residue definitions for enforcement (cyazofamid) but different residue definitions for risk assessment were proposed Processed commodities: Peer review proposal: Cyazofamid and CCIM. Due to data gaps regarding the genotoxic potential and a repeated dose toxicity study to conclude on the toxicological relevance of CCIM, a final decision whether the residue definition should cover the sum or the two compounds separately has not been taken yet Animal matrices: As the metabolism studies in poultry and ruminants clearly showed that residues are not expected in animal matrices considering the dietary burden calculation based on the representative uses, EFSA proposes for monitoring and risk assessment to set the residue definition by default as cyazofamid only and no MRLs are required. Also, in the framework of Art.12 MRL review, the livestock exposure assessment was not triggered based on the EU authorised uses and no RD for monitoring and risk assessment was derived for products of animal origin			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.22.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Bulb onions, Subgroup of (includes all commodities in this subgroup)	**1.5**	0.01*	Critical GAP: USA GAP (bulb vegetables, including dry bulb onions): 6 × 0.087 kg a.s./ha (minimum interval of 7 days between application) and a PHI: 0 d (max. seasonal rate: 0.47 kg a.s./ha) Number of trials: 10 US residue trials on onion bulbs with a possible extrapolation to garlic and shallots Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL covers garlic, onions, shallots. It is noted the MRL proposal was reported for the wrong code (VA0035) which refers to the group of bulb vegetables. The correct code for the subgroup of bulb onions is VA2031 Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable, considering the data gap related to the metabolite CCIM
Green onions, Subgroup of (includes all commodities in this subgroup)	**6**	0.01*	Critical GAP: US GAP (bulb vegetables, including spring onions and chive leaves): 6 × 0.087 kg a.s./ha (minimum interval of 7 days between application) and a PHI: 0 days (max. seasonal rate: 0.47 kg a.s./ha) Number of trials: 5 trials on spring onions matching the GAP and 5 trials on chives but conducted with 9 instead of 6 applications Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL covers spring onions, chives and leek. The MRL proposal for the green onions, subgroup was derived from the residue data set on chives only and extrapolated to the whole subgroup. According to the JMPR extrapolation rules, residue trials on spring onion or leek can be used to derive a group MRL; data on chives are not appropriate. In the given case, it would be more appropriate to derive a MRL proposal of 6 mg/kg for chives and a MRL of 2 mg/kg for green onions, subgroup of, except chives (this MRL would be applicable also to leek). This proposal is in line with the JMPR methodology (FAO manual p 91 ff) Conclusion: The proposed Codex MRL is not acceptable because this MRL is derived from the residue trials on chives extrapolated to the whole subgroup. Furthermore, it should be discussed whether the proposed Codex MRL is acceptable, considering the data gap related to the metabolite CCIM
General comments	–		

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

5.22.5. Consumer risk assessment

Table 107: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant. An ARfD was not allocated to cyazofamid	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015n) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the crops for which Codex MRLs were derived For the remaining commodities, the existing EU MRL was used as an input value The calculations are indicative, since the residue definitions of JMPR and EU level are not fully compatible. Furthermore, data to exclude genotoxicity of CCIM were considered as not sufficient in the recent EU peer review	**Specific comments:** None
Results: Not relevant. An ARfD was not allocated to cyazofamid and is not required	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 1% of the ADI (DE child) The contribution of the crops under consideration to the exposure was low (max. for leek, 0.24%)	**Results:** Long-term exposure: 0.3% of the ADI Short-term exposure: Not relevant

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

5.23. Lufenuron (286) R

5.23.1. Background information

Table 108: Background information

		Comments, references
Type of JMPR evaluation	New uses	
RMS	PT	
Approval status	Approved	Commission Directive 2009/77/EU[(a)]
EFSA conclusion	Yes, see comments	EFSA (2009a)
MRL review	Yes, see comments	EFSA (2017c)
MRL applications	No	
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not met ED: not concluded	Harmonised classification and labelling for CMR – Annex VI: none EU Peer Review proposal for CMR (EFSA, 2009a): none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

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

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

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.02 mg/kg bw per day	JMPR (2015) (2-year dietary study in rats, SF 100)	0.015 mg/kg bw per day	EFSA (2009a) (1-year dog study, UF 100) European Commission (2011d)	Yes
ARfD	Unnecessary	JMPR (2015)	Not needed	EFSA (2009a) European Commission (2011d)	Yes
Conclusion/ comment	An ADI of 0.02 mg/kg bw was established on the basis of the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in the 2-year dietary study in rats, using a safety factor of 100. The same NOAEL from the 2-year rat study was derived by the EU peer review However, the EU peer review set the ADI on the NOAEL of 1.5 mg/kg bw per day based on liver changes (increased weight and incidence of cell hypertrophy) from a 1-year study, while in the JMPR report of 2015 a NOAEL of 7.02 mg/kg bw per day was proposed for this study				

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

5.23.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Lufenuron	EU Reg. 2018/78: Lufenuron Art 12 MRL review: Lufenuron (any ratio of constituent isomers) Peer review (EFSA, 2009a): Constituent isomers of lufenuron	Yes
	Animal products	Lufenuron The residue is fat soluble	EU Reg. 2018/78: Lufenuron Art 12 MRL review: Lufenuron (any ratio of constituent isomers) Peer review (EFSA, 2009a): Constituent isomers of lufenuron The residue is fat soluble	Yes
RD RA	Plant products	Lufenuron	Peer review (EFSA, 2009a): constituent isomers of lufenuron Art 12 MRL review: Lufenuron (any ratio of constituent isomers)	Yes
	Animal products			Yes
Conclusion/ comments	**Plant:** Residue definitions for enforcement and risk assessment in plant commodities are comparable **Animal:** Residue definitions for enforcement and risk assessment in animal commodities are comparable			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.23.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Coffee beans	**0.07**	0.05*	Critical GAP: BR, 2 × 40 g a.i./ha, interval of 30 days; PHI = 7 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Trials from Brazil matching the critical GAP Conclusion: The proposed Codex MRL is acceptable
Edible offal (Mammalian)	**0.15**	0.04 kidney, liver, 0.7 other edible offals	See meat (mammalian)
Lime	**0.4**	0.01*	Critical GAP: BR, 1 × 3.75 g a.i./ha, PHI = 28 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Trials from Brazil on limes matching the critical GAP Conclusion: The proposed Codex MRL is acceptable
Mammalian fats	**2**	0.7	See meat (mammalian except marine mammals)
Meat (mammalian except marine mammals)	**2(fat)**	0.03 (muscle)	Two feeding studies on lactating cows and steer are available Sufficiently supported by data: Yes; according to the RMS the feeding studies evaluated in the JMPR are the same as the evaluated in the EU. Three dose levels were used in the feeding study. According to the RMS the quality of the study is acceptable Specific comments/observations: The Meeting based its recommendations for mammalian products on the lactating cow feeding study, generally showing higher residues than the study with steer Conclusion: The proposed Codex MRL is acceptable. However, at EU level, MRLs are established only for muscle. The expected residue in muscle is 0.06 mg/kg, thus, the MRL for muscle should be set between 0.06 mg/kg and 0.08 mg/kg
Maize	**0.01**	0.01*	Critical GAP: BR, 1 × 15 g a.i./ha; PHI = 35 days Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: Trials from Brazil matching the critical GAP (4). In addition, the no-residue situation is supported by four trials where two foliar applications were made with harvest at 35 days (immature corn=sweet corn) and at approximately 50 days after last application (maize), residues were < 0.01 mg/kg for both immature and mature maize Conclusion: The proposed Codex MRL is acceptable. However, it is recommended to label the Codex MRL with an asterisk, indicating that the MRL is equal to the LOQ, considering the no-residue situation
Milks	**0.15**	0.1	One feeding study on lactating cows is available. See comments on meat (mammalian except marine mammals) Conclusion: The proposed Codex MRL is acceptable
Milk fats	**5**	–	Not relevant

Commodity	Codex MRL proposal	EU MRL	Comment
Oranges sweet, sour, Subgroup of (includes all commodities in this subgroup)	**0.3**	0.01*	Critical GAP: BR, 1 × 3.75 g a.i./ha, PHI = 28 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residue trials from Brazil on oranges according to the critical GAP Conclusion: The proposed Codex MRL is acceptable
Orange oil, edible	**8**	–	The MRL proposal was derived taking into account the PF of 24 At EU level, MRLs are set only for the unprocessed products, but not for processed products like orange oil
Pome fruits, Group of (includes all commodities in this group)	**1**	0.15	Critical GAP: Chile, 3 × 5 g a.i./hL; PHI = 18 days Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residues in 8 trials approximating critical GAP in Chile (deviations were noted for the PHI with sampling between 14 and 21 days) Conclusion: The proposed Codex MRL is acceptable
Orange juice			PF < 0.02
Apple juice			PF < 0.2, based on 1 processing study; at EU level one processing study would not e sufficient to derive a processing factor
Apple pure			PF < 0.2, based on 1 processing study; at EU level one processing study would not e sufficient to derive a processing factor
General comments	–		

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

5.23.5. Consumer risk assessment

Table 112: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant	**RA assumptions:** The most recent long-term risk assessment EFSA (2017c) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for the commodities for which MRL proposals were derived The EU ADI was used	**Specific comments** –
Results: –	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 83% of the ADI	**Results:** Long-term exposure: 2–10% of the ADI

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

5.24. Isofetamid (290) R

5.24.1. Background information

Table 113: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	BE	
Approval status	Approved	Commission Implementing Regulation (EU) 2016/1425[(a)]
EFSA conclusion (including MRL application)	Yes, see comments	EFSA (2015q); in the conclusion, MRL proposals were derived for a number of crops
MRL review	No	Not foreseen, since MRLs were set in the framework of the first approval
MRL applications	Yes, see comments	EFSA (2018h) (tomatoes, peppers, aubergines, okra and cucurbits with edible peel)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	 Not met Not met Not met Not met	Harmonised classification: none for tox EU Peer Review proposal for CMR: none ED assessment: not conducted because the peer review was finalised before the implementation of the current ED criteria

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): 2016/1425: Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 231, 26.8.2016, p. 30–33.

5.24.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR (2016)	0.02 mg/kg bw per day	EFSA (2015g) (1-year dog study, UF 100) European Commission (2016b)	No
ARfD	3 mg/kg bw	JMPR (2016)	1 mg/kg bw	EFSA (2015g) (developmental toxicity study with rabbit, UF 100) European Commission (2016b)	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				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	According to EFSA, 2015g, the reference values of parent compound (isofetamid) are applicable to metabolites and therefore also for metabolite GPTC (*N*-{1-[4-(b-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				

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

5.24.3. Residue definitions

Table 115: 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: 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: Isofetamid Peer review (EFSA, 2015q): Isofetamid (provisional, not required) Fat solubility open (pending confirmation by livestock feeding study, not required at this stage)	No
RD RA	Plant products	Isofetamid	Peer review (EFSA, 2015q); Art 10 MRL (EFSA, 2018h): Sum isofetamid and 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, 2015q): Sum isofetamid and 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, 2015q). 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, 2015q, 2018h). 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, 2015q) Animal commodities: For the animal residue definitions for enforcement, the JMPR, in contrast to provisional EU definition, has included the metabolite PPA. EFSA set the residue definition provisionally as isofetamid (only) considering that significant intake of isofetamid residues by livestock was not expected by livestock. This residue definition would have to be reconsidered when additional uses will lead to significant residue intakes by animals and considering the results of animal feeding studies. It is noted that in 2017 CCPR, the EU made a reservation for MRL proposals for animal commodities due to the different residue definition for enforcement.			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	According to the EU assessment, isofetamid was extensively metabolised in poultry and goat, and almost only present in significant proportions in milk fat (76% TRR) and goat fat (62% TRR), and other identified metabolites were all below 5% TRR except metabolite PPA present at ca 20% in kidney and liver of goat (EFSA, 2015q) The risk assessment residue definitions in animal commodities are identical, as both refer to the parent isofetamid and PPA expressed as isofetamid			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; LOQ: limit of quantification.

5.24.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Beans with pods, subgroup of (includes all commodities in this subgroup)	**0.6**	0.01*	Critical GAP: Canada and USA, 2 × 500 g/ha, 7- to 14-day interval, PHI 7 days Number of trials: 7 Sufficiently supported by data: Yes Specific comments/observations: trials on snap beans. Beans (with pods) are classified as a major crop in the EU, requiring 8 trials, but according to Codex criteria, a minimum of 5 trials are required Conclusion: The proposed Codex MRL is acceptable
Bush berries, subgroup of (includes all commodities in this subgroup)	**5**	0.01* (blueberries, currants, gooseberries and rose hips)	Critical GAP: 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: According to the EU classification, the number of trials is not sufficient to support extrapolation to the group of small fruit and berries but compliant with the Codex criteria. 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); details on this trial should be checked in the JMPR evaluation Using the OECD MRL calculator, the residue trials would suggest a MRL of 4 mg/kg The bush berries MRL would be applicable also to currants (154030), gooseberries (154040) and rose hips (154050) Conclusion: A lower MRL should be sufficient (4 mg/kg), if the highest value is a valid result
Cane berries, subgroup of (includes all commodities in this subgroup)	**3**	0.01*	Critical GAP: Canada, 3 × 496 g/ha, 7-day interval, PHI 7 days Number of trials: 5 trials on raspberries 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: According to the EU classification, extrapolation to whole subgroup cane fruit (153000) is possible Conclusion: The proposed Codex MRL is acceptable
Cherries, subgroup of (includes all commodities in this subgroup)	**4**	0.01*	Critical GAP: Canada and USA, 3 × 365 g/ha, 7-day interval, PHI 1 days Number of trials: 13 Sufficiently supported by data: Yes Specific comments/observations: None Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Dry beans, subgroup of (except soya bean (dry))	**0.05**	0.01*	Critical GAP: 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 MRL of 0.05 mg/kg proposed by JMPR is questionable, as it is lower than the HR (0.08 mg/kg); The MRL proposal derived using the OECD calculator is 0.09 mg/kg. The Codex MRL would be applicable also to dry lupin (300040) Conclusion: The available residue trials would suggest a higher MRL of 0.09 mg/kg
Dry peas, subgroup of (includes all commodities in this subgroup)	**0.05**	0.01*	Critical GAP: Canada and USA, 2 × 500 g/ha, 7-day interval, PHI 30 days Number of trials: 11 trials on peas and 8 trials on beans Sufficiently supported by data: Yes Specific comments/observations: The MRL of 0.05 mg/kg proposed by JMPR is questionable, as it is lower than the HR (0.08 mg/kg); The MRL proposal derived using the OECD calculator is 0.09 mg/kg The MRL proposal for dry peas would be also applicable to dry lentils (300020) Conclusion: The available residue trials would suggest a higher MRL of 0.09 mg/kg
Peaches, subgroup of (including Nectarine and Apricots) (includes all commodities in this subgroup)	**3**	0.01*	Critical GAP: Canada and USA, 3 × 365 g/ha, 7-day interval, PHI 1 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL would be applicable also to apricots. At EU level, the trials on peaches would not be used for extrapolation to apricots Conclusion: The proposed Codex MRL is acceptable
Peas with pods, subgroup of (includes all commodities in this subgroup)	**0.6**	0.01*	Critical GAP: Canada and USA, 2 × 500 g/ha, 7- to 14-day interval, PHI 7 days Number of trials: 7 trials are available on snap beans (beans with pods) Sufficiently supported by data: Yes Specific comments/observations: According to the JMPR, beans with pods (*Phaseolus vulgaris* varieties) are a representative crop for peas with pods and therefore the trials can be used to support the use in peas with pods. The extrapolation from beans with pods to peas with pods is also allowed according to the EU guidance document on extrapolation Conclusion: The proposed Codex MRL is acceptable
Plums, subgroup of (including fresh Prunes) (includes all commodities in this subgroup)	**0.8**	0.01*	Critical GAP: Canada and USA, 3 × 365 g/ha, 7-day interval, PHI 1 day Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: None Conclusion: The proposed Codex MRL is acceptable
Pome fruits, group of (includes all commodities in this group)	**0.6**	0.01*	Critical GAP: USA, 6 × 365 g/ha, 7-day interval, PHI 20 days Number of trials: 16 apples, 9 pears Sufficiently supported by data: Yes Specific comments/observations: The JMPR combined residue trials as of the same residue populations (Mann-

Commodity	Codex MRL proposal	EU MRL	Comment
			Whitney test). The CXL would be applicable to the whole group of pome fruits and to azaroles (154070) and kaki (161060). At EU level the extrapolation from apples and pears to azaroles would not be accepted Conclusion: The proposed Codex MRL is acceptable
Prunes, dried	3	–	A concentration of residues in dried prunes occurs and a PF of 4.0 was derived from two processing studies. No EU MRLs are set for processed prunes
Apple juice	–	–	A reduction of residues in juice occurs and a PF of 0.31 was derived from one processing study. 1 study is not sufficient to derive a robust processing factor
General comments			

GAP: Good Agricultural Practice; PHI: preharvest interval; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; HR: highest residue; CXL: Codex Maximum Residue Limit; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.

5.24.5. Consumer risk assessment

Table 117: 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 performed using PRIMo rev.3, for commodities assessed by JMPR as outlined in Section 2 Assessment'. In order to estimate the contribution of the plant metabolite GPTC, according to the EU risk assessment residue definition, EFSA applied the previously derived conversion factor (CF) for risk assessment for peaches (also used for apricots) and plums (CF 1.1) (EFSA, 2015q). The risk assessment is indicative for the other commodities under consideration (pome fruit, cherries, blackberries, dewberries, raspberries, other cane fruit, blueberries, currants, gooseberries, rose hips, azarole, kaki, beans (with pods), peas (with pods), beans, lentils, peas, lupins and other pulses) because a conversion factor to accommodate the possible occurrence of residues of metabolite GPTC was not available which may lead to an underestimation of residue levels The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2018h) was updated using PRIMo rev.3 as outlined in the Section 'Assessment'. An indicative risk assessment was performed using the STMR values derived by the JMPR for pome fruit, apricots, cherries, peaches, plums, blackberries, dewberries, raspberries, other cane fruit, blueberries, currants, gooseberries, rose hips, azarole, kaki, beans (with pods), peas (with pods), beans, lentils, peas, lupins and other pulses. In order to estimate the contribution of the plant metabolite GPTC, according to the EU risk assessment residue definition, EFSA applied the previously derived conversion factor (CF) for risk assessment for peaches (also used for apricots) and plums (CF 1.1) (EFSA, 2015q). For other commodities under consideration, a conversion factor was not available which may lead to an underestimation of residue levels. For all other commodities EFSA applied the MRLs established in Commission Regulation (EU) 2018/1514 The EU ADI was used	**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
Results: No short-term exposure concern was identified. The commodities under consideration leading to highest exposure are (in rank order): peaches (18% of the ARfD), apricots (7% of the ARfD), pears (6% of the ARfD), apples (5% of the ARfD)	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 29% of the ADI (NL toddler). From the commodities under consideration, the contribution to the total exposure was the highest for residues in apples (7% of the ADI)	**Results:** Long-term exposure: 0–6% of the ADI Short-term exposure: 3% of the ARfD

RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level; ARfD: acute reference dose; ADI: acceptable daily intake.

5.25. Oxathiapiproline (291) R

5.25.1. Background information

Table 118: Background information

		Comments, references
Type of JMPR evaluation	New use	
RMS	IE	
Approval status	Approved	Commission Implementing Regulation (EU) 2017/239[(a)]
EFSA conclusion	Yes, see comments	EFSA (2016f) EU MRLs were derived in the EFSA conclusion (cucumber, gherkins, courgette, melons, as well as for the representative uses (table and wine grapes, tomatoes, aubergines, lettuces, grape leaves)
MRL review	No	Not foreseen, since EU MRLs were assessed in the framework of the first approval
MRL applications	ongoing	MRLs and IT applications in various crops (under clock stop)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disruptive (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: no entry EU Peer Review proposal for CMR: none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

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

(a): 2017/239: Commission Implementing Regulation (EU) 2017/239 of 10 February 2017 approving the active substance oxathiapiprolin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 39–42.

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	4 mg/kg bw per day	JMPR (2016) (2-generation rat, SF 100)	0.14 mg/kg bw per day	EFSA (2016f) (1-year dog, UF 100)	No
ARfD	Unnecessary	JMPR (2016)	Not necessary	EFSA (2016f)	Yes
Conclusion/ comment	For the 1-year dog study, JMPR has concluded that no adverse findings were observed up to the top dose level in the dog studies (i.e. at least 1,242 mg/kg bw per day), whereas the EU peer review concluded that the increase in relative liver weight (more than 20% compared to the control group) at the two high-dose levels was triggering a NOAEL of 13.6 mg/kg bw per day For the rat multigeneration study, JMPR established an ADI of 4 mg/kg bw per day on the basis of the NOAEL of 430 mg/kg bw per day for delayed balanopreputial separation in offspring at the top dose, whereas the EU peer review concluded that the NOAEL for the offspring was 86.37 mg/kg bw per day based on delayed preputial separation at the two high doses EU peer review (EFSA, 2016f): – the metabolite **IN-E8S72**, with no genotoxic potential, was granted an ADI of 1.157 mg/kg bw per day, on the basis of a 28-day rat study and applying an uncertainty factor of 1,000 to cover the extrapolation of subacute to long-term toxicity and for the lack of a complete toxicity data package – the metabolite **IN-SXS67**, with no genotoxic potential, was considered as covered by the toxicological profile of IN-E8S72, being its glucoside form It is noted that JMPR (in 2016f) concluded that these metabolites are all covered by studies in the rat For the metabolite **IN-WR791**, additional data (*in vitro* micronucleus test) have been submitted in the context of the MRL evaluation (February 2019). Based on the overall weight of evidence, EFSA considers that this metabolite is unlikely to be genotoxic. No further assessment of the toxicological profile of the metabolite in comparison with oxathiapiprolin has been provided				

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

5.25.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Oxathiapiprolin	EU Reg. 2017/1016: Oxathiapiprolin	Yes
	Animal products	Oxathiapiprolin The residue is not fat soluble	EU Reg. 2017/1016: Oxathiapiprolin The residue is not fat soluble	Yes
RD RA	Plant products	Sum of oxathiapiprolin, 5-(Trifluoromethyl)-1*H*-pyrazole-3-carboxylic acid (IN-E8S72) and 1-β-D-Glucopyranosyl-3-(-(trifluoromethyl)-1*H*-pyrazole-5-carboxylic acid (IN-SXS67), expressed as parent	Oxathiapiprolin	No
	Animal products			No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion/ comments	The enforcement residue definitions for plant and animal commodities are comparable The risk assessment residue definition derived by the JMPR includes two major soil/rotational crop metabolites IN-E8S72 and IN-SXS67 The EFSA peer review concluded that both metabolites are of lower toxicity than oxathiapiprolin and therefore did not include them in the risk assessment residue definition In the framework of Article 10 (Regulation (EC) No 396/2005), an MRL application was submitted to EFSA on the setting of import tolerances and modification of existing EU MRLs of oxathiapiprolin in a wide range of crops. An assessment was temporarily suspended, awaiting the applicant to address data requirements related to toxicity of metabolite IN-WR791, which is one of the major metabolites in crops following soil treatment (see also comments on IN-WR791 in section toxicological reverence values) The 2016 JMPR decided not to include this metabolite in the residue definitions as 1) its toxicity is no greater than parent, 2) low residues are expected and 3) low contribution to max long-term burden			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.25.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Basil (fresh)	**10**	0.02*	Critical GAP: USA, foliar, indoor/outdoor, 4 × 35 g/ha, interval 5 days, PHI 0 day Number of trials: 6 (outdoor) + 2 (indoor) Sufficiently supported by data: Yes Specific comments/observations: The indoor and outdoor residue data sets were merged. According to EU and JMPR rules, for indoor use, additional 2 trials would be necessary. Outdoor use is sufficiently supported, but from the merged data it is not possible to identify which values refer to outdoor use. For risk assessment, mean residues in rotational leafy vegetables added to the STMR value (see comments below) Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering the limited information on indoor uses and the ongoing discussion on the toxicological properties for IN-WR791
Basil, dry	**80**	–	Critical GAP: USA (indoor/outdoor) 4 × 35 g/ha, interval 5 days, PHI 0 days Number of trials: 4 Sufficiently supported by data: Choose an item. Specific comments/observations: Samples from 4 residue trials with fresh basil (see above) were dehydrated No EU MRLs are set for dry basil
Cane berries, Subgroup of (includes all commodities in this subgroup)	**0.5**	0.01*	Critical GAP: USA, soil 2 × 281 g/ha, 7-day interval, PHI 7 days Number of trials: 5 (4 raspberry, 1 blackberry) Sufficiently supported by data: Yes Specific comments/observations: On the basis of 5 trials, an extrapolation to cane berry subgroup is proposed (raspberries, blackberries, dewberries). According to EU rules, another trial on blackberry would be required, but according the Codex criteria, 5 trials are sufficient. The highest value 0.22 mg/kg seems to be an outlier (remaining values: 3 × < 0.01, 0.022) Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering the ongoing discussion on the toxicological properties for IN-WR791

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus fruit, Group of (includes all commodities in this group)	**0.05**	0.01*	Critical GAP: USA, foliar 1 × 35 g/ha, PHI 0 d Number of trials: 23 (5 lemon, 6 grapefruit, 12 orange) Sufficiently supported by data: Yes Specific comments/observations: The trials were performed with soil + foliar treatment and considered acceptable on the basis that side-by-side trials performed with only soil application indicated no-residue situation from soil treatments. CXL applies also to kumquat (miscellaneous fruit). The MRL proposal may not be sufficient for kumquat Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering the ongoing discussion on the toxicological properties for IN-WR791
Citrus oil, edible	**3**		The PF of 47 derived from 2 processing studies with parent compound. No EU MRLs are set for citrus oil
Citrus pulp, dry	0.15		The PF of 2.7 derived from 2 processing studies with parent compound. No EU MRLs are set for citrus pulp
Edible offal (mammalian)	W0.01*	0.01*	JMPR estimated the mean and maximum dietary burden for parent compound and for the sum of the two metabolites included in the residue definition for risk assessment (IN.E8S72 + IN-SXS67). However, from the presentation of the calculation in Annex 6 of the JMPR report, it is not possible to verify the correctness of the calculation for parent oxathiapiprolin (the tables presenting the dietary burden calculation cover only soybean meal and soybean seed; all other feed items are not considered/not reported) Feeding studies are not available. In 2016, MRL proposals were derived from the goat metabolism study with oxathiapiprolin (1.2 N the max Australian DB for dairy cattle). 2018 JMPR decided to withdraw the previously recommended MRLs for meat, edible offal, fat and milk. The rationale is not further explained in the JMPR report To discuss with risk managers whether it is acceptable to establish MRLs for commodities that are used as feed items (e.g. kale), if the expected residues in animal commodities cannot be estimated reliably
Eggs	0.01*	0.01*	The calculated critical dietary burden (EU) for poultry has increased but does not affect the conclusions of 2016 JMPR that residues of oxathiapiprolin, IN-E8S72 and IN-SXS67 are not expected in poultry commodities. However, from the presentation of the calculation in Annex 6 of the JMPR report, it is not possible to verify the correctness of the calculation for parent oxathiapiprolin (the tables only present soybean meal and soybean seed residues; all other feed items are not considered/ not reported) The Meeting confirmed the existing CXL which is set at the same level as the EU MRL
Leaves of Brassicaceae, Subgroup of (includes all commodities in this subgroup)	**10**	0.01* (leafy brassica; land cress, rucola, red mustards, baby leaf crops)	Critical GAP: USA, 4 × 35 g/ha, foliar, interval 5 days, PHI 0 day Number of trials: 10 (mustard greens) Sufficiently supported by data: Yes Specific comments/observations: According to EU rules, such extrapolation would not be acceptable (only kale to leafy brassica and no extrapolation from leafy brassica to crops in lettuce group). According to CCPR, the extrapolation is acceptable. For risk assessment mean residues in rotational leafy vegetables added to the STMR value (see comments below) Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering the ongoing discussion on the toxicological properties for IN-WR791

Commodity	Codex MRL proposal	EU MRL	Comment
Maize	0.01*	0.01*	Critical GAP: Indonesia, 1 × 0.882 g/kg seed (220 μ/seed) Number of trials: 8 Sufficiently supported by data: Yes Specific comments/observations: Residue trials on maize from India and Thailand. For risk assessment mean residues in rotational cereals (grain) added to the STMR value (see comments below) Conclusion: The proposed Codex MRL is acceptable, considering that the MRL is proposed at the LOQ
Maize fodder	0.01*	0.01*	The fodder and forage samples from maize (treated according to the GAP on maize, as mentioned above) were analysed for residues, which were < LOQ. For dietary burden calculation for metabolites IN-E8S72 and IN-SXS67, residues in rotational crops (cereal forage and straw) were added to the risk assessment values No EU MRLs are set for maize fodder
Mammalian fats (except milk fats)	W 0.01*	0.01*	See comments on edible offal (mammalian)
Meat (from mammals other than marine mammals)	W 0.01*	0.01*	See comments on edible offal (mammalian)
Milks	W 0.01*	0.01*	See comments on edible offal (mammalian)
Poppy seed	0.01*	0.01*	Critical GAP: Australia, foliar 1 × 35 g/ha, PHI 42 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments/observations: Trials from 5 locations (5 independent), consisting of 4 trials GAP compliant, 4 trials 2 × cGAP and 1 trial 4 × cGAP. Since residues in all trials < LOQ, overdosed trials acceptable. For risk assessment, mean residues in rape seed rotational crop added to the STMR value (see comment below) Conclusion: The proposed Codex MRL is acceptable, considering that the MRL is proposed at the LOQ
Potato	W 0.01*	0.01*	Existing CXL is proposed to be replaced by group MRL for tuberous and corm vegetables
Poultry edible offal	0.01*	0.01*	See comments on eggs
Poultry fats	0.01*	0.01*	See comments on eggs
Poultry meats	0.01*	0.01*	The calculated critical dietary burden (EU) for poultry has increased but does not affect the conclusions of 2016 JMPR that residues of oxathiapiprolin, IN-E8S72 and IN-SXS67 are not expected in poultry commodities. The Meeting confirmed the existing MRLs
Soya bean (dry)	0.01*	0.01*	Critical GAP: USA, 12–24 μg/seed Number of trials: 6 overdosed trials Sufficiently supported by data: Yes Specific comments/observations: No quantifiable residues were found in the overdosed residue trails; thus, the reduced number of trials is acceptable. For risk assessment, the mean residues measured in rotational crops (pulses) were to the STMR value derived in primary crops (see comments below) Conclusion: The proposed Codex MRL is acceptable, considering that the MRL is proposed at the LOQ

Commodity	Codex MRL proposal	EU MRL	Comment
Soya bean hay	0.02	0.01*	The hay and forage samples from soya (treated according to the GAP on soya bean, as mentioned above) were analysed for residues, which were <LOQ. For dietary burden calculation, for metabolites IN-E8S72 and IN-SXS67, residues in rotational crops (legume forage and hay) were added to the risk assessment values No EU MRLs are set for soya bean hay
Sunflower seed	0.01*	0.01*	Critical GAP: USA 1 × 9.4–18.8 μg/seed Number of trials: 8 (CAN/USA) Sufficiently supported by data: Yes Specific comments/observations: Identical NEU/SEU uses reported under Art. 10 MRL assessment (clock stop). For risk assessment mean residues in rape seed rotational crop added to the STMR value Conclusion: The proposed Codex MRL is acceptable, considering that the MRL is proposed at the LOQ
Sweet potato	W0.01*	0.01*	See comments on tuberous and corm vegetables
Tuberous and corm vegetables, Subgroup of (includes all commodities in this subgroup)	**0.04**	0.01* (potatoes, arrowroot, cassava, sweet potato, yams, yacons (listed in part B under chicory roots)	Critical GAP: USA, 2 × 140 g/ha (in-furrow+ soil) Number of trials: 16 trial on potatoes Sufficiently supported by data: Yes Specific comments/observations: Extrapolation from potatoes to whole group is in line with Codex rules. However, at EU level, extrapolation would not be acceptable to Jerusalem/Chinese artichoke and chicory roots (yacons). For risk assessment mean residues in rotational root vegetables added to the STMR value (see comments below) Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering the ongoing discussion on the toxicological properties for IN-WR791
Young shoots, Subgroup of (includes all commodities in this subgroup)	**2**	0.01* (asparagus, bamboo shoots)	Critical GAP: USA, 2 × 281 g/ha, soil, interval 14 days, PHI 0 days Number of trials: 8 trials in asparagus Sufficiently supported by data: Yes Specific comments/observations: Extrapolation from asparagus to whole group is in line with Codex rules, but is not allowed in the EU. For risk assessment mean residues in rotational stem vegetables added to the STMR value (see comments below). Conclusion: It is recommended to discuss with MS whether the proposed Codex MRL is acceptable considering the ongoing discussion on the toxicological properties for IN-WR791
Broccoli		0.01*	The STMR value derived by 2016 JMPR in primary crop (broccoli) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + In-SXS67. It is unclear why in this case residues in rotational stem vegetables group were considered, instead of leafy vegetables (0.33 mg/kg)
Cabbages, Head		0.01*	The STMR value derived by 2016 JMPR in primary crop (head cabbage) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + In-SXS67. It is unclear why in this case residues in rotational stem vegetables group were considered, instead of leafy vegetables (0.33 mg/kg)
Cauliflower		0.01*	The STMR value derived by 2016 JMPR in primary crop (cauliflower) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + In-SXS67. It is unclear why in this case residues in rotational stem vegetables group were considered, instead of leafy vegetables (0.33 mg/kg)

Commodity	Codex MRL proposal	EU MRL	Comment
Citrus juice			The processing factor of < 0.2 derived from 2 processing studies. Residues of parent and metabolites were below the LOQ. No EU MRLs are set for citrus juice
Garlic		0.01*	The STMR value derived by 2016 JMPR in primary crop (bulb onion) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + In-SXS67. It is unclear why in this case residues in rotational stem vegetables group were considered, instead of leafy vegetables (0.33 mg/kg)
Kumquats (whole fruit)		0.01*	
Leek		0.01*	The STMR value derived by 2016 JMPR in primary crop (leek) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + In-SXS67
Onion, bulb		0.01*	The STMR value derived by 2016 JMPR in primary crop (bulb onion) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + IN-SXS67. It is unclear why in this case residues in rotational stem vegetables group were considered, instead of leafy vegetables (0.33 mg/kg)
Spring onion		0.01*	The STMR value derived by 2016 JMPR in primary crop (spring onion) was updated, adding the residues observed in rotational crops, i.e. stem vegetables (0.056 mg/kg). The STMR value refers to the total residues of oxathiapiprolin + IN-E8S72 + IN-SXS67. It is unclear why in this case residues in rotational stem vegetables group were considered, instead of leafy vegetables (0.33 mg/kg)
General comments	JMPR accounted for the presence of metabolites IN-E8S72 and IN-SXS67 which are metabolites expected in rotational crops by adding a constant residue concentration of these two metabolites (expressed as parent) to the residue concentration measured in primary crops. These constant values ranged from 0.33 mg/kg for leafy vegetables to 0.056 for stem vegetables and cereal grains. Using the risk assessment values derived by JMPR is therefore leading to higher exposure compared to the EU residue definition		

GAP: Good Agricultural Practice; PHI: preharvest interval; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; STMR: supervised trials median residue; MRL: maximum residue level; CXL: Codex Maximum Residue Limit; MS: Member State; PF: processing factor; LOQ: limit of quantification; NEU: northern European Union; SEU: southern European Union; DB: Dietary Burden.
*: Indicates that the input value is proposed at the limit of quantification.

5.25.5. Consumer risk assessment

Table 122: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Short-term risk assessment was not undertaken as no ARfD is established	**RA assumptions:** An indicative long-term risk assessment was performed using PRIMo rev.3. The EU MRLs as established for oxathiapiprolin in Regulation (EC) No 2017/1016 were used as input values. For those commodities for which the CXL proposal is higher than the existing EU MRL, the STMR value proposed by JMPR was used as input value	**Specific comments:** The JMPR exposure assessment is more conservative, as it also considers the contribution of oxathiapiprolin metabolites E8S72 and IN-SXS67. In addition, the residue accumulation in primary commodities from the crop rotation is taken into account

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
	Further refinements of the calculation would be possible. The calculation is indicative, awaiting the assessment of the toxicological data for metabolite IN-WR791. The EU ADI was used	
	Results: No long-term consumer health risk was identified The overall chronic exposure accounted for 3% of the ADI	**Results:** Long-term exposure: 0% of the ADI

RA: risk assessment; ARfD: acute reference dose; MRL: maximum residue level; CXL: Codex Maximum Residue Limit; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake.

5.26. Ethiprole (304) R,T

5.26.1. Background information

Table 123: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	UK	
Approval status	Not approved	Never notified and authorised in the EU
EFSA conclusion	No	
MRL review	No	
MRL applications	ongoing	Application for setting of an import tolerance in rice (EMS: UK)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded.	Harmonised classification for CMR – Annex VI: no entry in Annex VI EU Peer Review proposal for CMR: not conducted ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(a)]): not conducted

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

5.26.2. Toxicological reference values

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

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.005 mg/kg bw per day	JMPR (2018)	–	No agreed EU ADI	No comparison possible
ARfD	0.005 mg/kg bw	JMPR (2018)	–	No agreed EU ARfD	No comparison possible

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
Conclusion/ comment	JMPR proposes to apply the ADI and the ARfD to ethiprole, ethiprole-amide and ethiprole-sulfone, expressed as ethiprole. The substance has not been assessed in Europe The assessment of an import tolerance application under Article 10 is ongoing. The main data gaps identified were the hazard assessment of the ED potential of ethiprole, the assessment of classification and labelling of ethiprole regarding carcinogenicity and reproductive toxicity and the assessment of the developmental neurotoxicity potential of ethiprole (including assessment of published one generation developmental neurotoxicity in mice) Data gaps were identified regarding the assessment of the clastogenic and aneugenic potential of RPA 112916 and clarifications on whether RPA097973 is covered by parent In the framework of the import tolerance application, the EMS proposed an ADI of 0.005 mg/kg bw per day and an ARfD of 0.03 mg/kg bw. As long as the data gaps are not sufficiently addressed, a conclusion on EU TRV is pending. EFSA noted that the published one generation developmental neurotoxicity in mice might trigger lower reference values as the one proposed by JMPR (this study seems not to be available to JMPR)				

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

5.26.3. Residue definitions

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

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Ethiprole	Ethiprole (no specific residue definition reported in Regulation (EC) No 396/2005; thus, the default residue definition containing parent compound only is applicable	Yes
	Animal products	Sum of ethiprole and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents The residue is fat soluble	Ethiprole (no specific residue definition reported in Regulation (EC) No 396/2005; thus, the default residue definition containing parent compound only is applicable Fat solubility currently not specified in the EU legislation. However, considering the findings of animal metabolism studies, it is recommended to classify the residues as fat soluble	No
RD RA	Plant products	Sum of ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-(ethylsulfinyl)-1*H*-pyrazole-3-carboxamide (ethiprole-amide) and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents	RD proposed in MRL application for rice (assessment ongoing): Sum of ethiprole and RPA097973 (ethiprole sulfone), expressed as ethiprole	No

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Animal products	Sum of ethiprole and 5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-ethylsulfonylpyrazole-3-carbonitrile (ethiprole-sulfone), expressed as parent equivalents	No residue definition set at EU level	No comparison possible
Conclusion/ comments	Metabolism in plants was investigated in rice, sweet pepper and cotton as well as in rotational crops. Metabolism studies in goats and poultry available			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.26.4. Codex MRL proposals

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

Commodity	Codex MRL proposal	EU MRL	Comment
Coffee beans	**0.07**	Default 0.01*	Critical GAP: BR, 2 × 500 g/ha, 60-day PHI Number of trials: 10 GAP-compliant trials Sufficiently supported by data: if it is confirmed that the trials are valid, yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
Coffee beans, roasted	0.2		The MRL proposal was derived from the trials in coffee beans (green) using PF derived from one processing study (1.95) and rounding to the next MRL class No MRLs are set in the EU for roasted coffee beans
Edible offal (mammalian)	**0.1**	Default 0.01*	JMPR calculated the dietary burden and estimated the expected residues in animal commodities using a feeding study (lactating cows). The dietary burden calculation was not reported in Annex 6 of the JMPR report to verify the calculations According to the information provided in the JMPR report, the MRL proposal is plausible
Eggs	**0.05**	Default 0.01*	JMPR calculated the dietary burden and estimated the expected residues in animal commodities using a feeding study (laying hens). The dietary burden calculation was not reported in Annex 6 of the JMPR report to verify the calculations According to the information provided in the JMPR report, the MRL proposal is plausible
Mammalian fats (except milk fats)	**0.15**	Default 0.01*	See comments on edible offal (mammalian)
Meat (from mammals other than marine mammals)	**0.15(fat)**	Default 0.01*	See comments on edible offal (mammalian) For muscle, no MRL proposal was derived by JMPR. From the feeding study, EFSA assumes that a value of 0.03 mg/kg would be appropriate for muscle
Milk fats	0.5	Default 0.01*	Usually, the MRL for milk fat would be expected to be 25 times higher than the MRL in milk. Thus, for milk fat, a value of 0.375 mg/kg would be derived using the default approach. In the current case, JMPR derived the MRL for milk fat from one samples of the feeding study where milk cream was analysed. The milk fat value was derived by using an assumption on the fat content of cream EFSA is of the opinion that the approach used by JMPR is not appropriate. A slightly lower MRL of 0.4 mg/kg would be sufficient for milk cream

Commodity	Codex MRL proposal	EU MRL	Comment
Milks	**0.015**	Default 0.01*	See comments on edible offal (mammalian)
Poultry meat	**0.05 (fat)**	Default 0.01*	See comments on eggs For muscle, no MRL proposal was derived by JMPR. From the feeding study, EFSA assumes that a value of < 0.02 mg/kg would be appropriate for poultry muscle
Poultry edible offal of	**0.05**	Default 0.01*	See comments on eggs
Poultry fats	**0.05**	Default 0.01*	See comments on eggs
Rice	3	–	In the EU, MRLs are set for husked rice, but not for paddy rice Critical GAP: TH, 94 g/ha (foliar application), 14-day PHI; number of applications not specified Number of trials: 12 trials with 3 or 4 × 91 to 110 g/ha (foliar applications), PHI 14–16 days
Rice, husked	**1.5**	Default 0.01*	MRL for husked rice was derived from residue trials in rice, using a PF derived from one processing study (0.36) and rounding the result up If the validity of the residue trials is confirmed, the MRL proposal would not be acceptable, because the number of processing studies is insufficient. In the EU at least 2 processing studies are required to derive a robust processing factor Furthermore, the proposed MRL is too high: the results of the residue trials should be recalculated to husked rice individually; these residue concentrations should be used in the MRL calculator to derive the MRL proposal. Following this approach, the derived MRL would be 0.8 mg/kg
Rice, polished	0.4		One processing study was provided (PF 0.11)
General comments	If risk managers decide to accept the Codex MRLs for animal products, the EU residue definition needs to be modified		

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

5.26.5. Consumer risk assessment

Table 127: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An indicative short-term dietary risk assessment was performed for coffee beans, rice husked and the animal products for which MRL proposals were derived by JMPR The JMPR ARfD was used. The risk assessment is indicative, pending a detailed evaluation of the toxicological properties of the active substance and a final conclusion on the residue definitions (Art. 10 application on rice)	**RA assumptions:** EFSA calculated an indicative long-term exposure, using the existing (default) EU MRLs and the STMR derived for the commodities under assessment The JMPR ADI was used The risk assessment is indicative, pending a detailed evaluation of the toxicological properties of the active substance and a final conclusion on the residue definitions (Art. 10 application on rice)	**Specific comments** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure concern was identified (35% of the ARfD for rice)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 29% of the ADI The highest contributor was milk (13% of the ADI)	**Results:** Long-term exposure: 1–6% of the ADI Short-term exposure: 80% of the ARfD

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

5.27. Fenpicoxamid (XDE-777) (305) R,T

5.27.1. Background information

Table 128: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	UK	Co-RMS: FR
Approval status	Approved	Commission Implementing Regulation (EU) 2018/1265[(a)]
EFSA conclusion	Yes, see comments	EFSA (2018d) (including MRL application)
MRL review	No	
MRL applications	Yes, see comments	Bananas, rye, wheat, assessed together with the application for approval, see EFSA (2018d)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not met. ED: not concluded	Harmonised classification and labelling for CMR – Annex VI: none EU Peer Review proposal for CMR: none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

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

(a): Commission Implementing Regulation (EU) 2018/1265 of 20 September 2018 approving the active substance fenpicoxamid 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 238, 21.9.2018, p. 77–80.

(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.

5.27.2. Toxicological reference values

Table 129: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.05 mg/kg bw per day	JMPR (2018) (18-month mouse study, SF 100)	0.05 mg/kg bw per day	EFSA (2018d) (18-month mouse study, UF 100) (European Commission, 2018b)	Yes
ARfD	Unnecessary	JMPR (2018)	1.8 mg/kg bw	EFSA (2018d) (Developmental study in rabbits, UF 100) (European Commission, 2018b)	No

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
Conclusion/ comment	Same ADI based on a NOAEL of 5.3 mg/kg bw per day from the 18-months mouse carcinogenicity study based on liver changes observed at 32 mg/kg bw per day. However, JMPR takes also into consideration an 'equivocal increase in the incidence of adenomas at 32 mg/kg bw per day', while the EU peer review concluded that the incidence of adenomas was not clearly dose-related and within historical control data. Therefore, this finding was not considered for the NOAEL setting Regarding the ARfD derivation, the EU peer review considered the maternal toxicity observed in the rabbit developmental study (i.e. a body weight loss occurring during the first days of the study (with subsequent recovery)) relevant for the derivation of the ARfD. Therefore, the agreed ARfD was 1.8 mg/kg bw based on the maternal NOAEL of 177 mg/kg bw per day from the rabbit developmental toxicity study It is also noted that for the same rabbit developmental toxicity study, JMPR proposes a NOAEL for maternal toxicity at 52.8 mg/kg bw per day based on decreased body weight gain, feed consumption and faecal output at 177 mg/kg bw per day, while the EU peer review did not consider the effects observed at this dose as adverse Concerning the metabolites considered during the **EU peer review**: – for X642188, same assessment for acute toxicity and Ames test as in JMPR report – for X12326349, the reference values of the parent are applicable, since it is considered a major rat metabolite, while in the **JMPR report** it is mentioned that **insufficient information** was available – for X12019520, X12335723 and X12264475, further data are needed to exclude a genotoxic potential – for X12314005, X12019520, X12264475, and X12335723 further data may be needed to perform a consumer risk assessment On the contrary, JMPR uses the TTC approach for X12314005, X12264475, X12335723 for the assessment of chronic toxicity The metabolite X696872 is mentioned in the JMPR report but not in the EU peer review				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; UF: uncertainty factor; NOAEL: no observed adverse effect level; TTC: threshold of toxicological concern.

5.27.3. Residue definitions

Table 130: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fenpicoxamid	Regulation 396/2005: Fenpicoxamid	Yes
	Animal products	No residue definition was derived by JMPR	Regulation 396/2005: Ruminants: X12326349 expressed as fenpicoxamid The residue is not fat soluble	Comparison not relevant
RD RA	Plant products	Fenpicoxamid	Peer review EFSA (2018d): Fenpicoxamid	Yes
	Animal products	No residue definition was derived by JMPR	Peer review EFSA (2018d): Ruminants: X12326349 expressed as fenpicoxamid Poultry: Not necessary (in the view of the representative use)	Comparison not relevant
Conclusion/ comments	The same metabolism studies in plant were submitted and assessed under EU peer review process. The residue definition for enforcement and risk assessment in plant proposed by the JMPR are comparable with the EU proposals			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Under processing condition simulating (pasteurisation, sterilisation, boiling), fenpicoxamid degraded completely into **X12314005, X12016520, X12335723, and X12264475**. Therefore, for processed commodities, the risk assessment residue definition was provisional proposed as fenpicoxamid, X12019520, X12314005, X12335723, X12264475 (EFSA, 2018d)			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

5.27.4. Codex MRL proposals

Table 131: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Banana	0.15	0.15 proposed in peer review	Critical GAP: 3 × 0.05 kg/ha, PHI 8 days Number of trials: 11 Sufficiently supported by data: Yes Specific comments/observations: Conclusion: The proposed Codex MRL is acceptable
General comments	The same residue data set was submitted and evaluated under peer review process. Although, no data on processed bananas were available, since the residue levels in peeled bananas were all below 0.01 mg/kg, currently, not further investigation is necessary. The proposed MRL is based on un-bagged bananas		

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

5.27.5. Consumer risk assessment

Table 132: 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 performed for bananas peeled as outlined in Section 2 The EU ARfD was used	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2018d) was updated using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for bananas	
Results: No short-term exposure concern was identified for bananas (0.05% of the ARfD)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 1% of the ADI The contribution of bananas peeled to the exposure was 0.11% of the ADI (NL toddler)	**Results:** Long-term exposure: 0–0.2% of the ADI Short-term exposure: not applicable since no ARfD was considered necessary by JMPR

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

5.28. Fluazinam (306) R,T

5.28.1. Background information

Table 133: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	AT	
Approval status	Approved	Commission Directive 2008/108/EC[(a)]
EFSA conclusion	Yes, see comments	EFSA (2008a)
MRL review	Yes, see comments	EFSA (2015p)
MRL applications	Yes, see comments	Blueberries: EFSA (2016c) Onions, shallots and garlic: EFSA (2017b)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonized classification and labelling for CMR – Annex VI: Toxic for reproduction cat. 2 Peer review proposal for CMR: Toxic for reproduction cat. 2. ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not yet available

JMPR: Joint FAO/WHO Meeting on Pesticide Residues; RMS: rapporteur Member State; MRL: maximum residue level.
(a): Commission Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–13.
(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.

5.28.2. Toxicological reference values

Table 134: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	Not established	JMPR (2018)	0.01 mg/kg bw per day	EFSA (2008a) (2-yr mouse, supported by 1-yr dog, UF 100) Same in European Commission (2011c)	No comparison possible
ARfD	Not established	JMPR (2018)	0.07 mg/kg bw	EFSA (2008a) (rabbit, developmental, UF 100) Same in European Commission (2011c)	No comparison possible
Conclusion/ comment	JMPR did not derive toxicological reference values because information on the level of impurity B-1457 (5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine) in batches used for toxicity studies was not reported The FAO specification for fluazinam limits the level of this impurity to 0.3% In the EU, the maximum concentration of this impurity is specified in Directive 2008/108/EC as not more than 2 g/kg (0.2%), based on the maximum amount present in the batches used for key toxicological studies				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	The RMS informed EFSA that in the framework of the renewal of the approval, the RMS will propose the same ADI/ARfD as currently in place The metabolite TFAA has been discussed during the first EU peer review (EFSA, 2008a), and its toxicological profile could not be concluded on the basis of the available data. It was also noted that a new assessment including a developmental toxicity study were provided after the peer review (and will be considered for the renewal)				

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

5.28.3. Residue definitions

Table 135: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fluazinam	EU Reg. 2018/70: fluazinam	Yes
	Animal products	No proposal; due to lack of information on storage stability, the validity of the livestock metabolism studies cannot be concluded	EU Reg. 2018/70: fluazinam Art 12 MRL review (EFSA, 2015p): No proposal, MRLs not needed	No comparison possible
RD RA	Plant products	No proposal	Art 12 MRL review (EFSA, 2015p): Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam	No comparison possible
	Animal products	No proposal	Art 12 MRL review (EFSA, 2015p): No proposal–MRLs not needed	Not relevant
Conclusion/ comments	Proposed EU enforcement RD for processed commodities: sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (tentative) (processed commodities subject to hydrolysis conditions such as boiling, baking, cooking, pasteurisation and sterilisation)			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.28.4. Codex MRL proposals

Table 136: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
General comments	JMPR did not derive MRL proposals, due to serious deficiencies of the dossier. The sponsor did not submit critical information on the levels of a toxicologically relevant impurity in batches used in the toxicity studies. The Meeting was aware that this information had been made available to a number of regulatory authorities. **The Meeting was therefore unable to proceed with the evaluation of fluazinam** No Maximum residue levels are recommended, nor are levels estimated for use in long-term and acute dietary exposure assessments as the Meeting could not reach a conclusion on the residue definition for dietary risk assessment for plant commodities In addition, the Meeting could not reach a conclusion on the residue levels of TFAA in the crops considered in this Meeting			

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

5.28.5. Consumer risk assessment

Table 137: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant	**RA assumptions:** Not relevant	**Specific comments:** Not relevant
Results: Not relevant	**Results:** Not relevant	**Results:** Not relevant

RD: residue definition; RA: risk assessment.

5.29. Norflurazon (308) R,T

5.29.1. Background information

Table 138: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	–	None
Approval status	Not approved	Commission Regulation (EC) No 2076/2002[(a)]
EFSA conclusion	No	
MRL review	No	
MRL applications	No	
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI EU Peer Review proposal for CMR: no assessment at EU level is available ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[b]): not conducted

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

5.29.2. Toxicological reference values

Table 139: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.005 mg/kg bw per day	JMPR (2018)	No toxicological information available at EU level		No
ARfD	0.3 mg/kg bw	JMPR (2018)			No
Conclusion/ comment	Norflurazon is not approved in the EU and TRV at EU level are not available. It is noted by the JMPR that the database was of poor quality. An additional uncertainty factor of 3 was applied to setting of the ADI because of poor quality. It is noted that all relevant endpoints appear to be covered. At EU level, the setting of a reference value using an additional factor to compensate for the poor quality of the data package might not be acceptable				

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
	According to 2018 JMPR, the toxicity of desmethyl norflurazon and its conjugates and 6-methyl sulfoxide norflurazon are covered by the parent compound, as these metabolites were identified in significant amounts in animal studies. Desmethyl norflurazon was found in rat urine (max. 7%); 6-methyl sulfoxide norflurazon appeared in rat urine at greater than 10%. During the peer review, a trigger of 10% is used to consider a metabolite covered by the parent compound. The JMPR monograph does not provide additional explanations. In this case, desmethyl norflurazon was present at 7% in urine For the metabolite NOA-452075 (ethanolamine conjugate) (major metabolite in milk accounting 17% TRR), no specific data were available on the toxicity. The JMPR estimated exposure to this metabolite would be well below the toxicological threshold of concern (TTC) (1.5 μg/kg bw) and therefore, based on the TTC approach, the JMPR concluded that NOA-452075 need not be included in the residue definition for dietary risk assessment for animal commodities. According to EFSA, the genotoxicity of this metabolite should be addressed first (it is note reported in the monograph if QSARs for genotoxicity were used). If the genotoxic potential of this metabolite can be excluded, the sum of the exposure for all non-toxicological characterised metabolites should be compared to the TTC. It is noted that currently the TTC is not used at European Level for assessing residues metabolites since there is no agreement yet on how this tool should be used The metabolite 5,6-dihydrodiol desmethyl norflurazon (major metabolite in milk accounting 22% TRR, 0.26 mg eq/kg) was identified in rat and goat matrices; however, an explicit conclusion on whether this metabolite is covered by the parent compound is not provided				

ADI: acceptable daily intake; bw: body weight; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; ARfD: acute reference dose; TRR: total radioactive residues; QSAR: quantitative structure–activity relationship; eq: residue expressed as a.s. equivalent.

5.29.3. Residue definitions

Table 140: 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 norflurazon and desmethyl norflurazon, expressed as norflurazon	No specific residue definition. Default residue definition covering parent compound only is applicable	No
	Animal products	Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon The residue is not fat soluble		No
RD RA	Plant products	Sum of norflurazon and desmethyl norflurazon (free and conjugated), expressed as norflurazon	–	Comparison not appropriate
	Animal products	Sum of desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon, expressed as norflurazon	–	Comparison not appropriate
Conclusion/ comments	Plant metabolism was investigated following either soil treatment or root treatment in crops belonging to the group of fruit crops (orange), cereals/grass (maize), pulses/oilseeds (alfalfa, cotton and soya bean). Similar metabolic pathways were observed in the three crop groups where the major residues identified were norflurazon (free and conjugated) and the metabolite desmethyl norflurazon (free and conjugated). The nature of residues was investigated in crops grown as confined rotational crops representative of the groups of leafy crops (spinach), cereals/grass (maize), pulses/oilseeds (soya bean) and root crops (beet and radish), where the nature of residues was found to be similar to that observed in the primary crops following soil or root treatment			

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Metabolism in animals has been assessed in rats, lactating goats and laying hens where animals were dosed with phenyl ring- or pyridazinyl ring-labelled norflurazon. The parent norflurazon was present in tissues at up to 9% TRR (goat fat) but was found only at low levels in other tissues and eggs (up to 2% TRR). The predominant residue in most tissue was desmethyl norflurazon (free and conjugated) which was found at around 10–25% TRR in liver, kidney and poultry muscle. Other major residues present at above 10% TRR and 0.01 mg eq/kg include 6-methyl sulfoxide norflurazon in milk (22% TRR), deschloro desmethyl norflurazon (free and conjugated) in eggs (10% TRR) and 6-methylsulfone desmethyl norflurazon (free and conjugated) in poultry muscle (45% TRR), poultry liver (20% TRR) and poultry fat (38% TRR). In a second high-dose study in lactating goats, major metabolites in milk were 5,6-dihydrodiol desmethyl norflurazon (22% TRR, 0.26 mg eq/kg) and NOA-452075 (ethanolamine conjugate) (17% TRR) The metabolites desmethyl norflurazon (free and conjugated) and 6-methyl sulfoxide norflurazon were identified in the rat metabolism study and the JMPR considered these metabolites were no more toxic than norflurazon. However, in rat urine desmethyl norflurazon was not found to be a major metabolite (7%). No specific toxicity data were available for the metabolite NOA-452075 (ethanolamine conjugate) and the JMPR applied a TTC approach. The metabolite 5,6-dihydrodiol desmethyl norflurazon (major metabolite in milk accounting 22% TRR, 0.26 mg eq/kg) in indicated to be identified in rat and goat matrices; however, a conclusion on whether this metabolite is covered by the parent compound is not provided Taking into account the results of the metabolism studies assessed by JMPR, EFSA recommends to set a specific residue definition for enforcement in the EU legislation, similar to the ones proposed by JMPR		

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; TRR: total radioactive residues; eq: residue expressed as a.s. equivalent.

5.29.4. Codex MRL proposals

Table 141: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Alfalfa fodder	7(DW)	–	Critical GAP: Canada and USA, 2,200 g/ha during dormancy or after cutting, PHI 28 days, maximum application 2,200 g/ha per annum Number of trials: 6 Sufficiently supported by data: Yes Specific comments/observations: The JMPR considered desmethyl norflurazon (free and conjugated) should be included in the livestock dietary burden calculation. In four trials, only free norflurazon and desmethyl norflurazon residues were measured and the JMPR applied a conversion factor of 2.2 derived from the alfalfa metabolism study to estimate the residues of total norflurazon and desmethyl norflurazon (free and conjugated). The HR/STMR derived for alfalfa forage/hay were taken into account for the dietary burden calculation of livestock No MRLs are set in the EU for feed items
Edible offal (Mammalian)	**0.3**	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	The dietary burden was calculated, including alfalfa forage and hay, rape forage, wheat forage, corn field forage/silage, corn sweet forage, rye straw, rice straw, rice grain, sorghum grain and corn field grain Apart from alfalfa forage and hay, the estimated residues in animal feed commodities were derived from the field rotational crop studies

Commodity	Codex MRL proposal	EU MRL	Comment
			The highest maximum dietary burden was calculated for the EU. EFSA is of the opinion that the calculations are not realistic, since wheat straw containing norflurazon is not expected to be fed to European ruminants A dairy cow feeding study was available; the calculated maximum and mean dietary burden was below the lowest feeding level To estimate total residues in the dietary risk assessment residue definition, the JMPR applied a conversion factor based on the relative proportions of metabolites in the goat metabolism studies Conclusion: It is recommended to discuss with MS whether the proposed Codex MRLs for animal products (mammalian) are acceptable, considering the deficiencies of the dossier (see below general comments)
Eggs	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	The dietary burden was calculated, including wheat straw, rice grain, sorghum grain and corn field grain. The estimated residues in animal feed commodities were derived from the field rotational crop studies The highest dietary burden was calculated for the EU diet, with wheat straw being the main contributor. EFSA is of the opinion that the calculations are not realistic, since wheat straw containing norflurazon is not expected to be fed to European poultry A feeding study in laying hens was assessed by JMPR; the calculated maximum and mean dietary burden was below the lowest feeding level Since the poultry feeding study did not measure conjugates, the JMPR used the poultry metabolism study to estimate STMRs, HRs and MRLs for poultry commodities Residues of 6-methylsulfoxide norflurazon and NOA-452075 (ethanolamine conjugate) were not detected in the poultry feeding study, and for desmethyl norflurazon (free and conjugated) the highest average concentration of was 0.085 mg/kg in liver. Since the highest dietary burden was approximately 50-fold lower than the metabolism study does, the JMPR concluded that residues of these metabolites are not expected in poultry commodities Conclusion: It is recommended to discuss with MS whether the proposed Codex MRLs for poultry products are acceptable, considering the deficiencies of the dossier (see below general comments)
Mammalian fats (except milk fats)	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	See comments on edible offal (mammalian)
Meat (from mammals other than marine mammals)	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	See comments on edible offal (mammalian)
Milks	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	See comments on edible offal (mammalian)

Commodity	Codex MRL proposal	EU MRL	Comment
Poultry fat	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	See comments on eggs
Poultry meat	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	See comments on eggs
Poultry, Edible offal of	**0.02***	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	See comments on eggs
Wheat, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position
Maize cereals, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position
Sorghum grain and Millet, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position
Rice cereals, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position
Leafy greens, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position
Leaves of Brassicaceae, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position

Commodity	Codex MRL proposal	EU MRL	Comment
Root vegetables, Subgroup of (includes all commodities in this subgroup)	–	0.01* (Default MRL according to Art 18(1)(b) Reg. 396/ 2005)	Specific comments/observations: The JMPR concluded the data were not sufficient to estimate MRLs for rotational crops. The field rotational crop studies were used to estimate consumer dietary exposure and livestock dietary burdens Conclusion: Since no Codex MRL proposal was made by JMPR, there is no need to take an EU position
General comments	Overall, the following deficiencies of the dossier were noted which should be taken into account by risk managers to decide whether the proposed Codex MRLs are acceptable: • the toxicological studies used to derive the ADI were of low quality; to compensate for outdated (non-GLP) studies an additional factor of 3 was used; • the applicability of the TRV to the metabolite desmethyl norflurazon is not sufficiently demonstrated (the metabolite was not a major metabolite in urine); • data to exclude genotoxicity for a major milk metabolite (NOA-452075) was not reported; • the rotational crop studies are not sufficient to predict in a reliable manner the residues in feed (used for dietary burden calculation) and food; • the calculation of the dietary burden for livestock is not reliable (see previous bullet point) and not realistic (EU livestock is not expected to be exposed to norflurazon via crops such as alfalfa forage, cereal straw, rape forage etc. containing residues mostly via uptake from soil (rotational crops), because these commodities are not traded		

GAP: Good Agricultural Practice; PHI: preharvest interval; STMR: supervised trials median residue; HR: highest residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; GLP: Good Laboratory Practice; TRV: toxicological reference values.
*: Indicates that the input value is proposed at the limit of quantification.

5.29.5. Consumer risk assessment

Table 142: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An indicative short-term dietary risk assessment was performed for mammalian fats, meat and edible offal, poultry fat, meat and edible offal, eggs and milks as outlined in Section 2 The JMPR ARfD was used The calculation is indicative, because no decision has been taken yet at EU level on the residue definition and the ARfD In contrast to the JMPR risk assessment, EFSA did not include the residue levels expected in rotational crops in the dietary intake calculation, since these residues (HR between 0.21 and 0.56 mg/kg) would violate the existing EU MRLs	**RA assumptions:** An indicative long-term risk assessment was performed using the approach as outlined in Section 'Assessment', using the STMR values derived by JMPR for mammalian fats, meat and edible offal, poultry fat, meat and edible offal, eggs and milks. For other commodities EFSA applied the default MRL according to Art 18(1)(b) Reg. 396/ 2005 The JMPR ADI was used The calculation is indicative, because no decision has been taken yet at EU level on the residue definition and the ADI. In contrast to the JMPR risk assessment, EFSA did not include the residue levels expected in rotational crops in the dietary intake calculation, since these residues (STMR values between 0.04 and 0.096 mg/kg) would violate the existing EU MRLs	**Specific comments:** For rotational crops, data were not sufficient to estimate MRLs however the JMPR used STMR and HR values derived from the field rotational crop studies to estimate consumer dietary exposure

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure concern was identified. The commodities under consideration leading to highest exposure are (in rank order): bovine liver (0.6% of the ARfD) and bovine edible offal (0.5% of the ARfD)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 14% of the ADI (NL toddler). From the commodities under consideration, the contribution to the total exposure was the highest for residues in bovine milk (2% of the ADI)	**Results:** Long-term exposure: 0–20% of the ADI Short-term exposure: 10% of the ARfD

RA: risk assessment; ARfD: acute reference dose; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; HR: highest residue; ADI: acceptable daily intake.

5.30. Mandestrobin (307) T

5.30.1. Background information

Table 143: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	AT	
Approval status	Approved	Commission Implementing Regulation (EU) 2015/2085[(a)]
EFSA conclusion	Yes, see comments	EFSA (2015k)
MRL review	Not required	MRLs have been established in the framework of the peer review.
MRL applications	Yes, see comments	Apricot, cherry, peach and plum: EFSA (2018f) Strawberry and grapes: EFSA (2018l)
Cut-off criteria: • Mutagen cat. 1A or 1B • Caringogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI EU Peer Review proposal for CMR: none ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

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

5.30.2. Toxicological reference values

Table 144: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	Comments (source, study)	Value	Comments (source, study)	
ADI	0.2 mg/kg bw per day	JMPR (2018) (1-year toxicity study in dogs, SF 100)	0.19 mg/kg bw per day	EFSA (2015k) (52-week dog (UF 100), supported by multigeneration rat (parental LOAEL, UF 300)	Yes

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ARfD	3 mg/kg bw	JMPR (2018) (developmental toxicity study in rats, SF 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), and supported by the parental LOAEL from the multigeneration rat study (applying an UF of 300). The JMPR proposes 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, the derivation of an ARfD was not considered needed on the basis of the low acute toxicity profile of mandestrobin by the peer review experts The ARfD of 3 mg/kg bw derived by JMPR applies only to women of childbearing age and is based on a 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 same NOAEL from this study was set by the EU peer review (based on foetal findings) but was not considered for the ARfD derivation Metabolites considered during the EU peer review: 4-OH-S-2200 and De-Xy-S-2200 were considered to be covered by the toxicological profile of mandestrobin, whereas the plant metabolite 2-CH_2OH-S-2200 was not covered by the studies performed with mandestrobin				

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

5.31. Pydiflumetofen (309)R,T

5.31.1. Background information

Table 145: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	FR	
Approval status	Approval process ongoing	NAS application under Regulation (EC) No 1107/2009
EFSA conclusion	ongoing	EFSA Conclusion not yet finalised, pending endocrine assessment to be conducted by EFSA
MRL review	No	
MRL applications	Yes, see comments	MRL application ongoing as part of the approval process for pome fruit, grapes, potatoes, tropical root and tuber vegetables, solanacea, cucurbits, brassica and soybeans
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification and labelling – Annex VI: Under discussion at the ECHA RAC (March 2019) RMS informed EFSA that a classification as Carc. 2 H351 and Repr. 2 H361f (fertility) has been proposed for during the meeting of the Committee for the risk assessment of ECHA (RAC-47; November 2018; minutes not available yet). This classification proposal will be re-discussed in RAC-48 (March 2019) in order to clarify the arguments justifying a double classification carcinogen and reprotoxic and to make the opinion more robust ED assessment ongoing

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

5.31.2. Toxicological reference values

Table 146: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.1 mg/kg bw per day	JMPR (2018)	0.09 mg/kg bw per day	18-month mouse study with an UF of 100 Proposal derived in peer review expert meeting (September 2018)	No
ARfD	0.3 mg/kg bw	JMPR (2018)	0.3 mg/kg bw	Developmental toxicity study in the rat and based on effects on body weight, with an UF of 100 Proposal derived in peer review expert meeting (September 2018)	Yes
Conclusion/ comment	The EFSA conclusion is not finalised, thus, EU TRV are not yet formally approved. The **ADI** established by the JMPR is based on the NOAEL of 9.9 mg/kg bw per day for reduced body weight in males from the two-year study in rats and applying an uncertainty factor (UF) of 100. The ADI discussed during the EU peer review and proposed in the RAR is based on the NOAEL of 9.2 mg/kg bw per day for reduced body weight from the 18-month carcinogenicity study in mice and applying an UF of 100. The **ARfD** set by the JMPR at 0.3 mg/kg bw is based on the NOAEL of 30 mg/kg bw per day for reduced maternal body weight gain and feed consumption early during treatment from the developmental toxicity study in rabbits and applying an UF of 100. This value is in agreement with the EU peer review discussion According to 2018 JMPR, the toxicity of **2,4,6-TCP and its conjugates** would be covered by the parent compound, as this metabolite was identified as a major metabolite in rats. The ADI/ARfD derived by JMPR applies to pydiflumetofen and the metabolites 2,4,6-TCP and SYN547897 In the ongoing EU peer review, additional toxicological data on 2,4,6-TCP were taken into consideration from the published literature[(a)] indicating that the metabolite present carcinogenic potential, the genotoxicity database was considered inconclusive and no toxicological reference values could be concluded An ADI of 0.25 mg/kg bw per day was discussed for **NOA449410**, based on NOAEL of 250 mg/kg bw per day from the developmental toxicity study in rabbits and applying an UF of 1,000. No ARfD being necessary for this metabolite An ADI and ARfD of 0.04 mg/kg bw (per day) were discussed for **SYN508272**, based on the 28-day study in rats, applying an UF of 1,000. The metabolites **SYN545547**, **SYN548263** and **SYN547897** were considered non-genotoxic; however insufficient data was available to conclude on their general toxicity				

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

(a): The RMS informed EFSA that a literature review on the 2,4,6-TCP metabolite performed according to the EFSA Guidance document (EFSA Journal 2011; 9(2):2092) was submitted by the applicant and assessed by the RMS. On this basis, the toxicological profile of 2,4,6-TCP (and conjugates) and appropriate reference values have been discussed in expert meeting PPR 182 (September 2018). It was concluded that although 2,4,6-TCP is the major metabolite in rat, its toxicity could not be covered by the parent. Indeed, 2,4,6-TCP is classified carcinogen category 2 (Reg 1272/2008, ATP0) based on lymphoma/leukaemias observed in male rats and liver tumours in mice. In addition, a genotoxic mode of action could not be ruled out since the genotoxicity database was considered inconclusive based on quality and limitations of the available studies performed on the metabolite; particularly for the in vivo studies. This was considered by the majority of experts as data gap and a complete data package, including in vivo Comet assay exploring the site of contact and the target organs identified in the carcinogenesis studies, was recommended. If a genotoxic potential can be ruled out for 2,4,6-TCP, the repeated-dose toxicity profile of the metabolite in comparison with the toxicity profile of the parent pydiflumetofen will need to be addressed to perform the consumer risk assessment.

5.31.3. Residue definitions

Table 147: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Pydiflumetofen	Peer Review proposal (September 2018): Pydiflumetofen	Yes
	Animal products	Pydiflumetofen The residue is fat soluble	Peer Review proposal (September 2018): Pydiflumetofen The residue is fat soluble	Yes
RD RA	Plant products	Pydiflumetofen	Peer Review proposal (September 2018): Pydiflumetofen (for all categories of 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 proposal (September 2018): Parent and 2,4,6-TCP for all animal matrices (provisional, pending on toxicological data on 2,4,6-TCP, including genotoxicity potential) (majority opinion) See also comments below	No
Conclusion/ comments	The EFSA conclusion is not finalised; thus, EU residue definitions are not yet formally approved. The EU pesticides peer review meeting of experts proposed a residue definition for enforcement for plant and animal products and for risk assessment for plant products which is identical to the JMPR residue definition, as both refer to the parent pydiflumetofen only As regards the residue definition for risk assessment (animal products), the peer review meeting of experts proposed a provisional residue definition as parent and 2,4,6-TCP for all animal matrices (provisional)(majority opinion). A minority of experts proposed residue definition for ruminant liver to also include SYN547897; and for ruminant kidney to also include SYN547897 and SYN548263 In contrast, the JMPR residue definition for animal products other than mammalian liver and kidney includes also conjugates of 2,4,6-TCP; and for mammalian liver and kidney it includes also conjugates of 2,4,6-TCP, and SYN547897 and its conjugates. Thus, the JMPR residue definitions would be wider than the provisional EU RD Considering that JMPR derived MRL proposals only for plant commodities, the open issue regarding the residue definition for animal commodities is not of immediate relevance		

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level.

5.31.4. Codex MRL proposals

Table 148: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Dried grapes (= Currants, Raisins and Sultanas)	4	–	A concentration of residues in dried grapes (currants, raisins, sultanas) occurs and a PF of 2.45 was derived from 6 processing studies No EU MRLs are set for processed grapes, such as raisins
Small fruit vine climbing, Subgroup of (includes all commodities in this subgroup)	**1.5**	0.01* (Default MRL according to Art 18 (1)(b) Reg. 396/ 2005)	Critical GAP: USA, grape and small fruit vine climbing, except fuzzy kiwifruit, up to 200 g/ha at a maximum annual rate of 400 g/ha, RTI not reported, PHI 7 days Number of trials: 11 trials on grapes Sufficiently supported by data: Yes Specific comments/observations: The Codex MRL for the subgroup 'Small fruit vine climbing' would be applicable to table grapes (0151010) and wine grapes (0151020) The NAS application under Regulation (EC) No 1107/2009 includes an application to set EU MRLs for table and wine grapes (proposed MRL 2 mg/kg on the basis of combined NEU and SEU residue trials; critical GAP (NEU and SEU: 2 × 200 g/ha at BBCH 67-89, 14-day interval, PHI 21 days) Conclusion: The proposed Codex MRL is acceptable
Grape juice	–	–	A reduction of residues in grape juice occurs and a PF of 0.06 was derived from 6 processing studies No EU MRLs are set for processed grape products
Grape must	–	–	A concentration of residues in grape must occurs and a PF of 1.06 was derived from 8 processing studies. No EU MRLs are set for processed grape products
Grape seed oil, refined	–	–	A concentration of residues in grape seed oil (refined) occurs and a PF of 1.05 was derived from 4 processing studies. No EU MRLs are set for processed grape products
Red wine	–	–	A reduction of residues in red wine occurs and a PF of 0.135 was derived from 4 processing studies. No EU MRLs are set for processed grape products
White wine	–	–	A reduction of residues in white wine occurs and a PF of 0.315 was derived from 4 processing studies. No EU MRLs are set for processed grape products
General comments	For several annual crops for which residue trials were received, the JMPR concluded that accumulation in soil and uptake of residues into rotational crops may significantly contribute to the terminal residue in food and feed commodities and no recommendations could be made. The NAS application under Regulation (EC) No 1107/2009 includes applications to set MRLs for various commodities and an import tolerance		

PF: processing factor; MRL: maximum residue limit; GAP: Good Agricultural Practice; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; BBCH: growth stages of mono- and dicotyledonous plants; RTI: re-treatment interval.
*: Indicates that the input value is proposed at the limit of quantification.

5.31.5. Consumer risk assessment

Table 149: Summary of the consumer risk assessment

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: An indicative short-term dietary risk assessment was performed for table grapes and wine grapes as outlined in Section 2 The proposed EU ARfD (equal to the JMPR ARfD) was used The calculation is indicative, because no decision has been taken yet on the residue definition and the ARfD	**RA assumptions:** An indicative long-term risk assessment was performed using the approach as outlined in Section 'Assessment', including the STMR values derived by JMPR for grapes (table grapes and wine grapes). EFSA applied the processing factors (PF) derived by JMPR for dried grapes, grape juice and wine (white wine) For other crop commodities, EFSA assumed no uses are authorised. The calculation is indicative, because no decision has been taken yet on the residue definition and the ADI	**Specific comments:** None
Results: No short-term exposure concern was identified. The estimated short-term exposure was 21% of the ARfD (table grapes) and 3% of the ARfD (wine grapes) Pydiflumetofen is applied as a racemic mixture and the risk assessment was performed disregarding the possible impact of enantiomer ratio due to plant or livestock metabolism. Considering a worst-case theoretical factor of 2 for the toxicological burden, the potential change of isomer ratios is of low concern since the exposure represent less than 50% of the ADI. Further consideration may be required in case future uses lead to a higher consumer exposure	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.9% of the ADI (PT general). The contributions of the grape commodities under consideration were 0.8% of the ADI (wine grapes) and 0.1% of the ADI (table grapes) Pydiflumetofen is applied as a racemic mixture and the risk assessment was performed disregarding the possible impact of enantiomer ratio due to plant or livestock metabolism Considering a worst-case theoretical factor of 2 for the toxicological burden, the potential change of isomer ratios is of low concern since the exposure represent less than 50% of the ADI. Further consideration may be required in case future uses lead to a higher consumer exposure	**Results:** Long-term exposure: 0% of the ADI Short-term exposure: 20% of the ARfD

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

5.32. Pyriofenone (310) R,T

5.32.1. Background information

Table 150: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	LV	Previous RMS UK
Approval status	Approved	Commission Implementing Regulation (EU) No 833/2013[(a)]
EFSA conclusion	Yes, see comments	EFSA (2013c)
MRL review	ongoing	Publication planned by June 2019
MRL applications	Yes, see comments	Wheat, barley and grapes, animal products: EFSA (2013f) Grapes: EFSA (2015h)

		Comments, references
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	Not concluded	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI EU Peer Review proposal for CMR (2013): Carc. 2 ED assessment according to ECHA/EFSA guidance (2018) and scientific criteria (Commission Regulation (EC) No 2018/605[(b)]): not conducted

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

5.32.2. Toxicological reference values

Table 151: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.09 mg/kg bw per day	JMPR (2018) (2-year rat study, SF 100)	0.07 mg/kg bw per day	EFSA (2013c) (rat, 2-year study, UF 100) European Commission (2013b)	No
ARfD	Unnecessary	JMPR (2018)	Not required	EFSA (2013c) European Commission (2013b)	Yes
Conclusion/ comment	Although ADI derived by EFSA is slightly lower than JMPR, the values are in the same order of magnitude The EU 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				

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

5.32.3. Residue definitions

Table 152: 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: 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: Pyriofenone The residue is not fat soluble: Peer review (EFSA, 2013c): Not required, considering the representative uses; Provisional RD proposed for ruminant products: pyriofenone	Yes

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Pyriofenone	Peer review (EFSA, 2013c): Pyriofenone	Yes
	Animal products	Pyriofenone	Peer review (EFSA, 2013c): Not required, considering the representative uses; Provisional RD proposed for ruminant products: Sum of pyriofenone and 2MDPM (free and conjugated)	No comparison appropriate
Conclusion/ comments	For plant commodities, the EU and JMPR residue definitions are the same For animal products, so far no definitive residue definitions have been derived in the EU, since no significant dietary intake is expected for livestock 2018 JMPR proposed the parent compound as the residue definition for animal products			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

5.32.4. Codex MRL proposals

Table 153: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cane berries, (includes all commodities in this subgroup)	0.9	Default MRL 0.01*	Critical GAP: max 110 g a.s./ha per application, up to a seasonal maximum rate of 350 g a.s./ha, RTI 7 days, PHI 0 days Number of trials: 6 trials in blackberries Sufficiently supported by data: Yes Specific comments/observations: Trials conducted with 4 × 85–93 g a.s./ha, max seasonal rate of 350–370 g a.s/ha. The proposed Codex MRL would cover blackberries and raspberries Conclusion: The proposed Codex MRL is acceptable
Bush berries, (includes all commodities in this subgroup)	1.5	Default MRL 0.01*	Critical GAP: USA, max 110 g a.s/ha per application, up to a seasonal maximum rate of 350 g a.s./ha, RTI 7 days, PHI 0 days Number of trials: 10 trials on blueberries Sufficiently supported by data: Yes Specific comments/observations: Trials conducted with 4 × 82–100 g a.s./ha, max seasonal rate of 350–380 g a.s/ha. The proposed Codex MRL would cover blueberries, currants, gooseberries, rose hips. At EU level, the extrapolation from blueberries to currants, gooseberries, and rose hops would not be acceptable Conclusion: The proposed Codex MRL is acceptable
Dried grapes (=Currants, Raisins and Sultanas)	2.5	–	Median value of PF (2.8) and the STMR of 0.23 mg/kg for grapes was used to derive a STMR-p of 0.64 mg/kg. Since residues concentrate in dried grapes, a MRL of 2.5 mg/kg is proposed At EU level, no MRLs are set for processed grapes
Fruiting vegetables, Cucurbits	0.2	Default MRL 0.01*	Critical GAP: USA, max 110 g a.s/ha per application, up to a seasonal maximum rate of 350 g a.s./ha, RTI 7 days, PHI 0 days Number of trials: 26 trials (8 trials in cucumbers, 9 trials in summer squash, 9 trials in cantaloupe) Sufficiently supported by data: Yes Specific comments/observations: MRL proposal was derived from the combined data set of trials on cucumbers,

Commodity	Codex MRL proposal	EU MRL	Comment
			summer squash and cantaloupe/melon; trials were approximating the GAP (4 applications of 88–100 g a.s./ha at 7 days interval). At EU level the setting of a group MRL for cucurbits (edible and inedible peel) based on a merged data set would not be accepted Conclusion: The proposed Codex MRL is acceptable
Low growing berries, (includes all commodities in this subgroup)	0.5	Default MRL 0.01*	Critical GAP: max 110 g a.s/ha per application, up to a seasonal maximum rate of 350 g a.s./ha, with an interval of 7 days, PHI 0 days Number of trials: 9 trials in strawberries Sufficiently supported by data: Yes Specific comments/observations: The proposed Codex MRL would cover cranberries and strawberries. Conclusion: The proposed Codex MRL is acceptable
Small fruit vine climbing (includes all commodities in this subgroup)	0.8	Table grapes: 0.9 Wine grapes: 0.2	Critical GAP: USA, max 110 g a.s/ha per application, up to a seasonal maximum rate of 350 g a.s./ha, RTI 14 days, PHI 0 days Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: The EU GAP on table grapes (3 × 90 g a.s./ha; PHI 14 days), for which a MRL of 0.9 mg/kg is set, is fully supported by data Conclusion: The proposed Codex MRL is acceptable
Grape juice	–	–	8 processing studies available, PF 0.06 At EU level, no MRLs are set for processed grapes
Grape must	–	–	2 processing studies available, PF 0.46 At EU level, no MRLs are set for processed grapes
Grape wine	–	–	16 processing studies available (8 for white wine and 8 for red wine); PF for red wine: 0.06, PF for white wine 0.04. At EU level, no MRLs are set for processed grapes
General comments	–		

GAP: Good Agricultural Practice; a.s.: active substance; PHI: preharvest interval; MRL: maximum residue level; PF: processing factor; STMR: supervised trials median residue; RTI: re-treatment interval.
*: Indicates that the input value is proposed at the limit of quantification.

5.32.5. Consumer risk assessment

Table 154: 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 (EFSA, 2013a–j)	**RA assumptions:** The most recent long-term risk assessment (EFSA, 2015h) was updated using the approach as outlined in Section 'Assessment', including the STMR values for the commodities for which the proposed Codex MRL is higher than the existing EU MRL The EU ADI was used	**Specific comments:** The chronic exposure made by JMPR was performed with the ADI of 0.09 mg/kg bw per day. The IEDI was 0% of the maximum ADI JMPR also considered that an ARfD is unnecessary. Therefore, the acute dietary exposure to residues of pyriofenone from the uses assessed was considered unlikely to present a public health concern

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure assessment is necessary	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 2% of the ADI	**Results:** Long-term exposure: 0% of the ADI

RA: risk assessment; ARfD: acute reference dose; ADI: acceptable daily intake; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; MRL: maximum residue level; IEDI: international estimated daily intake.

5.33. Tioxazafen (311) R,T

5.33.1. Background information

Table 155: Background information

		Comments, references
Type of JMPR evaluation	New compound evaluation	
RMS	–	N/A
Approval status	Not approved	Never notified and authorised in the EU
EFSA conclusion	No	
MRL review	No	
MRL applications	No	Import tolerance application under preparation in NL (cotton, maize and soybeans)
Cut-off criteria: • Mutagen cat. 1A or 1B • Carcinogen cat. 1A or 1B • Toxic for reproduction cat. 1A or 1B • Endocrine disrupting (ED) potential	No assessment at EU level	Harmonised classification and labelling for CMR – Annex VI: no entry in Annex VI

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

5.33.2. Toxicological reference values

Table 156: Comparison of toxicological reference values (TRV) derived by JMPR and at EU level

	JMPR evaluation		EU evaluation		TRV comparable
	Value	**Comments (source, study)**	**Value**	**Comments (source, study)**	
ADI	0.05 mg/kg bw per day	JMPR (2018) (2-year toxicity study in rats, SF 100)	No information available		Comparison not appropriate
ARfD	0.5 mg/kg bw	JMPR (2018) (acute neurotoxicity study in rats, SF 500)			Comparison not appropriate
Conclusion/ comment	So far no assessment of the active substance was performed in the EU JMPR assessment: The ADI is based on a 2-year toxicity study in rats, applying a safety factor of 100 The ARfD was derived from the acute neurotoxicity study in rats, using a safety factor of 500; the additional factor of 5 was applied for the use of a LOAEL instead of a NOAEL Both the ADI and the ARfD can be applied to benzamidine Since the detailed study reports are not available, no comment on the acceptability of the toxicological reference values derived by JMPR can be provided				

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

5.33.3. Residue definitions

Table 157: 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 tioxazafen and benzamidine (benzenecarboximidamide), expressed as tioxazafen	No specific residue definition is set in the EU; the default residue definition covering the parent compound only is applicable	No comparison possible
	Animal products	Sum of tioxazafen and benzamidine (benzenecarboximidamide), expressed as tioxazafen The residue is not fat soluble		No comparison possible
RD RA	Plant products	Sum of tioxazafen and benzamidine (benzenecarboximidamide), expressed as tioxazafen		No comparison possible
	Animal products			No comparison possible
Conclusion/ comments	The plant residue definitions derived by JMPR are based on metabolism studies in GM soya bean, GM maize and cotton, reflecting seed treatments (the GM varieties used in the metabolism studies are not reported) and rotational crop studies For animal commodities, JMPR assessed metabolism study in rats, lactating goats and laying hens Considering that tioxazafen was found to be extensively metabolised, parent compound is not a good marker substance. Thus, at EU level the setting of specific residue definitions as proposed by JMPR is recommended			

RD: residue definition; RA: risk assessment; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GM: genetically modified.

5.33.4. Codex MRL proposals

Table 158: Comparison of Codex MRL proposals derived by JMPR and EU MRLs

Commodity	Codex MRL proposal	EU MRL	Comment
Cotton gin trash	0.02	Default 0.01*	Critical GAP: USA, see GAP for cotton seed Number of trials: 4 Sufficiently supported by data: Yes Specific comments/observations: In the EU, MRLs are not set for feed items
Cottonseed	0.01*	Default 0.01*	Critical GAP: USA, 1 mg/seed, 210 g a.i./ha Number of trials: 12 Sufficiently supported by data: Yes Specific comments/observations: In all trials residues were < 0.005 mg/kg Conclusion: The proposed Codex MRL is acceptable
Edible offal (mammalian)	0.03	Default 0.01*	Feeding study in lactating cows was available. The lowest feeding level tested was 6 times higher than the calculated maximum dietary burden Conclusion: The proposed Codex MRL is acceptable However, a lower level would be sufficient (0.02 or 0.015 mg/kg)
Eggs	0.02*	Default 0.01*	The MRL proposal was derived from metabolism studies in poultry performed with a feeding level approximately 30 times the calculated maximum dietary burden Conclusion: The proposed Codex MRL is acceptable
Maize	0.01*	Default 0.01*	Critical GAP: USA, seed treatment 1 mg/seed; 99 g a.i./ha Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: In all trials residues were < 0.005 mg/kg Conclusion: The proposed Codex MRL is acceptable

Commodity	Codex MRL proposal	EU MRL	Comment
Maize fodder	0.03(DM)		Critical GAP: USA, see GAP for maize Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: In the EU, MRLs are not set for feed items
Mammalian fats (except milk fats)	0.03	Default 0.01*	See comments on edible offal (mammalian) Conclusion: The proposed Codex MRL is acceptable. However, a lower level would be sufficient (0.02 or 0.015 mg/kg)
Meat (from mammals other than marine mammals)	0.02	Default 0.01*	See comments on edible offal (mammalian) Conclusion: The proposed Codex MRL is not compatible with the EU legislation, because MRLs are not set for meat but for muscle. The corresponding MRL for muscle would be 0.01 mg/kg
Milks	0.02	Default 0.01*	See comments on edible offal (mammalian) Conclusion: The proposed Codex MRL is acceptable
Poultry edible offal	0.02*	Default 0.01*	See comments on eggs Conclusion: The proposed Codex MRL is acceptable
Poultry fat	0.02*	Default 0.01*	See comments on eggs Conclusion: The proposed Codex MRL is acceptable
Poultry meat	0.02*	Default 0.01*	See comments on eggs Conclusion: The proposed Codex MRL is acceptable
Soya bean (dry)	0.04	Default 0.01*	Critical GAP: USA, 0.5 mg/seed (309 g a.i./ha) Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: – Conclusion: The proposed Codex MRL is acceptable
Soya bean fodder	0.4(DM)		Critical GAP: USA, see GAP for soya beans dry Number of trials: 22 Sufficiently supported by data: Yes Specific comments/observations: In the EU, MRLs are not set for feed items
Soya bean meal	0.06		MRL proposal was derived by applying a PF of 1.41 to soybeans. One processing study would not be sufficient in the EU
Soya bean oil, Refined			PF < 0.06. One processing study would not be sufficient in the EU
General comments	–		

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

5.33.5. Consumer risk assessment

Table 159: 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 performed for the commodities under consideration. The JMPR ARfD was used	**RA assumptions:** The long-term exposure was calculated using the STMR values derived by JMPR for the commodities under consideration. For the remaining commodities, the default MRL of 0.01 mg/kg was used in the exposure calculation The JMPR ADI was used	**Specific comments:** –

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term exposure concern was identified (maximum exposure via poultry meat, 0.07% of the ARfD)	**Results:** No long-term consumer health risk was identified The overall chronic exposure accounted for 4% of the ADI The contribution of milk to the exposure was 2% of the ADI	**Results:** Long-term exposure: 0% of the ADI Short-term exposure: 0% of the ARfD

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

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Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
AOEL	acceptable operator exposure level
a.s.	active substance
BMD	benchmark dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	draft assessment report (prepared under Council Directive 91/414/EEC)
DART	developmental and reproductive toxicity
DB	dietary burden
DM	dry matter
DMS	document management system

dw	dry weight
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
GM	genetically modified
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated of short-term intake
ILV	independent laboratory validation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LD_{50}	lethal dose, median
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification (determination)
LP	large portion
MOR	magnitude of residue
MRL	maximum residue limit
MS	Member States
MW	molecular weight
NEU	northern European Union
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QSAR	quantitative structure–activity relationship
RA	risk assessment
RAC	raw agricultural commodity
RAR	renewal assessment report
RD-RA	residue definition for risk assessment
RD-ENF	residue definition for enforcement practice
RMS	rapporteur Member State
RTI	re-treatment interval
RVIM	National Institute for Public Health and the Environment
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
VF	variation factor
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; 2018/11/18

Diquat

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.002	ARfD (mg/kg bw):	0.01
Source of ADI:	EFSA	Source of ARfD:	EFSA
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:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 4

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	193%	DK child	3.87	139%	Rye	38%	Oat	4%	Wheat	7%	
	126%	GEMS/Food G08	2.51	69%	Barley	15%	Rye	10%	Oat	10%	
	107%	NL toddler	2.15	19%	Oat	13%	Barley	11%	Apples	21%	
	101%	GEMS/Food G15	2.01	60%	Barley	6%	Rye	5%	Potatoes	11%	
	98%	IE adult	1.95	37%	Linseeds	18%	Oat	14%	Sweet potatoes	8%	
	98%	GEMS/Food G11	1.95	60%	Barley	9%	Soyabeans	6%	Potatoes	10%	
	97%	FI 3 years	1.95	58%	Oat	16%	Rye	7%	Potatoes	5%	
	94%	GEMS/Food G07	1.88	47%	Barley	13%	Oat	6%	Rapeseeds/canola seeds	10%	
	89%	GEMS/Food G10	1.79	46%	Barley	8%	Soyabeans	8%	Oat	11%	
	82%	DE child	1.63	21%	Oat	20%	Rye	12%	Apples	10%	
	80%	DE general	1.60	39%	Barley	15%	Rye	10%	Oat	7%	
	67%	FI 6 years	1.33	32%	Oat	15%	Rye	6%	Potatoes	4%	
	53%	DE women 14–50 years	1.06	15%	Barley	12%	Rye	10%	Oat	8%	
	51%	LT adult	1.01	27%	Rye	9%	Oat	5%	Potatoes	2%	
	50%	ES adult	1.01	38%	Barley	2%	Wheat	1%	Potatoes	5%	
	48%	NL child	0.97	6%	Apples	5%	Potatoes	5%	Oat	13%	
	47%	NL general	0.94	23%	Barley	4%	Oat	4%	Potatoes	6%	
	46%	FI adult	0.91	18%	Rye	13%	Oat	6%	Coffee beans	8%	
	44%	UK infant	0.88	25%	Oat	5%	Potatoes	3%	Wheat	7%	
	39%	GEMS/Food G06	0.78	7%	Wheat	6%	Barley	3%	Soyabeans	18%	
	34%	FR child 3–15 years	0.68	8%	Oat	5%	Wheat	3%	Oranges	11%	
	31%	PT general	0.62	8%	Potatoes	4%	Wheat	3%	Rye	8%	
	27%	UK toddler	0.55	5%	Potatoes	5%	Oat	4%	Wheat	8%	
	27%	FR toddler 2–3 years	0.54	6%	Oat	3%	Apples	3%	Wheat	9%	
	26%	SE general	0.52	7%	Rye	6%	Potatoes	3%	Wheat	7%	
	22%	RO general	0.45	6%	Potatoes	5%	Wheat	3%	Sunflower seeds	11%	
	22%	ES child	0.43	4%	Wheat	3%	Potatoes	2%	Lentils	9%	
	21%	DK adult	0.41	13%	Rye	2%	Potatoes	1%	Wheat	3%	
	18%	UK vegetarian	0.35	5%	Oat	2%	Potatoes	2%	Wheat	5%	
	17%	IT toddler	0.34	7%	Wheat	2%	Other cereals	1%	Potatoes	10%	
	14%	FR adult	0.28	2%	Wheat	2%	Oat	1%	Wine grapes	6%	
	13%	UK adult	0.25	2%	Potatoes	2%	Barley	2%	Oat	4%	
	12%	IT adult	0.24	4%	Wheat	0.9%	Potatoes	0.8%	Apples	7%	
	11%	FR infant	0.21	3%	Potatoes	2%	Apples	0.8%	Wheat	4%	
	10%	PL general	0.20	5%	Potatoes	2%	Apples	0.4%	Tomatoes	2%	
	5%	IE child	0.10	1%	Wheat	1%	Oat	0.9%	Potatoes	2%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0–193.5% of the ADI.
For 4 diet(s), the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
154%	Potatoes	0.1/0.1	15
87%	Barley	5/1.55	8.7
54%	Linseeds	5/5	5.4
32%	Rye	1.5/0.51	3.2
28%	Pears	0.02/0.02	2.8
27%	Oranges	0.02/0.02	2.7
22%	Oat	2/2	2.2
22%	Apples	0.02/0.02	2.2
19%	Bananas	0.02/0.02	1.9
19%	Peaches	0.02/0.02	1.9
16%	Peas	0.9/0.24	1.6
16%	Grapefruits	0.02/0.02	1.6
15%	Melons	0.01/0.01	1.5
13%	Lentils	0.2/0.2	1.3
12%	Watermelons	0.01/0.01	1.2

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 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)
75%	Barley	5/1.55	7.5
30%	Potatoes	0.1/0.1	3.0
25%	Rye	1.5/0.51	2.5
24%	Linseeds	5/5	2.4
13%	Oat	2/2	1.3
12%	Lentils	0.2/0.2	1.2
8%	Peas	0.9/0.24	0.80
6%	Oranges	0.02/0.02	0.61
6%	Pears	0.02/0.02	0.61
6%	Apples	0.02/0.02	0.56
5%	Strawberries	0.05/0.05	0.47
4%	Kaki/Japanese persimmons	0.02/0.02	0.44
4%	Bananas	0.02/0.02	0.42
4%	Head cabbages	0.01/0.01	0.42
4%	Watermelons	0.01/0.01	0.41

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
281%	Barley	5/5	28
95%	Rye	1.5/1.5	9.5
73%	Beans	0.4/0.4	7.3
66%	Potatoes	0.1/0.1	6.6
59%	Peas	0.9/0.9	5.9
54%	Linseeds	5/5	5.4
29%	Sunflower seeds	0.9/0.9	2.9
22%	Oat	2/2	2.2
21%	Rapeseeds/canola seeds	1.5/1.5	2.1
13%	Lentils	0.2/0.2	1.3
13%	Oranges	0.02/0.02	1.3
12%	Apples	0.02/0.02	1.2
12%	Bananas	0.02/0.02	1.2
12%	Pears	0.02/0.02	1.2
11%	Peaches	0.02/0.02	1.1

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
242%	Barley	5/5	24
73%	Rye	1.5/1.5	7.3
31%	Potatoes	0.1/0.1	3.1
30%	Peas	0.9/0.9	3.0
26%	Beans	0.4/0.4	2.6
24%	Linseeds	5/5	2.4
22%	Soyabeans	0.4/0.4	2.2
13%	Oat	2/2	1.3
12%	Lentils	0.2/0.2	1.2
9%	Oranges	0.02/0.02	0.94
9%	Sunflower seeds	0.9/0.9	0.90
8%	Rapeseeds/canola seeds	1.5/1.5	0.79
8%	Plums	0.02/0.02	0.78
7%	Pears	0.02/0.02	0.71
7%	Mandarins	0.02/0.02	0.66

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)
93%	Potatoes/fried	0.1/0.1	9.3
73%	Oat/boiled	2/2	7.3
60%	Oat/milling (flakes)	2/2	6.0
56%	Barley/cooked	5/1.55	5.6
28%	Barley/milling (flour)	5/1.55	2.8
18%	Rye/boiled	1.5/0.51	1.8
18%	Potatoes/dried (flakes)	0.1/0.14	1.8
18%	Rye/milling (wholemeal)-	1.5/0.51	1.8
17%	Peas/canned	0.9/0.1	1.7
16%	Lentils/boiled	0.2/0.2	1.6
11%	Sugar beets (root)/sugar	0.01/0.12	1.1
11%	Apples/juice	0.02/0.02	1.1
11%	Oranges/juice	0.02/0.02	1.1
9%	Pumpkins/boiled	0.01/0.01	0.89
9%	Witloofs/boiled	0.01/0.01	0.87

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)
112%	Barley/beer	5/0.31	11
30%	Oat/boiled	2/2	3.0
7%	Apples/juice	0.02/0.02	0.67
6%	Peas/canned	0.9/0.1	0.64
6%	Pumpkins/boiled	0.01/0.01	0.55
4%	Sugar beets (root)/sugar	0.01/0.12	0.44
4%	Cauliflowers/boiled	0.01/0.01	0.42
4%	Beans/canned	0.4/0.05	0.36
3%	Celeries/boiled	0.01/0.01	0.34
3%	Oranges/juice	0.02/0.02	0.30
3%	Maize/oil	0.02/0.5	0.25
3%	Potatoes/chips	0.1/0.03	0.25
2%	Broccoli/boiled	0.01/0.01	0.24
2%	Courgettes/boiled	0.01/0.01	0.23
2%	Beetroots/boiled	0.01/0.01	0.22

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
73%	Oat/boiled	2/2	7.3
60%	Oat/milling (flakes)	2/2	6.0
56%	Barley/cooked	5/1.55	5.6
44%	Potatoes/fried	0.1/0.1	4.4
28%	Barley/milling (flour)	5/1.55	2.8
18%	Rye/boiled	1.5/0.51	1.8
18%	Potatoes/dried (flakes)	0.1/0.14	1.8
18%	Rye/milling (wholemeal)-	1.5/0.51	1.8
17%	Peas/canned	0.9/0.1	1.7
16%	Lentils/boiled	0.2/0.2	1.6
11%	Sugar beets (root)/sugar	0.01/0.12	1.1
11%	Apples/juice	0.02/0.02	1.1
11%	Oranges/juice	0.02/0.02	1.1
7%	Pears/juice	0.02/0.02	0.65
5%	Pumpkins/boiled	0.01/0.01	0.53

IESTI new
Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 1

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
112%	Barley/beer	5/0.31	11
30%	Oat/boiled	2/2	3.0
7%	Apples/juice	0.02/0.02	0.67
6%	Peas/canned	0.9/0.1	0.64
4%	Sugar beets (root)/sugar	0.01/0.12	0.44
4%	Pumpkins/boiled	0.01/0.01	0.40
4%	Beans/canned	0.4/0.05	0.36
3%	Oranges/juice	0.02/0.02	0.30
3%	Maize/oil	0.02/0.5	0.25
3%	Potatoes/chips	0.1/0.03	0.25
2%	Cauliflowers/boiled	0.01/0.01	0.25
2%	Grapefruits/juice	0.02/0.02	0.22
2%	Witloofs/boiled	0.01/0.01	0.22
2%	Wine grapes/juice	0.01/0.01	0.21
2%	Celeries/boiled	0.01/0.01	0.20

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

For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Lambda-cyhalothrin (146)

LOQs (mg/kg) range from: 0.02 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.0025	ARfD (mg/kg bw):	0.005
Source of ADI:	EU 2016/146	Source of ARfD:	EU 2016/146
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 : 24

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)
	429%	NL toddler	10.73	119%	Milk: Cattle	43%	Apples	25%	Rice	19%	
	253%	DE child	6.33	50%	Apples	40%	Milk: Cattle	32%	Oranges	7%	
	243%	NL child	6.07	49%	Milk: Cattle	23%	Apples	22%	Swine: Muscle/meat	15%	
	242%	FR child 3–15 years	6.06	46%	Milk: Cattle	30%	Bovine: Muscle/meat	30%	Swine: Muscle/meat	8%	
	235%	GEMS/Food G10	5.87	50%	Rice	18%	Bovine: Muscle/meat	17%	Swine: Muscle/meat	12%	
	226%	GEMS/Food G08	5.65	39%	Swine: Muscle/meat	32%	Olives for oil production	18%	Barley	10%	
	220%	GEMS/Food G06	5.51	62%	Rice	15%	Olives for oil production	14%	Wheat	8%	
	220%	FR toddler 2–3 years	5.49	59%	Milk: Cattle	24%	Bovine: Muscle/meat	24%	Rice	7%	
	216%	SE general	5.40	88%	Bovine: Muscle/meat	25%	Milk: Cattle	16%	Rice	6%	
	210%	ES child	5.26	29%	Olives for oil production	28%	Bovine: Muscle/meat	25%	Milk: Cattle	5%	
	209%	GEMS/Food G07	5.22	23%	Swine: Muscle/meat	18%	Bovine: Muscle/meat	14%	Rice	10%	
	200%	GEMS/Food G11	4.99	24%	Swine: Muscle/meat	16%	Milk: Cattle	16%	Barley	15%	
	194%	GEMS/Food G15	4.84	28%	Swine: Muscle/meat	16%	Barley	14%	Milk: Cattle	10%	
	192%	UK infant	4.81	77%	Milk: Cattle	25%	Rice	25%	Bovine: Muscle/meat	7%	
	180%	DK child	4.50	45%	Swine: Muscle/meat	26%	Bovine: Muscle/meat	25%	Milk: Cattle	4%	
	171%	IE adult	4.28	10%	Wine grapes	9%	Rice	9%	Milk: Cattle	9%	
	163%	UK toddler	4.07	41%	Milk: Cattle	26%	Bovine: Muscle/meat	23%	Rice	7%	
	154%	RO general	3.86	23%	Milk: Cattle	23%	Swine: Muscle/meat	13%	Wine grapes	6%	
	147%	DE general	3.68	25%	Milk: Cattle	22%	Swine: Muscle/meat	13%	Oranges	7%	
	143%	ES adult	3.56	17%	Olives for oil production	15%	Bovine: Muscle/meat	14%	Swine: Muscle/meat	3%	
	139%	DE women 14–50 years	3.48	25%	Milk: Cattle	17%	Swine: Muscle/meat	15%	Oranges	7%	
	137%	NL general	3.42	19%	Swine: Muscle/meat	17%	Milk: Cattle	15%	Bovine: Muscle/meat	8%	
	122%	PT general	3.05	31%	Rice	20%	Wine grapes	10%	Olives for oil production	6%	
	120%	FR adult	2.99	19%	Wine grapes	13%	Swine: Muscle/meat	12%	Bovine: Muscle/meat	4%	
	96%	FR infant	2.40	34%	Milk: Cattle	7%	Swine: Muscle/meat	7%	Bovine: Muscle/meat	4%	
	86%	DK adult	2.16	18%	Swine: Muscle/meat	11%	Bovine: Muscle/meat	11%	Milk: Cattle	2%	
	80%	FI 3 years	2.01	22%	Rice	7%	Strawberries	5%	Bananas	5%	
	76%	UK adult	1.91	15%	Rice	13%	Bovine: Muscle/meat	9%	Wine grapes	3%	
	76%	IT toddler	1.90	13%	Wheat	8%	Rice	6%	Lettuces	2%	
	74%	LT adult	1.85	19%	Swine: Muscle/meat	9%	Rice	8%	Milk: Cattle	4%	
	71%	IT adult	1.77	8%	Wheat	8%	Lettuces	7%	Rice	1%	
	70%	UK vegetarian	1.76	15%	Rice	7%	Oranges	7%	Milk: Cattle	2%	
	63%	FI 6 years	1.56	17%	Rice	6%	Strawberries	3%	Potatoes	5%	
	48%	FI adult	1.20	11%	Coffee beans	5%	Rice	3%	Oranges	13%	
	38%	IE child	0.94	12%	Rice	7%	Milk: Cattle	3%	Swine: Muscle/meat	1%	
	34%	PL general	0.86	8%	Apples	4%	Tomatoes	3%	Head cabbages	3%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0–429.1% of the ADI.
For 24 diet(s), the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):	33	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	13	**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new):	24	**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new):	9

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
880%	Kales	1/1	44
803%	Escaroles/broad-leaved	1/1	40
643%	Chinese cabbages/pe-tsai	1/1	32
530%	Oranges	0.2/0.2	27
381%	Lettuces	0.5/0.5	19
380%	Peaches	0.2/0.2	19
354%	Leeks	0.3/0.3	18
315%	Mangoes	0.2/0.2	16
314%	Grapefruits	0.2/0.2	16
292%	Table grapes	0.2/0.2	15
277%	Pears	0.1/0.1	14
252%	Rice	1/1	13
250%	Aubergines/egg plants	0.5/0.5	13
237%	Mandarins	0.2/0.2	12
226%	Spinaches	0.5/0.5	11

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
506%	Chinese cabbages/pe-tsai	1/1	25
403%	Escaroles/broad-leaved	1/1	20
385%	Kales	1/1	19
271%	Aubergines/egg plants	0.5/0.5	14
189%	Chards/beet leaves	0.5/0.5	9.4
170%	Rice	1/1	8.5
168%	Head cabbages	0.2/0.2	8.4
136%	Table grapes	0.2/0.2	6.8
123%	Oranges	0.2/0.2	6.1
121%	Lettuces	0.5/0.5	6.1
112%	Florence fennels	0.3/0.3	5.6
106%	Red mustards	1/1	5.3
104%	Mangoes	0.2/0.2	5.2
96%	Celeries	0.3/0.3	4.8
95%	Wine grapes	0.2/0.2	4.7

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
528%	Kales	1/1	26
482%	Escaroles/broad-leaved	1/1	24
386%	Chinese cabbages/pe-tsai	1/1	19
267%	Oranges	0.2/0.2	13
252%	Rice	1/1	13
228%	Lettuces	0.5/0.5	11
226%	Spinaches	0.5/0.5	11
216%	Peaches	0.2/0.2	11
197%	Apricots	0.2/0.2	9.8
189%	Mangoes	0.2/0.2	9.4
188%	Grapefruits	0.2/0.2	9.4
175%	Table grapes	0.2/0.2	8.8
163%	Strawberries	0.5/0.5	8.2
152%	Leeks	0.3/0.3	7.6
150%	Aubergines/egg plants	0.5/0.5	7.5

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
304%	Chinese cabbages/pe-tsai	1/1	15
294%	Escaroles/broad-leaved endives	1/1	15
231%	Kales	1/1	12
193%	Aubergines/egg plants	0.5/0.5	9.7
187%	Oranges	0.2/0.2	9.4
170%	Rice	1/1	8.5
156%	Plums	0.2/0.2	7.8
132%	Mandarins	0.2/0.2	6.6
101%	Head cabbages	0.2/0.2	5.0
95%	Wine grapes	0.2/0.2	4.7
93%	Mangoes	0.2/0.2	4.7
93%	Strawberries	0.5/0.5	4.7
88%	Chards/beet leaves	0.5/0.5	4.4
84%	Grapefruits	0.2/0.2	4.2
81%	Peaches	0.2/0.2	4.1

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

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) #N/A

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	14	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	5	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new):	11	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new):	2

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1325%	Escaroles/broad-leaved end	1/1	66
552%	Kales/boiled	1/1	28
344%	Leeks/boiled	0.3/0.3	17
311%	Chards/beet leaves/boiled	0.5/0.5	16
272%	Florence fennels/boiled	0.3/0.3	14
211%	Oranges/juice	0.2/0.2	11
175%	Wine grapes/juice	0.2/0.2	8.7
158%	Broccoli/boiled	0.1/0.1	7.9
139%	Cauliflowers/boiled	0.1/0.1	7.0
139%	Spinaches/frozen; boiled	0.5/0.5	7.0
122%	Rice/milling (polishing)	1/0.4	6.1
114%	Currants (red, black and wh	0.2/0.2	5.7
108%	Apples/juice	0.1/0.1	5.4
104%	Peaches/canned	1/0.2	5.2
89%	Pumpkins/boiled	0.05/0.05	4.4

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
409%	Escaroles/broad-leaved	1/1	20
203%	Celeries/boiled	0.3/0.3	10
125%	Chards/beet leaves/boiled	0.5/0.5	6.3
116%	Florence fennels/boiled	0.3/0.3	5.8
105%	Leeks/boiled	0.3/0.3	5.2
83%	Cauliflowers/boiled	0.1/0.1	4.2
83%	Wine grapes/juice	0.2/0.2	4.2
83%	Spinaches/frozen; boiled	0.5/0.5	4.1
77%	Rice/milling (polishing)	1/0.4	3.9
72%	Barley/beer	0.5/0.1	3.6
67%	Apples/juice	0.1/0.1	3.3
60%	Oranges/juice	0.2/0.2	3.0
55%	Pumpkins/boiled	0.05/0.05	2.8
51%	Currants (red, black and	0.2/0.2	2.6
48%	Broccoli/boiled	0.1/0.1	2.4

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
795%	Escaroles/broad-leaved	1/1	40
331%	Kales/boiled	1/1	17
211%	Oranges/juice	0.2/0.2	11
197%	Leeks/boiled	0.3/0.3	9.9
175%	Wine grapes/juice	0.2/0.2	8.7
163%	Florence fennels/boiled	0.3/0.3	8.2
139%	Spinaches/frozen; boiled	0.5/0.5	7.0
133%	Chards/beet leaves/boiled	0.5/0.5	6.7
122%	Rice/milling (polishing)	1/0.4	6.1
114%	Currants (red, black and	0.2/0.2	5.7
108%	Apples/juice	0.1/0.1	5.4
95%	Broccoli/boiled	0.1/0.1	4.7
84%	Cauliflowers/boiled	0.1/0.1	4.2
77%	Peaches/canned	1/0.2	3.9
66%	Peaches/juice	0.2/0.2	3.3

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
311%	Escaroles/broad-leaved endives/	1/1	16
122%	Celeries/boiled	0.3/0.3	6.1
88%	Chards/beet leaves/boiled	0.5/0.5	4.4
83%	Wine grapes/juice	0.2/0.2	4.2
83%	Spinaches/frozen; boiled	0.5/0.5	4.1
81%	Leeks/boiled	0.3/0.3	4.1
77%	Rice/milling (polishing)	1/0.4	3.9
74%	Florence fennels/boiled	0.3/0.3	3.7
72%	Barley/beer	0.5/0.1	3.6
67%	Apples/juice	0.1/0.1	3.3
60%	Oranges/juice	0.2/0.2	3.0
51%	Currants (red, black and white)/	0.2/0.2	2.6
50%	Cauliflowers/boiled	0.1/0.1	2.5
43%	Grapefruits/juice	0.2/0.2	2.2
41%	Purslanes/boiled	0.5/0.5	2.1

Conclusion:
#N/A

For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Propamocarb

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.24	ARfD (mg/kg bw):	0.84
Source of ADI:	EU	Source of ARfD:	EU
Year of evaluation:	2007	Year of evaluation:	2007

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)
	24%	NL toddler	58.02	12%	Spinaches	3%	Cauliflowers	2%	Escaroles/broad-leaved endives	0.2%	
	17%	GEMS/Food G06	41.14	6%	Tomatoes	2%	Watermelons	1%	Cucumbers	0.1%	
	12%	DE child	28.57	3%	Spinaches	2%	Tomatoes	1%	Cucumbers	0.1%	
	11%	GEMS/Food G10	25.77	2%	Tomatoes	1%	Chinese cabbages/pe-tsai	0.8%	Spinaches	0.1%	
	11%	FR infant	25.34	4%	Spinaches	2%	Leeks	1%	Cauliflowers	0.0%	
	10%	NL child	24.56	4%	Spinaches	0.9%	Tomatoes	0.8%	Escaroles/broad-leaved endives	0.1%	
	10%	SE general	24.54	2%	Chinese cabbages/pe-tsai	1%	Tomatoes	1%	Spinaches	0.0%	
	10%	IE adult	23.07	2%	Spinaches	2%	Melons	0.7%	Leeks	0.1%	
	9%	GEMS/Food G11	21.96	2%	Leeks	2%	Spinaches	2%	Tomatoes	0.1%	
	9%	FR toddler 2–3 years	21.78	3%	Spinaches	2%	Leeks	1.0%	Cauliflowers	0.1%	
	9%	NL general	21.64	3%	Spinaches	1%	Leeks	0.8%	Escaroles/broad-leaved endives	0.1%	
	9%	IT adult	21.04	2%	Tomatoes	2%	Spinaches	1%	Other spinach and similar	0.0%	
	9%	FR child 3–15 years	20.71	2%	Spinaches	2%	Leeks	1%	Tomatoes	0.1%	
	9%	GEMS/Food G08	20.43	2%	Tomatoes	0.6%	Leeks	0.6%	Lamb's lettuce/corn salads	0.1%	
	8%	IT toddler	18.86	2%	Tomatoes	1%	Chards/beet leaves	1.0%	Spinaches	0.1%	
	8%	RO general	18.12	3%	Tomatoes	1.0%	Watermelons	0.6%	Onions	0.1%	
	7%	ES child	17.97	2%	Tomatoes	1%	Spinaches	1%	Chards/beet leaves	0.1%	
	7%	GEMS/Food G15	17.81	2%	Tomatoes	1.0%	Watermelons	0.7%	Sweet peppers/bell peppers	0.1%	
	7%	GEMS/Food G07	17.00	2%	Tomatoes	0.6%	Spinaches	0.6%	Leeks	0.1%	
	7%	ES adult	16.98	1%	Chards/beet leaves	1%	Tomatoes	1%	Spinaches	0.0%	
	7%	DK child	16.80	3%	Cucumbers	0.9%	Tomatoes	0.5%	Melons	0.1%	
	7%	FI 3 years	16.47	2%	Cucumbers	1%	Spinaches	0.9%	Tomatoes	0.0%	
	6%	DE women 14–50 years	13.70	1%	Tomatoes	0.8%	Spinaches	0.6%	Cauliflowers	0.1%	
	5%	FI 6 years	13.18	1%	Cucumbers	0.9%	Spinaches	0.7%	Tomatoes	0.0%	
	5%	DE general	12.73	1%	Tomatoes	0.8%	Spinaches	0.6%	Cauliflowers	0.1%	
	5%	FR adult	12.72	1%	Leeks	0.9%	Spinaches	0.8%	Tomatoes	0.1%	
	5%	PT general	11.82	2%	Kales	1%	Tomatoes	0.7%	Potatoes	0.1%	
	4%	UK vegetarian	9.97	1%	Tomatoes	0.6%	Spinaches	0.5%	Cauliflowers	0.0%	
	4%	PL general	9.40	1%	Tomatoes	0.4%	Potatoes	0.4%	Cauliflowers	0.0%	
	3%	UK toddler	8.19	1.0%	Tomatoes	0.5%	Cauliflowers	0.5%	Cauliflowers	0.1%	
	3%	FI adult	7.86	0.9%	Tomatoes	0.8%	Cucumbers	0.3%	Lettuces	0.1%	
	3%	DK adult	7.57	0.9%	Tomatoes	0.5%	Cucumbers	0.3%	Melons	0.0%	
	3%	UK infant	7.13	1%	Cauliflowers	0.6%	Tomatoes	0.4%	Potatoes	0.1%	
	3%	LT adult	6.50	1%	Tomatoes	0.8%	Cucumbers	0.4%	Potatoes	0.0%	
	3%	UK adult	6.33	0.7%	Tomatoes	0.3%	Spinaches	0.3%	Cauliflowers	0.0%	
	0.7%	IE child	1.58	0.1%	Cauliflowers	0.1%	Tomatoes	0.1%	Potatoes	0.0%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results of IESTI calculation for all crops

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): ---	**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): 2	**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
133%	Lettuces	40/29.3	1115
105%	Leeks	20/15	884
90%	Melons	5/5	758
77%	Chinese cabbages/pe-tsai	20/20	643
73%	Watermelons	5/5	611
69%	Cauliflowers	10/10	579
67%	Spinaches	40/25	565
62%	Kales	20/11.8	519
56%	Spring onions/green onions	30/30	471
46%	Chards/beet leaves	40/25	390
39%	Cucumbers	5/5	328
39%	Escaroles/broad-leaved	20/8.1	325
38%	Witloofs/Belgian endives	15/8	317
28%	Tomatoes	4/4	233
28%	Courgettes	5/5	232

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
60%	Chinese cabbages/pe-tsai	20/20	506
56%	Chards/beet leaves	40/25	472
42%	Lettuces	40/29.3	356
28%	Cauliflowers	10/10	232
27%	Kales	20/11.8	227
24%	Watermelons	5/5	203
23%	Leeks	20/15	197
23%	Melons	5/5	196
19%	Escaroles/broad-leaved	20/8.1	163
18%	Witloofs/Belgian endives	15/8	147
17%	Cucumbers	5/5	139
16%	Spring onions/green onions	30/30	135
14%	Courgettes	5/5	116
13%	Aubergines/egg plants	4/4	108
13%	Red mustards	20/20	106

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
109%	Lettuces	40/40	914
108%	Spinaches	40/40	904
63%	Kales	20/20	528
60%	Leeks	20/20	505
59%	Witloofs/Belgian endives	15/15	496
57%	Escaroles/broad-leaved	20/20	482
54%	Melons	5/5	455
49%	Spring onions/green onions	30/30	411
46%	Chinese cabbages/pe-tsai	20/20	386
44%	Watermelons	5/5	367
41%	Cauliflowers	10/10	348
32%	Chards/beet leaves	40/40	267
23%	Cucumbers	5/5	197
14%	Tomatoes	4/4	121
12%	Courgettes	5/5	100

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
42%	Chards/beet leaves	40/40	353
36%	Chinese cabbages/pe-tsai	20/20	304
35%	Escaroles/broad-leaved endives	20/20	294
35%	Lettuces	40/40	291
28%	Kales	20/20	231
23%	Witloofs/Belgian endives	15/15	190
19%	Spinaches	40/40	160
17%	Cauliflowers	10/10	139
15%	Watermelons	5/5	122
14%	Melons	5/5	118
14%	Leeks	20/20	116
12%	Spring onions/green onions and	30/30	101
10%	Cucumbers	5/5	83
9%	Aubergines/egg plants	4/4	77
9%	Tomatoes	4/4	77

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 2		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)** 2	

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
102%	Leeks/boiled	20/15	859
93%	Chards/beet leaves/boiled	40/25	778
83%	Witloofs/boiled	15/8	698
83%	Cauliflowers/boiled	10/10	696
64%	Escaroles/broad-leaved end	20/8.1	537
53%	Pumpkins/boiled	5/5	443
41%	Spinaches/frozen; boiled	40/25	348
39%	Kales/boiled	20/11.8	325
28%	Broccoli/boiled	3/3	236
21%	Courgettes/boiled	5/5	177
14%	Gherkins/pickled	5/5	115
9%	Tomatoes/juice	4/4	76
5%	Tomatoes/sauce/puree	4/4	38
4%	Shallots/boiled	2/2	32
3%	Potatoes/fried	0.3/0.3	28

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
50%	Cauliflowers/boiled	10/10	417
37%	Chards/beet leaves/boiled	40/25	313
33%	Pumpkins/boiled	5/5	276
31%	Leeks/boiled	20/15	262
25%	Spinaches/frozen; boiled	40/25	207
20%	Escaroles/broad-leaved	20/8.1	166
20%	Purslanes/boiled	40/40	165
18%	Witloofs/boiled	15/8	148
14%	Courgettes/boiled	5/5	114
9%	Broccoli/boiled	3/3	72
4%	Tomatoes/sauce/puree	4/4	33
2%	Onions/boiled	2/2	19
1%	Shallots/boiled	2/2	12
0.8%	Head cabbages/canned	0.7/0.7	6.6
0.8%	Kohlrabies/boiled	0.3/0.3	6.4

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
59%	Leeks/boiled	20/15	493
50%	Cauliflowers/boiled	10/10	418
45%	Witloofs/boiled	15/8	378
41%	Spinaches/frozen; boiled	40/25	348
40%	Chards/beet leaves/boiled	40/25	333
38%	Escaroles/broad-leaved	20/8.1	322
32%	Pumpkins/boiled	5/5	266
23%	Kales/boiled	20/11.8	195
17%	Broccoli/boiled	3/3	142
13%	Courgettes/boiled	5/5	106
9%	Tomatoes/juice	4/4	76
6%	Gherkins/pickled	5/5	49
5%	Tomatoes/sauce/puree	4/4	38
2%	Brussels sprouts/boiled	2/2	20
2%	Potatoes/dried (flakes)	0.3/1.38	18

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Cauliflowers/boiled	10/10	250
26%	Chards/beet leaves/boiled	40/25	221
25%	Spinaches/frozen; boiled	40/25	207
24%	Leeks/boiled	20/15	203
24%	Pumpkins/boiled	5/5	200
21%	Witloofs/boiled	15/8	172
20%	Purslanes/boiled	40/40	165
15%	Escaroles/broad-leaved endives/	20/8.1	126
9%	Courgettes/boiled	5/5	80
7%	Broccoli/boiled	3/3	60
4%	Tomatoes/sauce/puree	4/4	33
2%	Onions/boiled	2/2	14
2%	Shallots/boiled	2/2	14
0.8%	Head cabbages/canned	0.7/0.7	6.6
0.3%	Kohlrabies/boiled	0.3/0.3	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; 2018/11/18

Propiconazole

LOQs (mg/kg) range from:	0.01	to:	0.07
Toxicological reference values			
ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2017	Year of evaluation:	2017

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)
21%	NL toddler	8.31	3%	Apples	3%	Maize/corn	2%	Tomatoes	2%	
16%	GEMS/Food G06	6.41	6%	Tomatoes	3%	Rice	1%	Wheat	0.3%	
14%	DE child	5.56	3%	Apples	2%	Oranges	2%	Tomatoes	0.8%	
13%	NL child	5.03	2%	Sugar beet roots	2%	Apples	1%	Tomatoes	0.9%	
11%	GEMS/Food G10	4.28	2%	Tomatoes	2%	Rice	0.7%	Peaches	0.4%	
10%	GEMS/Food G07	4.12	2%	Tomatoes	2%	Bovine: Liver	0.8%	Oranges	0.4%	
10%	FR child 3–15 years	4.06	2%	Oranges	2%	Tomatoes	1.0%	Sugar beet roots	0.8%	
9%	IE adult	3.69	3%	Sheep: Liver	1%	Peaches	0.7%	Tomatoes	0.5%	
9%	GEMS/Food G15	3.63	2%	Tomatoes	0.7%	Wheat	0.6%	Bovine: Liver	0.4%	
9%	GEMS/Food G08	3.52	2%	Tomatoes	0.8%	Peaches	0.6%	Wheat	0.4%	
9%	RO general	3.49	3%	Tomatoes	0.8%	Wheat	0.5%	Wine grapes	0.5%	
8%	ES child	3.32	2%	Tomatoes	1%	Oranges	0.8%	Rice	0.5%	
8%	UK infant	3.28	1%	Rice	1%	Bovine: Liver	1.0%	Milk: Cattle	1%	
8%	FR toddler 2–3 years	3.18	1.0%	Rice	0.9%	Apples	0.9%	Tomatoes	1.0%	
8%	GEMS/Food G11	3.16	2%	Tomatoes	0.5%	Wheat	0.5%	Rice	0.5%	
8%	UK toddler	3.11	1%	Oranges	1%	Tomatoes	0.9%	Rice	0.7%	
8%	DE women 14–50 years	3.06	1%	Tomatoes	1%	Sugar beet roots	1%	Oranges	0.4%	
8%	DK child	3.04	1.0%	Tomatoes	0.8%	Rye	0.7%	Wheat	0.5%	
7%	PT general	2.86	2%	Tomatoes	1%	Peaches	1%	Rice	0.2%	
7%	DE general	2.86	1%	Tomatoes	1%	Sugar beet roots	0.9%	Oranges	0.4%	
7%	SE general	2.82	2%	Bovine: Muscle/meat	1%	Tomatoes	0.7%	Rice	0.6%	
7%	IT toddler	2.62	3%	Tomatoes	1%	Peaches	1.0%	Wheat	0.1%	
6%	ES adult	2.31	1%	Tomatoes	0.8%	Peaches	0.7%	Oranges	0.3%	
6%	NL general	2.26	0.8%	Tomatoes	0.8%	Sugar beet roots	0.6%	Oranges	0.4%	
5%	IT adult	2.20	2%	Tomatoes	1%	Peaches	0.6%	Wheat	0.1%	
5%	FR adult	1.95	0.8%	Tomatoes	0.7%	Wine grapes	0.5%	Peaches	0.2%	
5%	FI 3 years	1.90	1%	Tomatoes	0.9%	Rice	0.4%	Peaches	0.2%	
4%	UK vegetarian	1.57	1%	Tomatoes	0.6%	Rice	0.5%	Oranges	0.2%	
4%	DK adult	1.48	0.9%	Tomatoes	0.3%	Wine grapes	0.3%	Peaches	0.2%	
4%	FI 6 years	1.46	0.8%	Tomatoes	0.7%	Rice	0.4%	Peaches	0.2%	
4%	UK adult	1.44	0.8%	Tomatoes	0.6%	Rice	0.3%	Wine grapes	0.2%	
4%	LT adult	1.42	1%	Tomatoes	0.5%	Apples	0.4%	Rice	0.2%	
3%	FI adult	1.34	1%	Tomatoes	0.8%	Coffee beans	0.2%	Oranges	0.1%	
3%	PL general	1.25	2%	Tomatoes	0.6%	Apples	0.2%	Peaches	0.1%	
3%	FR infant	1.06	0.5%	Apples	0.4%	Milk: Cattle	0.4%	Sugar beet roots	0.6%	
1%	IE child	0.53	0.5%	Rice	0.2%	Wheat	0.1%	Tomatoes	0.1%	

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	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children	Results for adults	IESTI new Results for children	IESTI new Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2	No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 6	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
209%	Peaches	5/2.2	209
102%	Tomatoes	3/1.76	102
57%	Oranges	10/0.43	57
46%	Bovine: Liver	0.5/5.67	46
35%	Table grapes	0.3/0.48	35
25%	Mandarins	10/0.43	25
23%	Bananas	0.15/0.24	23
23%	Apples	0.15/0.21	23
22%	Cherries (sweet)	3/1.8	22
19%	Pineapples	2/0.19	19
18%	Bovine: Kidney	0.5/4.8	18
15%	Lemons	10/0.43	15
13%	Grapefruits	5/0.16	13
10%	Cucumbers	0.01/0.15	9.8
9%	Plums	0.01/0.22	9.3

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
41%	Peaches	5/2.2	41
28%	Tomatoes	3/1.76	28
23%	Bovine: Liver	0.5/5.67	23
18%	Cherries (sweet)	3/1.8	18
16%	Table grapes	0.3/0.48	16
16%	Sheep: Liver	0.5/5.67	16
13%	Oranges	10/0.43	13
11%	Wine grapes	0.3/0.48	11
11%	Swine: Kidney	0.5/4.8	11
10%	Bovine: Kidney	0.5/4.8	10
8%	Mandarins	10/0.43	7.7
6%	Apples	0.15/0.21	5.9
6%	Pineapples	2/0.19	5.6
6%	Rice	1.5/0.66	5.6
5%	Bananas	0.15/0.24	5.1

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
668%	Oranges	10/10	668
370%	Mandarins	10/10	370
270%	Peaches	5/5	270
236%	Grapefruits	5/5	236
233%	Lemons	10/10	233
121%	Pineapples	2/2	121
91%	Tomatoes	3/3	91
86%	Limes	10/10	86
37%	Cherries (sweet)	3/3	37
19%	Rice	1.5/1.5	19
13%	Table grapes	0.3/0.3	13
11%	Barley	2/2	11
9%	Apples	0.15/0.15	9.2
9%	Bananas	0.15/0.15	9.2
7%	Apricots	0.15/0.15	7.4

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
469%	Oranges	10/10	469
330%	Mandarins	10/10	330
105%	Grapefruits	5/5	105
102%	Peaches	5/5	102
58%	Tomatoes	3/3	58
38%	Lemons	10/10	38
36%	Pineapples	2/2	36
30%	Limes	10/10	30
30%	Cherries (sweet)	3/3	30
13%	Rice	1.5/1.5	13
10%	Barley	2/2	9.7
7%	Wine grapes	0.3/0.3	7.1
6%	Table grapes	0.3/0.3	6.1
5%	Apples	0.15/0.15	4.5
4%	Bananas	0.15/0.15	4.2

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)	
2		6	

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
57%	Peaches/canned	1/2.2	57
26%	Peaches/juice	5/1.55	26
14%	Tomatoes/juice	3/0.72	14
12%	Oranges/juice	10/0.22	12
12%	Sugar beets (root)/sugar	0.15/1.26	12
8%	Pineapples/canned	2/0.19	7.8
7%	Tomatoes/sauce/puree	3/0.72	6.9
6%	Apples/juice	0.15/0.11	5.9
5%	Wine grapes/juice	0.3/0.12	5.2
4%	Currants (red, black and wh	0.01/0.15	4.3
4%	Rice/milling (polishing)	1.5/0.26	4.0
3%	Maize/oil	0.05/3.75	3.5
2%	Pineapples/juice	2/0.16	2.3
2%	Peanuts/peanut butter	0.01/0.6	2.2
2%	Plums/juice	0.01/0.19	1.7

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Peaches/canned	5/2.2	18
6%	Tomatoes/sauce/puree	3/0.72	5.9
5%	Sugar beets (root)/sugar	0.15/1.26	4.6
5%	Wine grapes/wine	0.3/0.48	4.5
4%	Apples/juice	0.15/0.11	3.6
3%	Oranges/juice	10/0.22	3.3
3%	Table grapes/raisins	0.3/2.26	2.8
3%	Rice/milling (polishing)	1.5/0.26	2.6
3%	Pineapples/canned	2/0.19	2.5
2%	Wine grapes/juice	0.3/0.12	2.5
2%	Currants (red, black and	0.01/0.15	1.9
2%	Maize/oil	0.05/3.75	1.9
1%	Pineapples/juice	2/0.16	1.4
1%	Grapefruits/juice	5/0.11	1.2
0.9%	Barley/beer	2/0.02	0.86

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
43%	Peaches/canned	1/2.2	43
26%	Peaches/juice	5/1.55	26
14%	Tomatoes/juice	3/0.72	14
12%	Oranges/juice	10/0.22	12
12%	Sugar beets (root)/sugar	0.15/1.26	12
7%	Tomatoes/sauce/puree	3/0.72	6.9
6%	Apples/juice	0.15/0.11	5.9
5%	Wine grapes/juice	0.3/0.12	5.2
5%	Pineapples/canned	2/0.19	4.7
4%	Currants (red, black and	0.01/0.15	4.3
4%	Rice/milling (polishing)	1.5/0.26	4.0
3%	Maize/oil	0.05/3.75	3.5
2%	Pineapples/juice	2/0.16	2.3
2%	Peanuts/peanut butter	0.01/0.6	2.2
2%	Plums/juice	0.01/0.19	1.7

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Peaches/canned	5/2.2	18
6%	Tomatoes/sauce/puree	3/0.72	5.9
5%	Sugar beets (root)/sugar	0.15/1.26	4.6
5%	Wine grapes/wine	0.3/0.48	4.5
4%	Apples/juice	0.15/0.11	3.6
3%	Oranges/juice	10/0.22	3.3
3%	Table grapes/raisins	0.3/2.26	2.8
3%	Rice/milling (polishing)	1.5/0.26	2.6
2%	Wine grapes/juice	0.3/0.12	2.5
2%	Currants (red, black and white)/	0.01/0.15	1.9
2%	Maize/oil	0.05/3.75	1.9
2%	Pineapples/canned	2/0.19	1.5
1%	Pineapples/juice	2/0.16	1.4
1%	Grapefruits/juice	5/0.11	1.2
0.9%	Barley/beer	2/0.02	0.86

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Profenofos (F) (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.005	ARfD (mg/kg bw):	0.01
Source of ADI:	Germany	Source of ARfD:	Germany
Year of evaluation:	2001	Year of evaluation:	2001

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 : 1

	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)	113%	GEMS/Food G06	5.64	93%	Tomatoes	19%	Cotton seeds	0.7%	Papayas		113%
	50%	RO general	2.51	50%	Tomatoes		FRUIT AND TREE NUTS				50%
	44%	GEMS/Food G10	2.18	36%	Tomatoes	8%	Cotton seeds	0.4%	Papayas		44%
	39%	GEMS/Food G07	1.96	28%	Tomatoes	11%	Cotton seeds	0.2%	Papayas		39%
	37%	IT toddler	1.85	37%	Tomatoes	0.0%	Other herbs	0.0%	Parsley		37%
	34%	GEMS/Food G08	1.71	30%	Tomatoes	4%	Cotton seeds	0.1%	Papayas		34%
	34%	GEMS/Food G15	1.71	31%	Tomatoes	3%	Cotton seeds	0.1%	Papayas		34%
	30%	IT adult	1.51	30%	Tomatoes	0.0%	Other herbs	0.0%	Parsley		30%
	30%	GEMS/Food G11	1.50	24%	Tomatoes	6%	Cotton seeds	0.4%	Papayas		30%
	27%	DE child	1.37	26%	Tomatoes	0.4%	Papayas	0.1%	Juniper berry		27%
	27%	NL toddler	1.33	26%	Tomatoes	0.5%	Papayas	0.2%	Mangoes		27%
	26%	ES child	1.28	26%	Tomatoes		FRUIT AND TREE NUTS				26%
	23%	PT general	1.16	23%	Tomatoes	0.0%	Parsley				23%
	23%	PL general	1.15	23%	Tomatoes	0.0%	Celery leaves	0.0%	Parsley		23%
	22%	FR child 3–15 years	1.09	22%	Tomatoes	0.0%	Other herbs	0.0%	Parsley		22%
	21%	SE general	1.03	20%	Tomatoes	0.7%	Papayas	0.0%	Mangoes		21%
	20%	ES adult	1.02	20%	Tomatoes	0.0%	Papayas	0.0%	Mangoes		20%
	20%	DE women 14–50 years	0.98	19%	Tomatoes	0.2%	Coffee beans	0.1%	Papayas		20%
	17%	DE general	0.87	17%	Tomatoes	0.2%	Coffee beans	0.1%	Papayas		17%
	17%	FI adult	0.84	14%	Tomatoes	2%	Coffee beans				17%
	16%	UK vegetarian	0.81	16%	Tomatoes	0.0%	Mangoes	0.0%	Parsley		16%
	16%	LT adult	0.81	16%	Tomatoes		FRUIT AND TREE NUTS				16%
	15%	UK toddler	0.77	15%	Tomatoes	0.0%	Mangoes				15%
	15%	NL child	0.75	15%	Tomatoes	0.3%	Papayas	0.1%	Mangoes		15%
	15%	FI 3 years	0.73	15%	Tomatoes	0.0%	Coffee beans				15%
	14%	DK child	0.70	14%	Tomatoes	0.1%	Papayas	0.0%	Mangoes		14%
	14%	DK adult	0.68	13%	Tomatoes	0.0%	Papayas	0.0%	Mangoes		14%
	12%	FR toddler 2–3 years	0.62	12%	Tomatoes	0.1%	Mangoes	0.0%	Parsley		12%
	12%	FR adult	0.61	12%	Tomatoes	0.2%	Coffee beans	0.0%	Parsley		12%
	11%	FI 6 years	0.57	11%	Tomatoes	0.0%	Coffee beans				11%
	11%	UK adult	0.57	11%	Tomatoes	0.0%	Mangoes	0.0%	Parsley		11%
	11%	NL general	0.55	11%	Tomatoes	0.1%	Coffee beans	0.0%	Mangoes		11%
	11%	IE adult	0.54	10%	Tomatoes	0.3%	Mangoes	0.0%	Basil and edible flowers		11%
	10%	UK infant	0.48	10%	Tomatoes		FRUIT AND TREE NUTS				10%
	2%	FR infant	0.12	2%	Tomatoes	0.0%	Parsley	0.0%	Chives		2%
	1%	IE child	0.07	1%	Tomatoes	0.0%	Mangoes	0.0%	Sage		1%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0–112.7% of the ADI.
For 1 diet(s), the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): 1				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): 1			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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)
2733%	Tomatoes	10/4.7	273	745%	Tomatoes	10/4.7	75	3034%	Tomatoes	10/10	303	1929%	Tomatoes	10/10	193
55%	Mangoes	0.2/0.07	5.5	18%	Mangoes	0.2/0.07	1.8	94%	Mangoes	0.2/0.2	9.4	47%	Mangoes	0.2/0.2	4.7
4%	Papayas	0.01/0.01	0.42	3%	Cardamom	3/3	0.30	2%	Papayas	0.01/0.01	0.18	3%	Cardamom	3/3	0.30
0.8%	Fennel seed	0.1/0.1	0.08	1%	Papayas	0.01/0.01	0.14	0.8%	Fennel seed	0.1/0.1	0.08	0.8%	Papayas	0.01/0.01	0.08
0.6%	Chervil	0.05/0.05	0.06	0.6%	Rose	0.1/0.1	0.06	0.6%	Chervil	0.05/0.05	0.06	0.6%	Rose	0.1/0.1	0.06
0.5%	Parsley	0.05/0.05	0.05	0.6%	Parsley	0.05/0.05	0.06	0.5%	Parsley	0.05/0.05	0.05	0.6%	Parsley	0.05/0.05	0.06
0.4%	Vanilla pods	0.07/0.07	0.04	0.2%	Tamarind	0.07/0.07	0.02	0.4%	Vanilla pods	0.07/0.07	0.04	0.3%	Coffee beans	0.04/0.04	0.03
0.4%	Chives	0.05/0.05	0.04	0.2%	Celery leaves	0.05/0.05	0.02	0.4%	Chives	0.05/0.05	0.04	0.2%	Celery leaves	0.05/0.05	0.02
0.4%	Sage	0.05/0.05	0.04	0.2%	Coffee beans	0.04/0.02	0.02	0.4%	Sage	0.05/0.05	0.04	0.10%	Sage	0.05/0.05	0.01
0.4%	Basil and edible flowers	0.05/0.05	0.04	0.1%	Sage	0.05/0.05	0.01	0.4%	Basil and edible flowers	0.05/0.05	0.04	0.10%	Sage	0.05/0.05	0.01
0.3%	Cardamom	3/3	0.03	0.1%	Sage	0.05/0.05	0.01	0.3%	Cardamom	3/3	0.03	0.10%	Sage	0.05/0.05	0.01
0.3%	Cumin seed	5/5	0.03	0.1%	Sage	0.05/0.05	0.01	0.3%	Coffee beans	0.04/0.04	0.03	0.10%	Tamarind	0.07/0.07	0.01
0.2%	Celery leaves	0.05/0.05	0.02	0.09%	Chives	0.05/0.05	0.01	0.3%	Cumin seed	5/5	0.03	0.09%	Chives	0.05/0.05	0.01
0.2%	Rose	0.1/0.1	0.02	0.08%	Cumin seed	5/5	0.01	0.2%	Celery leaves	0.05/0.05	0.02	0.08%	Cumin seed	5/5	0.01
0.1%	Coffee beans	0.04/0.02	0.01	0.07%	Vanilla pods	0.07/0.07	0.01	0.2%	Rose	0.1/0.1	0.02	0.07%	Vanilla pods	0.07/0.07	0.01
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)** 1							

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				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 2				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 1			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
247%	Tomatoes/juice	10/1.3	25	107%	Tomatoes/sauce/puree	10/1.3	11	247%	Tomatoes/juice	10/1.3	25	107%	Tomatoes/sauce/puree	10/1.3	11
124%	Tomatoes/sauce/puree	10/1.3	12	1.0%	Coffee beans/extraction	0.04/0	0.10	124%	Tomatoes/sauce/puree	10/1.3	12	1.0%	Coffee beans/extraction	0.04/0	0.10
0.4%	Coffee beans/extraction	0.04/0	0.04	0.2%	Cumin seed/processed	0.1/0.64	0.02	0.4%	Coffee beans/extraction	0.04/0	0.04	0.2%	Cumin seed/processed (not	0.1/0.64	0.02
Expand/collapse list															

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

For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Profenofos (F) (F)

LOQs (mg/kg) range from:	0.01	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.03	ARfD (mg/kg bw):	1
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2007	Year of evaluation:	2007

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)
19%	GEMS/Food G06	5.64	16%	Tomatoes	3%	Cotton seeds	0.1%	Papayas		19%
8%	RO general	2.51	8%	Tomatoes		FRUIT AND TREE NUTS				8%
7%	GEMS/Food G10	2.18	6%	Tomatoes	1%	Cotton seeds	0.1%	Papayas		7%
7%	GEMS/Food G07	1.96	5%	Tomatoes	2%	Cotton seeds	0.0%	Papayas		7%
6%	IT toddler	1.85	6%	Tomatoes	0.0%	Other herbs	0.0%	Parsley		6%
6%	GEMS/Food G08	1.71	5%	Tomatoes	0.7%	Cotton seeds	0.0%	Papayas		6%
6%	GEMS/Food G15	1.71	5%	Tomatoes	0.5%	Cotton seeds	0.0%	Papayas		6%
5%	IT adult	1.51	5%	Tomatoes	0.0%	Other herbs	0.0%	Parsley		5%
5%	GEMS/Food G11	1.50	4%	Tomatoes	0.9%	Cotton seeds	0.1%	Papayas		5%
5%	DE child	1.37	4%	Tomatoes	0.1%	Papayas	0.0%	Juniper berry		5%
4%	NL toddler	1.33	4%	Tomatoes	0.1%	Papayas	0.0%	Mangoes		4%
4%	ES child	1.28	4%	Tomatoes		FRUIT AND TREE NUTS				4%
4%	PT general	1.16	4%	Tomatoes	0.0%	Parsley				4%
4%	PL general	1.15	4%	Tomatoes	0.0%	Celery leaves	0.0%	Parsley		4%
4%	FR child 3–15 years	1.09	4%	Tomatoes	0.0%	Other herbs	0.0%	Parsley		4%
3%	SE general	1.03	3%	Tomatoes	0.1%	Papayas	0.0%	Mangoes		3%
3%	ES adult	1.02	3%	Tomatoes	0.0%	Papayas	0.0%	Mangoes		3%
3%	DE women 14–50 years	0.98	3%	Tomatoes	0.0%	Coffee beans	0.0%	Papayas		3%
3%	DE general	0.87	3%	Tomatoes	0.0%	Coffee beans	0.0%	Papayas		3%
3%	FI adult	0.84	2%	Tomatoes	0.4%	Coffee beans				3%
3%	UK vegetarian	0.81	3%	Tomatoes	0.0%	Mangoes	0.0%	Parsley		3%
3%	LT adult	0.81	3%	Tomatoes		FRUIT AND TREE NUTS				3%
3%	UK toddler	0.77	3%	Tomatoes	0.0%	Mangoes				3%
3%	NL child	0.75	2%	Tomatoes	0.1%	Papayas	0.0%	Mangoes		3%
2%	FI 3 years	0.73	2%	Tomatoes	0.0%	Coffee beans				2%
2%	DK child	0.70	2%	Tomatoes	0.0%	Papayas	0.0%	Mangoes		2%
2%	DK adult	0.68	2%	Tomatoes	0.0%	Papayas	0.0%	Mangoes		2%
2%	FR toddler 2–3 years	0.62	2%	Tomatoes	0.0%	Mangoes	0.0%	Parsley		2%
2%	FR adult	0.61	2%	Tomatoes	0.0%	Coffee beans	0.0%	Parsley		2%
2%	FI 6 years	0.57	2%	Tomatoes	0.0%	Coffee beans				2%
2%	UK adult	0.57	2%	Tomatoes	0.0%	Mangoes	0.0%	Parsley		2%
2%	NL general	0.55	2%	Tomatoes	0.0%	Coffee beans	0.0%	Mangoes		2%
2%	IE adult	0.54	2%	Tomatoes	0.1%	Mangoes	0.0%	Basil and edible flowers		2%
2%	UK infant	0.48	2%	Tomatoes		FRUIT AND TREE NUTS				2%
0.4%	FR infant	0.12	0.4%	Tomatoes	0.0%	Parsley	0.0%	Chives		0.4%
0.2%	IE child	0.07	0.2%	Tomatoes	0.0%	Mangoes	0.0%	Sage		0.2%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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)
27%	Tomatoes	10/4.7	273	7%	Tomatoes	10/4.7	75	30%	Tomatoes	10/10	303	19%	Tomatoes	10/10	193
3%	Papayas	0.01/0.7	30	1.0%	Papayas	0.01/0.7	9.8	0.9%	Mangoes	0.2/0.2	9.4	0.5%	Mangoes	0.2/0.2	4.7
2%	Mangoes	0.2/0.2	16	0.5%	Mangoes	0.2/0.2	5.2	0.02%	Papayas	0.01/0.01	0.18	0.03%	Cardamom	3/3	0.30
0.01%	Fennel seed	0.1/0.1	0.08	0.03%	Cardamom	3/3	0.30	0.01%	Fennel seed	0.1/0.1	0.08	0.01%	Papayas	0.01/0.01	0.08
0.01%	Chervil	0.05/0.05	0.06	0.01%	Rose	0.1/0.1	0.06	0.01%	Chervil	0.05/0.05	0.06	0.01%	Rose	0.1/0.1	0.06
0.01%	Parsley	0.05/0.05	0.05	0.01%	Parsley	0.05/0.05	0.06	0.01%	Parsley	0.05/0.05	0.05	0.01%	Parsley	0.05/0.05	0.06
0.00%	Vanilla pods	0.07/0.07	0.04	0.00%	Tamarind	0.07/0.07	0.02	0.00%	Vanilla pods	0.07/0.07	0.04	0.00%	Coffee beans	0.04/0.04	0.03
0.00%	Chives	0.05/0.05	0.04	0.00%	Celery leaves	0.05/0.05	0.02	0.00%	Chives	0.05/0.05	0.04	0.00%	Celery leaves	0.05/0.05	0.02
0.00%	Sage	0.05/0.05	0.04	0.00%	Coffee beans	0.04/0.02	0.02	0.00%	Sage	0.05/0.05	0.04	0.00%	Sage	0.05/0.05	0.01
0.00%	Basil and edible flowers	0.05/0.05	0.04	0.00%	Sage	0.05/0.05	0.01	0.00%	Basil and edible flowers	0.05/0.05	0.04	0.00%	Sage	0.05/0.05	0.01
0.00%	Cardamom	3/3	0.03	0.00%	Sage	0.05/0.05	0.01	0.00%	Cardamom	3/3	0.03	0.00%	Sage	0.05/0.05	0.01
0.00%	Cumin seed	5/5	0.03	0.00%	Sage	0.05/0.05	0.01	0.00%	Coffee beans	0.04/0.04	0.03	0.00%	Tamarind	0.07/0.07	0.01
0.00%	Celery leaves	0.05/0.05	0.02	0.00%	Chives	0.05/0.05	0.01	0.00%	Cumin seed	5/5	0.03	0.00%	Chives	0.05/0.05	0.01
0.00%	Rose	0.1/0.1	0.02	0.00%	Cumin seed	5/5	0.01	0.00%	Celery leaves	0.05/0.05	0.02	0.00%	Cumin seed	5/5	0.01
0.00%	Coffee beans	0.04/0.02	0.01	0.00%	Vanilla pods	0.07/0.07	0.01	0.00%	Rose	0.1/0.1	0.02	0.00%	Vanilla pods	0.07/0.07	0.01
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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%	Tomatoes/juice	10/1.3	25	1%	Tomatoes/sauce/puree	10/1.3	11	2%	Tomatoes/juice	10/1.3	25	1%	Tomatoes/sauce/puree	10/1.3	11
1%	Tomatoes/sauce/puree	10/1.3	12	0.01%	Coffee beans/extraction	0.04/0	0.10	1%	Tomatoes/sauce/puree	10/1.3	12	0.01%	Coffee beans/extraction	0.04/0	0.10
0.0%	Coffee beans/extraction	0.04/0	0.04	0.00%	Cumin seed/processed	0.1/0.64	0.02	0.00%	Coffee beans/extraction	0.04/0	0.04	0.00%	Cumin seed/processed (not	0.1/0.64	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 Profenofos (F) (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; 2018/11/18

Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone) (R)

LOQs (mg/kg) range from: 0.02 to: 0.10

Toxicological reference values

ADI (mg/kg bw per day):	0.09	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:

Refined calculation 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)	3%	NL toddler	2.38	1%	Milk: Cattle	0.4%	Maize/corn	0.3%	Potatoes	0.0%	3%
	2%	DK child	1.57	0.6%	Rye	0.3%	Wheat	0.3%	Milk: Cattle	0.0%	2%
	2%	UK infant	1.40	0.9%	Milk: Cattle	0.3%	Potatoes	0.2%	Wheat	0.0%	2%
	1%	GEMS/Food G11	1.27	0.4%	Soyabeans	0.3%	Potatoes	0.2%	Wheat		1%
	1%	GEMS/Food G10	1.26	0.3%	Soyabeans	0.3%	Wheat	0.2%	Potatoes		1%
	1%	DE child	1.22	0.4%	Milk: Cattle	0.3%	Wheat	0.2%	Potatoes	0.0%	1%
	1%	NL child	1.22	0.5%	Milk: Cattle	0.3%	Wheat	0.3%	Potatoes	0.0%	1%
	1%	GEMS/Food G08	1.21	0.3%	Potatoes	0.3%	Wheat	0.2%	Soyabeans		1%
	1%	GEMS/Food G15	1.20	0.3%	Wheat	0.3%	Potatoes	0.2%	Soyabeans		1%
	1%	UK toddler	1.16	0.5%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	0.0%	1%
	1%	FR toddler 2–3 years	1.14	0.7%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	0.0%	1%
	1%	GEMS/Food G07	1.13	0.3%	Potatoes	0.3%	Wheat	0.2%	Soyabeans		1%
	1%	FR child 3–15 years	1.11	0.5%	Milk: Cattle	0.3%	Wheat	0.1%	Potatoes	0.0%	1%
	1%	GEMS/Food G06	1.10	0.5%	Wheat	0.2%	Potatoes	0.1%	Soyabeans		1%
	1%	RO general	1.03	0.3%	Wheat	0.3%	Potatoes	0.3%	Milk: Cattle	0.0%	1%
	1%	SE general	1.00	0.3%	Potatoes	0.3%	Milk: Cattle	0.2%	Wheat	0.0%	1%
	0.9%	ES child	0.85	0.3%	Wheat	0.3%	Milk: Cattle	0.1%	Potatoes	0.0%	0.9%
	0.9%	PT general	0.77	0.4%	Potatoes	0.3%	Wheat	0.0%	Onions		0.9%
	0.8%	FI 3 years	0.68	0.4%	Potatoes	0.1%	Cucumbers	0.1%	Wheat		0.8%
	0.7%	DE general	0.67	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.0%	0.7%
	0.7%	IE adult	0.66	0.2%	Potatoes	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	0.7%
	0.7%	DE women 14–50 years	0.64	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.0%	0.7%
	0.7%	NL general	0.64	0.2%	Potatoes	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	0.7%
	0.7%	FR infant	0.62	0.4%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	0.0%	0.7%
	0.6%	LT adult	0.58	0.2%	Potatoes	0.1%	Rye	0.1%	Milk: Cattle	0.0%	0.6%
	0.6%	FI 6 years	0.55	0.3%	Potatoes	0.1%	Cucumbers	0.1%	Rye		0.6%
	0.6%	IT toddler	0.51	0.4%	Wheat	0.1%	Potatoes	0.0%	Onions		0.6%
	0.5%	DK adult	0.47	0.1%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	0.0%	0.5%
	0.5%	ES adult	0.46	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	0.5%
	0.4%	UK vegetarian	0.40	0.1%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	0.4%
	0.4%	FR adult	0.40	0.1%	Wheat	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	0.4%
	0.4%	UK adult	0.37	0.1%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	0.4%
	0.4%	IT adult	0.34	0.3%	Wheat	0.0%	Potatoes	0.0%	Parsley		0.4%
	0.3%	PL general	0.30	0.3%	Potatoes	0.0%	Onions	0.0%	Celery leaves		0.3%
	0.3%	FI adult	0.25	0.1%	Potatoes	0.1%	Rye	0.0%	Cucumbers		0.3%
	0.3%	IE child	0.24	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.0%	0.3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone) (R) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
2%	Potatoes	0.2/0.1	15
1.0%	Chervil	10/7.72	10.0
0.9%	Sweet corn	0.3/0.21	9.1
0.8%	Parsley	10/7.72	8.4
0.7%	Cucumbers	0.03/0.1	6.6
0.6%	Chives	10/7.72	6.3
0.6%	Sage	10/7.72	5.8
0.6%	Basil and edible flowers	10/7.72	5.6
0.5%	Leeks	0.15/0.08	4.8
0.4%	Celery leaves	10/7.72	3.7
0.2%	Milk: Cattle	0.02/0.02	2.5
0.2%	Beans (with pods)	0.3/0.21	2.4
0.2%	Onions	0.1/0.1	2.3
0.2%	Peas (with pods)	0.3/0.21	1.7
0.2%	Bovine: Fat tissue	1/0.81	1.7

Expand/collapse list

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

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)
0.9%	Parsley	10/7.72	9.2
0.3%	Sweet corn	0.3/0.21	3.3
0.3%	Potatoes	0.2/0.1	3.0
0.3%	Cucumbers	0.03/0.1	2.8
0.3%	Celery leaves	10/7.72	2.5
0.2%	Beans (with pods)	0.3/0.21	1.6
0.2%	Sage	10/7.72	1.5
0.1%	Onions	0.1/0.1	1.5
0.1%	Chives	10/7.72	1.3
0.1%	Leeks	0.15/0.08	1.1
0.09%	Basil and edible flowers	10/7.72	0.95
0.08%	Bovine: Fat tissue	1/0.81	0.79
0.08%	Rosemary	10/7.72	0.77
0.08%	Rosemary	10/7.72	0.77
0.08%	Rosemary	10/7.72	0.77

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Potatoes	0.2/0.2	13
1%	Chervil	10/10	13
1%	Parsley	10/10	11
0.9%	Beans	0.5/0.5	9.1
0.8%	Chives	10/10	8.2
0.8%	Sage	10/10	7.6
0.7%	Basil and edible flowers	10/10	7.3
0.7%	Peas	1/1	6.6
0.6%	Sweet corn	0.3/0.3	5.6
0.5%	Celery leaves	10/10	4.8
0.4%	Leeks	0.15/0.15	3.8
0.3%	Beans (with pods)	0.3/0.3	3.4
0.2%	Milk: Cattle	0.02/0.02	2.5
0.2%	Peas (with pods)	0.3/0.3	2.4
0.2%	Bovine: Fat tissue	1/1	2.1

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Parsley	10/10	12
0.6%	Potatoes	0.2/0.2	6.2
0.4%	Sweet corn	0.3/0.3	3.8
0.3%	Peas	1/1	3.3
0.3%	Beans	0.5/0.5	3.3
0.3%	Celery leaves	10/10	3.3
0.3%	Soyabeans	0.5/0.5	2.8
0.2%	Beans (with pods)	0.3/0.3	2.3
0.2%	Sage	10/10	2.0
0.2%	Chives	10/10	1.7
0.1%	Basil and edible flowers	10/10	1.2
0.1%	Peas (with pods)	0.3/0.3	1.0
0.10%	Tarragon	10/10	1.00
0.10%	Rosemary	10/10	1.00
0.10%	Rosemary	10/10	1.00

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)
0.9%	Potatoes/fried	0.2/0.1	9.3
0.5%	Leeks/boiled	0.15/0.08	4.6
0.4%	Potatoes/dried (flakes)	0.2/0.32	4.2
0.3%	Beans (with pods)/boiled	0.3/0.21	2.6
0.1%	Maize/oil	0.2/1.25	1.2
0.1%	Peas/canned	1/0.06	1.1
0.1%	Shallots/boiled	0.06/0.06	0.97
0.1%	Wheat/milling (flour)	0.1/0.06	0.73
0.0%	Soyabeans/soy milk	0.5/0.09	0.38
0.0%	Rye/boiled	0.1/0.1	0.36
0.0%	Rye/milling (wholemeal)-bal	0.1/0.1	0.35
0.0%	Wheat/milling (wholemeal)-l	0.1/0.06	0.33
0.0%	Peas (without pods)/canned	0.05/0.03	0.24
0.0%	Oat/boiled	0.1/0.06	0.22
0.0%	Barley/cooked	0.1/0.06	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)
0.1%	Leeks/boiled	0.15/0.08	1.4
0.09%	Onions/boiled	0.1/0.1	0.94
0.07%	Peas (with pods)/boiled	0.3/0.21	0.72
0.06%	Beans/canned	0.5/0.09	0.64
0.06%	Maize/oil	0.2/1.25	0.63
0.06%	Potatoes/chips	0.2/0.07	0.59
0.04%	Barley/beer	0.1/0.01	0.43
0.04%	Peas/canned	1/0.06	0.42
0.04%	Potatoes/dried (flakes)	0.2/0.32	0.40
0.04%	Shallots/boiled	0.06/0.06	0.37
0.03%	Wheat/bread/pizza	0.1/0.06	0.26
0.02%	Wheat/pasta	0.1/0.06	0.23
0.02%	Wheat/bread (wholemeal)	0.1/0.06	0.21
0.02%	Beans (without pods)/	0.05/0.04	0.21
0.01%	Peas (without pods)/boiled	0.05/0.04	0.13

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Potatoes/fried	0.2/0.1	4.4
0.4%	Potatoes/dried (flakes)	0.2/0.32	4.2
0.3%	Leeks/boiled	0.15/0.08	2.7
0.3%	Beans (with pods)/boiled	0.3/0.21	2.6
0.1%	Maize/oil	0.2/1.25	1.2
0.1%	Peas/canned	1/0.06	1.1
0.07%	Wheat/milling (flour)	0.1/0.06	0.73
0.05%	Shallots/boiled	0.06/0.06	0.45
0.04%	Soyabeans/soy milk	0.5/0.09	0.38
0.04%	Rye/boiled	0.1/0.1	0.36
0.04%	Rye/milling (wholemeal)-	0.1/0.1	0.35
0.03%	Wheat/milling	0.1/0.06	0.33
0.02%	Peas (without pods)/	0.05/0.03	0.24
0.02%	Oat/boiled	0.1/0.06	0.22
0.02%	Barley/cooked	0.1/0.06	0.22

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Leeks/boiled	0.15/0.08	1.1
0.07%	Peas (with pods)/boiled	0.3/0.21	0.72
0.07%	Onions/boiled	0.1/0.1	0.72
0.06%	Beans/canned	0.5/0.09	0.64
0.06%	Maize/oil	0.2/1.25	0.63
0.06%	Potatoes/chips	0.2/0.07	0.59
0.04%	Barley/beer	0.1/0.01	0.43
0.04%	Shallots/boiled	0.06/0.06	0.43
0.04%	Peas/canned	1/0.06	0.42
0.04%	Potatoes/dried (flakes)	0.2/0.32	0.40
0.03%	Wheat/bread/pizza	0.1/0.06	0.26
0.02%	Wheat/pasta	0.1/0.06	0.23
0.02%	Wheat/bread (wholemeal)	0.1/0.06	0.21
0.02%	Beans (without pods)/boiled	0.05/0.04	0.21
0.01%	Peas (without pods)/boiled	0.05/0.04	0.13

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Abamectin (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.0025	ARfD (mg/kg bw):	0.005
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:

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)	74%	NL toddler	1.86	24%	Milk: Cattle	13%	Apples	5%	Pears	38%	0.3%
	58%	DE child	1.45	15%	Apples	8%	Milk: Cattle	6%	Oranges	16%	0.2%
	41%	NL child	1.02	10%	Milk: Cattle	7%	Apples	3%	Sugar beet roots	21%	0.2%
	37%	GEMS/Food G06	0.93	13%	Tomatoes	3%	Wheat	2%	Oranges	11%	0.1%
	35%	FR child 3–15 years	0.87	9%	Milk: Cattle	5%	Oranges	3%	Tomatoes	18%	0.1%
	34%	FR toddler 2–3 years	0.85	12%	Milk: Cattle	4%	Apples	2%	Oranges	19%	0.1%
	33%	GEMS/Food G11	0.82	7%	Lamb's lettuce/corn salads	3%	Tomatoes	3%	Milk: Cattle	14%	0.2%
	33%	GEMS/Food G08	0.81	6%	Lamb's lettuce/corn salads	4%	Tomatoes	3%	Parsley	12%	0.1%
	31%	UK infant	0.77	15%	Milk: Cattle	2%	Oranges	2%	Apples	22%	0.0%
	29%	GEMS/Food G07	0.73	4%	Tomatoes	3%	Milk: Cattle	2%	Oranges	12%	0.2%
	29%	GEMS/Food G10	0.73	5%	Tomatoes	3%	Parsley	2%	Milk: Cattle	12%	0.1%
	27%	GEMS/Food G15	0.68	4%	Tomatoes	3%	Milk: Cattle	2%	Parsley	12%	0.1%
	27%	DE women 14–50 years	0.67	5%	Milk: Cattle	3%	Apples	3%	Oranges	12%	0.1%
	27%	SE general	0.66	5%	Milk: Cattle	3%	Tomatoes	2%	Bovine: Muscle/meat	12%	0.1%
	26%	UK toddler	0.65	8%	Milk: Cattle	3%	Oranges	2%	Tomatoes	15%	0.1%
	25%	IE adult	0.64	3%	Basil and edible flowers	2%	Milk: Cattle	2%	Oranges	10%	0.2%
	25%	ES child	0.63	5%	Milk: Cattle	4%	Tomatoes	3%	Oranges	12%	0.0%
	25%	DK child	0.63	5%	Milk: Cattle	3%	Apples	3%	Cucumbers	13%	0.0%
	25%	DE general	0.63	5%	Milk: Cattle	3%	Apples	3%	Oranges	11%	0.1%
	25%	RO general	0.63	7%	Tomatoes	5%	Milk: Cattle	2%	Wheat	12%	0.2%
	19%	FI adult	0.47	11%	Coffee beans	2%	Tomatoes	0.8%	Strawberries	13%	0.1%
	18%	NL general	0.45	3%	Milk: Cattle	2%	Apples	2%	Oranges	10%	0.1%
	17%	FR infant	0.43	7%	Milk: Cattle	2%	Apples	1%	Strawberries	10%	0.0%
	17%	IT toddler	0.42	5%	Tomatoes	3%	Wheat	1%	Apples	4%	0.0%
	17%	ES adult	0.41	3%	Tomatoes	2%	Oranges	2%	Milk: Cattle	6%	0.0%
	15%	FI 3 years	0.37	2%	Strawberries	2%	Tomatoes	2%	Potatoes	5%	0.2%
	15%	FR adult	0.37	2%	Milk: Cattle	2%	Tomatoes	2%	Lamb's lettuce/corn salads	6%	0.2%
	14%	PT general	0.35	3%	Tomatoes	2%	Potatoes	2%	Wheat	6%	0.2%
	14%	IT adult	0.35	4%	Tomatoes	2%	Wheat	1%	Lettuces	3%	0.0%
	12%	FI 6 years	0.29	2%	Strawberries	2%	Tomatoes	2%	Potatoes	4%	0.1%
	11%	LT adult	0.28	2%	Apples	2%	Tomatoes	2%	Milk: Cattle	5%	0.0%
	11%	UK vegetarian	0.28	2%	Tomatoes	1%	Oranges	1%	Milk: Cattle	4%	0.1%
	11%	DK adult	0.27	2%	Milk: Cattle	2%	Tomatoes	1%	Apples	5%	0.1%
	9%	PL general	0.24	3%	Tomatoes	2%	Apples	1%	Potatoes	2%	0.0%
	9%	UK adult	0.22	2%	Tomatoes	1%	Milk: Cattle	0.9%	Oranges	4%	0.1%
	4%	IE child	0.10	1%	Milk: Cattle	0.5%	Wheat	0.4%	Apples	3%	0.0%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
24%	Blackberries	0.2/0.11	1.2
23%	Table grapes	0.03/0.02	1.2
20%	Raspberries (red and	0.2/0.11	1.0
5%	Leeks	0.01/0	0.24
4%	Dewberries	0.2/0.11	0.19
3%	Wine grapes	0.03/0.02	0.15
1%	Spring onions/green onions	0.01/0	0.06

Expand/collapse list

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

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)
18%	Blackberries	0.2/0.11	0.90
12%	Raspberries (red and	0.2/0.11	0.59
11%	Table grapes	0.03/0.02	0.54
8%	Wine grapes	0.03/0.02	0.38
3%	Dewberries	0.2/0.11	0.16
1%	Leeks	0.01/0	0.05
0.4%	Spring onions/green onions	0.01/0	0.02

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
43%	Blackberries	0.2/0.2	2.1
37%	Raspberries (red and	0.2/0.2	1.8
26%	Table grapes	0.03/0.03	1.3
7%	Dewberries	0.2/0.2	0.35
6%	Wine grapes	0.03/0.03	0.28
5%	Leeks	0.01/0.01	0.25
3%	Spring onions/green onions	0.01/0.01	0.14

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
33%	Blackberries	0.2/0.2	1.6
22%	Raspberries (red and yellow)	0.2/0.2	1.1
14%	Wine grapes	0.03/0.03	0.71
12%	Table grapes	0.03/0.03	0.61
6%	Dewberries	0.2/0.2	0.29
1%	Leeks	0.01/0.01	0.06
0.7%	Spring onions/green onions and	0.01/0.01	0.03

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)
5%	Raspberries/juice	0.2/0.02	0.27
5%	Leeks/boiled	0.01/0	0.23
2%	Wine grapes/juice	0.03/0	0.09

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)
3%	Wine grapes/wine	0.03/0.02	0.15
2%	Table grapes/raisins	0.03/0.08	0.09
1%	Leeks/boiled	0.01/0	0.07
0.9%	Wine grapes/juice	0.03/0	0.04

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Raspberries/juice	0.2/0.02	0.27
3%	Leeks/boiled	0.01/0	0.13
2%	Wine grapes/juice	0.03/0	0.09

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wine grapes/wine	0.03/0.02	0.15
2%	Table grapes/raisins	0.03/0.08	0.09
1%	Leeks/boiled	0.01/0	0.05
0.9%	Wine grapes/juice	0.03/0	0.04

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Abamectin (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; 2018/11/18

Fenpyroximate (A) (F) (R)

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):	0.02
Source of ADI:	EFSA 2013	Source of ARfD:	EFSA 2013
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 : ---

	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)	25%	NL toddler	2.49	9%	Apples	4%	Pears	2%	Table grapes	4%	
	19%	DE child	1.91	10%	Apples	1%	Table grapes	1.0%	Tomatoes	2%	
	14%	NL child	1.37	5%	Apples	1%	Table grapes	1%	Pears	3%	
	10%	GEMS/Food G06	1.04	4%	Tomatoes	1%	Table grapes	0.8%	Apples	2%	
	9%	GEMS/Food G07	0.85	2%	Wine grapes	1%	Tomatoes	0.9%	Apples	2%	
	8%	FR child 3–15 years	0.85	1%	Apples	0.8%	Tomatoes	0.6%	Swine: Other products	2%	
	8%	RO general	0.84	2%	Tomatoes	2%	Wine grapes	1%	Apples	2%	
	8%	GEMS/Food G15	0.84	1%	Tomatoes	1%	Wine grapes	0.9%	Apples	2%	
	8%	IE adult	0.81	1%	Wine grapes	0.6%	Sheep: Liver	0.6%	Apples	2%	
	8%	FR toddler 2–3 years	0.80	3%	Apples	0.9%	Beans (with pods)	0.5%	Tomatoes	2%	
	8%	GEMS/Food G11	0.80	1%	Apples	1%	Wine grapes	0.9%	Tomatoes	2%	
	8%	GEMS/Food G08	0.79	1%	Tomatoes	1%	Wine grapes	1%	Apples	2%	
	8%	DE women 14–50 years	0.76	2%	Apples	0.9%	Wine grapes	0.7%	Tomatoes	2%	
	7%	DE general	0.75	2%	Apples	0.9%	Wine grapes	0.7%	Tomatoes	1%	
	7%	GEMS/Food G10	0.72	1%	Tomatoes	0.6%	Apples	0.4%	Wine grapes	2%	
	7%	PT general	0.71	3%	Wine grapes	0.9%	Tomatoes	0.9%	Apples	1%	
	7%	DK child	0.70	2%	Apples	0.6%	Pears	0.6%	Rye	2%	
	6%	FR adult	0.64	2%	Wine grapes	0.6%	Apples	0.5%	Tomatoes	1%	
	6%	ES child	0.59	1.0%	Tomatoes	1.0%	Apples	0.4%	Wheat	2%	
	6%	UK toddler	0.58	1%	Apples	0.6%	Tomatoes	0.4%	Wheat	2%	
	6%	UK infant	0.56	1%	Apples	0.6%	Milk: Cattle	0.4%	Tomatoes	2%	
	6%	NL general	0.56	1%	Apples	0.6%	Wine grapes	0.4%	Tomatoes	1%	
	5%	SE general	0.54	0.9%	Apples	0.8%	Tomatoes	0.5%	Bovine: Muscle/meat	2%	
	5%	FI adult	0.52	3%	Coffee beans	0.6%	Tomatoes	0.5%	Apples	3%	
	5%	IT toddler	0.49	1%	Tomatoes	0.7%	Apples	0.7%	Wheat	1%	
	5%	ES adult	0.45	0.8%	Tomatoes	0.6%	Apples	0.4%	Wine grapes	0.9%	
	4%	FI 3 years	0.44	0.8%	Apples	0.6%	Tomatoes	0.5%	Potatoes	1%	
	4%	PL general	0.42	2%	Apples	0.9%	Tomatoes	0.3%	Potatoes	0.5%	
	4%	DK adult	0.42	1.0%	Wine grapes	0.8%	Apples	0.5%	Tomatoes	0.6%	
	4%	IT adult	0.41	1%	Tomatoes	0.7%	Apples	0.4%	Wheat	0.8%	
	4%	FR infant	0.40	1%	Apples	0.6%	Beans (with pods)	0.3%	Milk: Cattle	0.8%	
	4%	LT adult	0.37	2%	Apples	0.6%	Tomatoes	0.3%	Potatoes	0.8%	
	4%	UK vegetarian	0.36	0.8%	Wine grapes	0.6%	Tomatoes	0.5%	Apples	0.8%	
	4%	UK adult	0.36	1%	Wine grapes	0.4%	Tomatoes	0.4%	HOPS (dried)	0.7%	
	3%	FI 6 years	0.33	0.5%	Apples	0.4%	Tomatoes	0.4%	Potatoes	1%	
	1.0%	IE child	0.10	0.3%	Apples	0.1%	Wheat	0.1%	Potatoes	0.3%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Detailsacute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
117%	Peaches	0.3/0.25	23
100%	Pears	0.3/0.14	20
78%	Apples	0.3/0.14	16
71%	Table grapes	0.3/0.2	14
49%	Tomatoes	0.3/0.17	9.9
43%	Apricots	0.3/0.25	8.6
43%	Sweet peppers/bell peppers	0.3/0.14	8.6
36%	Celeriacs/turnip rooted	0.01/0.13	7.2
34%	Raspberries (red and	1.5/0.73	6.8
26%	Blackberries	0.7/0.49	5.3
26%	Beans (with pods)	0.7/0.45	5.1
20%	Bovine: Liver	0.08/0.5	4.0
20%	Strawberries	0.3/0.25	4.0
18%	Quinces	0.2/0.14	3.5
17%	Oranges	0.5/0.03	3.4

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 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)
33%	Table grapes	0.3/0.2	6.6
23%	Peaches	0.3/0.25	4.6
23%	Wine grapes	0.3/0.2	4.6
22%	Pears	0.3/0.14	4.4
20%	Blackberries	0.7/0.49	4.1
20%	Apples	0.3/0.14	4.0
20%	Raspberries (red and	1.5/0.73	3.9
17%	Beans (with pods)	0.7/0.45	3.5
16%	Aubergines/egg plants	0.2/0.12	3.2
15%	Blueberries	0.4/0.34	3.1
14%	Cherries (sweet)	2/0.27	2.7
13%	Tomatoes	0.3/0.17	2.7
13%	Apricots	0.3/0.25	2.7
12%	Sweet peppers/bell peppers	0.3/0.14	2.3
12%	Strawberries	0.3/0.25	2.3

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): 3

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
167%	Oranges	0.5/0.5	33
122%	Cherries (sweet)	2/2	24
118%	Grapefruits	0.5/0.5	24
93%	Mandarins	0.5/0.5	19
92%	Apples	0.3/0.3	18
89%	Pears	0.3/0.3	18
81%	Peaches	0.3/0.3	16
74%	Apricots	0.3/0.3	15
69%	Raspberries (red and	1.5/1.5	14
66%	Table grapes	0.3/0.3	13
58%	Lemons	0.5/0.5	12
46%	Tomatoes	0.3/0.3	9.1
40%	Beans (with pods)	0.7/0.7	8.0
38%	Sweet peppers/bell	0.3/0.3	7.7
38%	Blackberries	0.7/0.7	7.5

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) 3

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
117%	Oranges	0.5/0.5	23
100%	Cherries (sweet)	2/2	20
82%	Mandarins	0.5/0.5	16
53%	Pears	0.3/0.3	11
52%	Grapefruits	0.5/0.5	10
45%	Apples	0.3/0.3	9.0
40%	Raspberries (red and yellow)	1.5/1.5	8.1
36%	Wine grapes	0.3/0.3	7.1
31%	Peaches	0.3/0.3	6.1
31%	Table grapes	0.3/0.3	6.1
29%	Tomatoes	0.3/0.3	5.8
29%	Blackberries	0.7/0.7	5.7
27%	Beans (with pods)	0.7/0.7	5.4
20%	Plums	0.1/0.1	3.9
19%	Aubergines/egg plants	0.2/0.2	3.9

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)
32%	Peaches/canned	1/0.25	6.4
29%	Pumpkins/boiled	0.01/0.07	5.8
28%	Beans (with pods)/boiled	0.7/0.45	5.6
23%	Currants (red, black and wh	0.4/0.16	4.6
23%	Apples/juice	0.3/0.08	4.5
23%	Wine grapes/juice	0.3/0.1	4.5
14%	Pears/juice	0.3/0.08	2.7
13%	Elderberries/juice	0.4/0.16	2.6
10%	Tomatoes/juice	0.3/0.1	1.9
9%	Celeriacs/juice	0.01/0.13	1.9
9%	Courgettes/boiled	0.08/0.05	1.8
9%	Peaches/juice	0.3/0.1	1.7
6%	Raspberries/juice	1.5/0.11	1.3
6%	Gherkins/pickled	0.08/0.05	1.2
6%	Sugar beets (root)/sugar	0.01/0.12	1.1

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)
18%	Pumpkins/boiled	0.01/0.07	3.6
14%	Apples/juice	0.3/0.08	2.8
12%	Celeriacs/boiled	0.01/0.13	2.4
11%	Wine grapes/juice	0.3/0.1	2.2
10%	Currants (red, black and	0.4/0.16	2.1
10%	Peaches/canned	0.3/0.25	2.0
9%	Wine grapes/wine	0.3/0.2	1.8
7%	Elderberries/juice	0.4/0.16	1.5
6%	Courgettes/boiled	0.08/0.05	1.2
6%	Table grapes/raisins	0.3/0.92	1.1
4%	Tomatoes/sauce/puree	0.3/0.1	0.82
4%	Hops/beer	15/0.02	0.80
2%	Sugar beets (root)/sugar	0.01/0.12	0.44
2%	Cauliflowers/boiled	0.01/0.01	0.42
2%	Celeries/boiled	0.01/0.01	0.34

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
28%	Beans (with pods)/boiled	0.7/0.45	5.6
24%	Peaches/canned	1/0.25	4.8
23%	Currants (red, black and	0.4/0.16	4.6
23%	Apples/juice	0.3/0.08	4.5
23%	Wine grapes/juice	0.3/0.1	4.5
17%	Pumpkins/boiled	0.01/0.07	3.5
14%	Pears/juice	0.3/0.08	2.7
13%	Elderberries/juice	0.4/0.16	2.6
10%	Tomatoes/juice	0.3/0.1	1.9
9%	Celeriacs/juice	0.01/0.13	1.9
9%	Peaches/juice	0.3/0.1	1.7
6%	Raspberries/juice	1.5/0.11	1.3
6%	Courgettes/boiled	0.08/0.05	1.1
6%	Sugar beets (root)/sugar	0.01/0.12	1.1
5%	Tomatoes/sauce/puree	0.3/0.1	0.95

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Apples/juice	0.3/0.08	2.8
13%	Pumpkins/boiled	0.01/0.07	2.6
11%	Wine grapes/juice	0.3/0.1	2.2
10%	Currants (red, black and white)/	0.4/0.16	2.1
10%	Peaches/canned	0.3/0.25	2.0
9%	Wine grapes/wine	0.3/0.2	1.8
7%	Elderberries/juice	0.4/0.16	1.5
7%	Celeriacs/boiled	0.01/0.13	1.4
6%	Table grapes/raisins	0.3/0.92	1.1
4%	Courgettes/boiled	0.08/0.05	0.83
4%	Tomatoes/sauce/puree	0.3/0.1	0.82
4%	Hops/beer	15/0.02	0.80
2%	Sugar beets (root)/sugar	0.01/0.12	0.44
1%	Cauliflowers/boiled	0.01/0.01	0.25
1%	Coffee beans/extraction	0.05/0.01	0.24

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; 2018/11/18

Kresoxim-methyl

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.4	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC 99/1	Source of ARfD:	EC 99/1
Year of evaluation:	1999	Year of evaluation:	1999

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	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 years	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 years	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	2.39	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 years	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 years	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 years	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	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	IESTI new	IESTI new
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)	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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	**IESTI new**	**IESTI new**
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)	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; 2018/11/18

Pyriproxyfen

LOQs (mg/kg) range from: 0.05 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.1	ARfD (mg/kg bw):	not necessary
Source of ADI:	Dir 08/69	Source of ARfD:	Dir 08/69
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:

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)
15%	NL toddler	14.87	4%	Bananas	3%	Milk: Cattle	2%	Apples	5%	
11%	DE child	10.64	2%	Apples	2%	Oranges	1%	Bananas	2%	
8%	GEMS/Food G06	8.37	4%	Tomatoes	0.8%	Tea (dried leaves of Camellia sinensis)	0.6%	Oranges	1%	
8%	NL child	7.87	1%	Bananas	1%	Milk: Cattle	1%	Apples	3%	
7%	FR child 3–15 years	6.74	2%	Oranges	1%	Milk: Cattle	0.8%	Tomatoes	2%	
7%	IE adult	6.54	2%	Tea (dried leaves of Camellia sinensis)	0.6%	Oranges	0.5%	Bananas	1%	
6%	UK infant	6.29	2%	Milk: Cattle	1%	Bananas	0.9%	Tea (dried leaves of Camellia sinens	3%	
6%	UK toddler	5.53	1%	Oranges	1%	Milk: Cattle	0.8%	Bananas	2%	
5%	FR toddler 2–3 years	5.44	1%	Milk: Cattle	0.9%	Oranges	0.6%	Apples	2%	
5%	GEMS/Food G07	5.33	1%	Tomatoes	0.8%	Oranges	0.7%	Tea (dried leaves of Camellia sinens	2%	
5%	GEMS/Food G10	5.23	1%	Tomatoes	0.7%	Oranges	0.5%	Tea (dried leaves of Camellia sinens	2%	
5%	ES child	5.20	1%	Oranges	1.0%	Tomatoes	0.7%	Bananas	1%	
5%	RO general	5.18	2%	Tomatoes	0.6%	Milk: Cattle	0.4%	Sweet peppers/bell peppers	2%	
5%	DE women 14–50 years	5.13	1%	Oranges	0.7%	Tomatoes	0.6%	Milk: Cattle	1%	
5%	SE general	5.11	1%	Bananas	0.8%	Tomatoes	0.6%	Milk: Cattle	2%	
5%	GEMS/Food G15	5.01	1%	Tomatoes	0.6%	Sweet peppers/bell peppers	0.4%	Oranges	2%	
5%	GEMS/Food G11	5.00	0.9%	Tomatoes	0.6%	Tea (dried leaves of Camellia sinensis)	0.4%	Oranges	2%	
5%	GEMS/Food G08	4.86	1%	Tomatoes	0.4%	Tea (dried leaves of Camellia sinensis)	0.3%	Sweet peppers/bell peppers	2%	
5%	DE general	4.71	0.9%	Oranges	0.7%	Tomatoes	0.6%	Milk: Cattle	1%	
4%	FR adult	4.29	2%	Tea (dried leaves of Camellia sinensis)	0.5%	Tomatoes	0.4%	Oranges	0.8%	
4%	DK child	4.28	0.8%	Bananas	0.6%	Milk: Cattle	0.5%	Tomatoes	2%	
4%	NL general	3.60	0.6%	Oranges	0.5%	Tea (dried leaves of Camellia sinensis)	0.4%	Milk: Cattle	1%	
4%	IT toddler	3.52	1%	Tomatoes	0.4%	Bananas	0.3%	Wheat	0.6%	
3%	ES adult	3.29	0.8%	Tomatoes	0.8%	Oranges	0.3%	Bananas	0.8%	
3%	PT general	3.13	0.9%	Tomatoes	0.4%	Oranges	0.3%	Potatoes	0.8%	
3%	UK vegetarian	3.12	0.7%	Tea (dried leaves of Camellia sinensis)	0.6%	Tomatoes	0.5%	Oranges	0.6%	
3%	FI 3 years	2.94	0.9%	Bananas	0.6%	Tomatoes	0.2%	Potatoes	0.6%	
3%	IT adult	2.74	1%	Tomatoes	0.2%	Oranges	0.2%	Wheat	0.4%	
3%	UK adult	2.65	0.8%	Tea (dried leaves of Camellia sinensis)	0.4%	Tomatoes	0.3%	Oranges	0.6%	
2%	DK adult	2.24	0.5%	Tomatoes	0.3%	Bananas	0.3%	Milk: Cattle	0.7%	
2%	FR infant	2.24	0.8%	Milk: Cattle	0.3%	Apples	0.1%	Bananas	1%	
2%	FI 6 years	2.15	0.5%	Bananas	0.4%	Tomatoes	0.2%	Mandarins	0.5%	
2%	PL general	2.11	0.9%	Tomatoes	0.4%	Apples	0.2%	Potatoes	0.3%	
2%	LT adult	1.89	0.6%	Tomatoes	0.4%	Apples	0.2%	Milk: Cattle	0.6%	
2%	FI adult	1.84	0.6%	Tomatoes	0.3%	Coffee beans	0.2%	Oranges	0.5%	
0.7%	IE child	0.74	0.2%	Milk: Cattle	0.1%	Bananas	0.1%	Apples	0.4%	

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	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	IESTI new	IESTI new
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)	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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	**IESTI new**	**IESTI new**
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)	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; 2018/08/18

Cyprodinil (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.03	ARfD (mg/kg bw):	1.5
Source of ADI:	EFSA	Source of ARfD:	EFSA
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:

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)
	55%	NL toddler	16.60	17%	Apples	7%	Spinaches	7%	Pears		
	42%	DE child	12.70	20%	Apples	3%	Table grapes	2%	Spinaches		
	28%	NL child	8.32	9%	Apples	3%	Spinaches	2%	Table grapes		
	27%	GEMS/Food G11	8.16	8%	Celeries	2%	Apples	2%	Wine grapes		
	23%	GEMS/Food G07	7.05	4%	Celeries	3%	Wine grapes	2%	Lettuces		
	22%	GEMS/Food G08	6.49	2%	Wine grapes	2%	Barley	2%	Lettuces		
	20%	IE adult	5.96	4%	Celeries	3%	Wine grapes	1%	Spinaches		
	19%	GEMS/Food G10	5.78	3%	Lettuces	2%	Wheat	2%	Celeries		
	19%	GEMS/Food G15	5.73	2%	Celeries	2%	Wine grapes	2%	Wheat		
	19%	GEMS/Food G06	5.69	3%	Wheat	2%	Table grapes	2%	Tomatoes		
	18%	DK child	5.34	4%	Apples	2%	Rye	2%	Carrots		
	17%	FR child 3–15 years	5.15	3%	Apples	2%	Wheat	2%	Milk: Cattle		
	17%	FR toddler 2–3 years	5.04	5%	Apples	2%	Milk: Cattle	2%	Spinaches		
	17%	IT adult	4.98	4%	Lettuces	2%	Wheat	2%	Other lettuce and other salad plants		
	16%	IT toddler	4.82	3%	Lettuces	3%	Wheat	1%	Apples		
	16%	ES adult	4.72	6%	Lettuces	1%	Apples	1%	Barley		
	15%	SE general	4.59	4%	Lettuces	2%	Apples	1%	Wheat		
	15%	DE women 14–50 years	4.57	4%	Apples	2%	Wine grapes	1%	Lettuces		
	15%	DE general	4.49	4%	Apples	2%	Wine grapes	1%	Barley		
	15%	ES child	4.47	4%	Lettuces	2%	Wheat	2%	Apples		
	15%	PT general	4.37	6%	Wine grapes	2%	Wheat	2%	Apples		
	14%	RO general	4.25	4%	Wine grapes	2%	Apples	2%	Wheat		
	14%	FR adult	4.24	5%	Wine grapes	2%	Other lettuce and other salad plants	1%	Apples		
	13%	NL general	4.05	2%	Apples	2%	Spinaches	1%	Wine grapes		
	13%	FR infant	3.93	3%	Spinaches	3%	Apples	2%	Carrots		
	13%	UK infant	3.86	3%	Milk: Cattle	3%	Apples	2%	Carrots		
	12%	UK toddler	3.59	3%	Apples	2%	Wheat	1%	Milk: Cattle		
	11%	FI 3 years	3.28	2%	Apples	1%	Oat	1%	Carrots		
	9%	UK vegetarian	2.76	2%	Wine grapes	1%	Lettuces	1.0%	Celeries		
	9%	DK adult	2.72	2%	Wine grapes	2%	Apples	0.9%	Lettuces		
	8%	FI 6 years	2.53	0.9%	Strawberries	0.9%	Apples	0.9%	Carrots		
	8%	UK adult	2.28	2%	Wine grapes	1%	Lettuces	0.7%	Wheat		
	8%	PL general	2.25	3%	Apples	0.7%	Table grapes	0.5%	Tomatoes		
	7%	LT adult	2.09	3%	Apples	0.7%	Lettuces	0.5%	Rye		
	6%	FI adult	1.92	1%	Lettuces	0.9%	Apples	0.7%	Wine grapes		
	2%	IE child	0.75	0.5%	Apples	0.5%	Wheat	0.3%	Carrots		

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
40%	Celeries	30/16	599
24%	Escarioles/broad-leaved	15/8.9	358
23%	Lettuces	15/8.9	339
13%	Spinaches	15/8.9	201
12%	Granate	5/3.4	187
12%	Pears	2/1.3	180
11%	Table grapes	3/2.3	168
11%	Peaches	2/1.7	162
9%	Apples	2/1.3	140
9%	Chards/beet leaves	15/8.9	139
5%	Plums	2/1.7	72
4%	Carrots	1.5/1.04	66
4%	Cauliflowers	2/1.1	64
4%	Strawberries	5/3.74	61
4%	Kaki/Japanese	2/1.3	61
4%	Apricots	2/1.7	59
4%	Tomatoes	1.5/0.97	56
4%	Melons	0.6/0.36	55
3%	Sweet peppers/bell peppers	1.5/0.78	46
3%	Beetroots	1.5/1.04	46
3%	Broccoli	2/1.1	46
3%	Watermelons	0.6/0.36	44
3%	Parsnips	1.5/1.04	38
2%	Salsifies	1.5/1.04	32
2%	Quinces	2/1.3	32
2%	Avocados	1/0.6	30

Expand/collapse list

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

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)
17%	Celeries	30/16	256
12%	Escarioles/broad-leaved	15/8.9	179
11%	Chards/beet leaves	15/8.9	168
7%	Lettuces	15/8.9	108
5%	Table grapes	3/2.3	78
4%	Granate	5/3.4	60
4%	Wine grapes	3/2.3	55
3%	Red mustards	15/8.9	47
3%	Pears	2/1.3	40
2%	Apples	2/1.3	36
2%	Spinaches	15/8.9	36
2%	Strawberries	5/3.74	35
2%	Florence fennels	4/1.71	32
2%	Peaches	2/1.7	32
2%	Plums	2/1.7	30
2%	Kaki/Japanese persimmons	2/1.3	29
2%	Broccoli	2/1.1	26
2%	Cauliflowers	2/1.1	26
1%	Aubergines/eqq plants	1.5/0.97	21
1%	Carrots	1.5/1.04	20
1%	Quinces	2/1.3	20
1%	Parsley	40/16	19
1%	Apricots	2/1.7	18
1%	Cherries (sweet)	2/1.7	17
1%	Purslanes	15/8.9	17
1%	Globe artichokes	4/1.3	17

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
45%	Celeries	30/30	673
24%	Escarioles/broad-leaved	15/15	362
23%	Lettuces	15/15	343
23%	Spinaches	15/15	339
9%	Table grapes	3/3	131
8%	Apples	2/2	123
8%	Pears	2/2	119
8%	Granate	5/5	118
7%	Peaches	2/2	108
7%	Chards/beet leaves	15/15	100
7%	Apricots	2/2	98
5%	Strawberries	5/5	82
5%	Cauliflowers	2/2	70
4%	Melons	0.6/0.6	55
3%	Chervil	40/40	52
3%	Plums	2/2	51
3%	Globe artichokes	4/4	50
3%	Broccoli	2/2	50
3%	Tomatoes	1.5/1.5	46
3%	Watermelons	0.6/0.6	44
3%	Parsley	40/40	44
3%	Lamb's lettuce/corn salads	15/15	42
3%	Carrots	1.5/1.5	41
3%	Roman rocket/rucola	15/15	40
3%	Kaki/Japanese	2/2	40
3%	Sweet peppers/bell	1.5/1.5	38

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Celeries	30/30	288
15%	Escarioles/broad-leaved endives	15/15	221
9%	Chards/beet leaves	15/15	132
7%	Lettuces	15/15	109
5%	Plums	2/2	78
5%	Pears	2/2	71
5%	Wine grapes	3/3	71
4%	Table grapes	3/3	61
4%	Spinaches	15/15	60
4%	Apples	2/2	60
4%	Kaki/Japanese persimmons	2/2	54
3%	Granate apples/pomegranates	5/5	49
3%	Parsley	40/40	48
3%	Strawberries	5/5	47
3%	Globe artichokes	4/4	43
3%	Peaches	2/2	41
3%	Broccoli	2/2	39
2%	Red mustards	15/15	34
2%	Florence fennels	4/4	32
2%	Tomatoes	1.5/1.5	29
2%	Purslanes	15/15	29
2%	Lamb's lettuce/corn salads	15/15	28
2%	Cauliflowers	2/2	28
2%	Blueberries	3/3	27
2%	Apricots	2/2	26
2%	Blackberries	3/3	25

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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)
39%	Escarioles/broad-leaved end	15/8.9	590
19%	Spinaches/frozen; boiled	15/8.9	292
18%	Chards/beet leaves/boiled	15/8.9	277
6%	Broccoli/boiled	2/1.1	87
5%	Florence fennels/boiled	4/1.71	78
5%	Cauliflowers/boiled	2/1.1	77
4%	Parsnips/boiled	1.5/1.04	53
3%	Beetroots/boiled	1.5/1.04	46
2%	Peaches/canned	2/1.7	35
2%	Pumpkins/boiled	0.6/0.36	32
2%	Wine grapes/juice	3/0.67	29
2%	Salsifies/boiled	1.5/1.04	27
2%	Apples/juice	2/0.48	26
2%	Head cabbages/boiled	0.7/0.36	23
1%	Currants (red, black and wh	3/0.69	20
1%	Carrots/juice	1.5/0.45	16
1%	Pears/juice	2/0.48	16
1.0%	Beans (with pods)/boiled	2/1.15	14
0.9%	Courgettes/boiled	0.5/0.36	13
0.8%	Peaches/juice	2/0.68	11
0.7%	Elderberries/juice	3/0.69	11
0.6%	Raspberries/juice	3/0.81	9.5
0.6%	Pomegranates/juice	5/3.3	9.0
0.6%	Gherkins/pickled	0.5/0.36	8.3
0.4%	Plums/juice	2/0.68	6.4
0.3%	Cranberries/juice	3/0.69	4.0
0.3%	Azarole (mediteranean med	3/0.69	3.8
0.2%	Tomatoes/juice	1.5/0.17	3.2
0.2%	Oat/boiled	4/0.75	2.7
0.2%	Barley/cooked	4/0.75	2.7
0.2%	Oat/milling (flakes)	4/0.75	2.3
0.1%	Rose hips/jam	3/0.69	2.1
0.1%	Wheat/milling (flour)	0.5/0.13	1.6
0.1%	Witloofs/boiled	0.06/0.03	1.5
0.1%	Quinces/jam	2/0.48	1.5
0.1%	Ginger/jam	1.5/0.45	1.4
0.1%	Barley/milling (flour)	4/0.75	1.4
0.1%	Celeriacs/juice	0.3/0.08	1.2
0.1%	Guavas/juice	1.5/0.49	0.84
0.1%	Shallots/boiled	0.07/0.05	0.81
0.0%	Wheat/milling (wholemeal)-l	0.5/0.13	0.72
0.0%	Rye/boiled	0.5/0.13	0.47
0.0%	Rye/milling (wholemeal)-bal	0.5/0.13	0.46
0.0%	Coconuts/milk	0.04/0.02	0.17

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)
36%	Celeries/boiled	30/16	540
12%	Escarioles/broad-leaved	15/8.9	182
7%	Chards/beet leaves/boiled	15/8.9	111
5%	Spinaches/frozen; boiled	15/8.9	74
3%	Cauliflowers/boiled	2/1.1	46
2%	Purslanes/boiled	15/8.9	37
2%	Florence fennels/boiled	4/1.71	33
2%	Broccoli/boiled	2/1.1	26
2%	Beetroots/boiled	1.5/1.04	23
2%	Peaches/canned	2/1.7	23
1%	Wine grapes/wine	3/2.3	22
1%	Pumpkins/boiled	0.6/0.36	20
1%	Apples/juice	2/0.48	16
0.9%	Wine grapes/juice	3/0.67	14
0.6%	Currants (red, black and	3/0.69	8.8
0.6%	Salsifies/boiled	1.5/1.04	8.6
0.5%	Courgettes/boiled	0.5/0.36	8.2
0.4%	Elderberries/juice	3/0.69	6.3
0.4%	Barley/beer	4/0.15	5.4
0.3%	Peas (with pods)/boiled	2/1.15	3.9
0.2%	Carrots/canned	1.5/0.45	3.7
0.1%	Celeriacs/boiled	0.3/0.11	2.0
0.09%	Table grapes/raisins	3/3.2	1.3
0.06%	Onions/boiled	0.3/0.1	0.94
0.06%	Rose hips/jam	3/0.69	0.86
0.04%	Quinces/jam	2/0.48	0.60
0.04%	Wheat/bread/pizza	0.5/0.13	0.57
0.04%	Tomatoes/sauce/puree	1.5/0.17	0.56
0.04%	Ginger/jam	1.5/0.45	0.56
0.04%	Witloofs/boiled	0.06/0.03	0.55
0.03%	Cranberries/dried	3/0.69	0.52
0.03%	Wheat/pasta	0.5/0.13	0.50
0.03%	Beans/canned	0.2/0.06	0.43
0.02%	Shallots/boiled	0.07/0.05	0.31
0.02%	Beans (without pods)/	0.08/0.05	0.26
0.01%	Wheat/bread (wholemeal)	0.5/0.13	0.22
0.01%	Head cabbages/canned	0.7/0.03	0.16
0.01%	Peas (without pods)/boiled	0.08/0.05	0.16
0.00%	Coconuts/milk	0.04/0.02	0.07
0.00%	Peas/canned	0.1/0.01	0.05
0.00%	Turmeric (Curcuma)/boiled	1.5/1.04	0.02
0.00%	Valerian root/infusion	1.5/0	0.00

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Escarioles/broad-leaved	15/8.9	354
19%	Spinaches/frozen; boiled	15/8.9	292
8%	Chards/beet leaves/boiled	15/8.9	119
3%	Broccoli/boiled	2/1.1	52
3%	Florence fennels/boiled	4/1.71	47
3%	Cauliflowers/boiled	2/1.1	46
2%	Wine grapes/juice	3/0.67	29
2%	Apples/juice	2/0.48	26
2%	Salsifies/boiled	1.5/1.04	23
2%	Parsnips/boiled	1.5/1.04	23
1%	Beetroots/boiled	1.5/1.04	20
1%	Currants (red, black and	3/0.69	20
1%	Pumpkins/boiled	0.6/0.36	19
1%	Carrots/juice	1.5/0.45	16
1%	Pears/juice	2/0.48	16
1%	Peaches/canned	2/1.7	15
1.0%	Beans (with pods)/boiled	2/1.15	14
0.9%	Head cabbages/boiled	0.7/0.36	14
0.8%	Peaches/juice	2/0.68	11
0.7%	Elderberries/juice	3/0.69	11
0.6%	Raspberries/juice	3/0.81	9.5
0.6%	Pomegranates/juice	5/3.3	9.0
0.5%	Courgettes/boiled	0.5/0.36	7.7
0.4%	Plums/juice	2/0.68	6.4
0.3%	Cranberries/juice	3/0.69	4.0
0.3%	Azarole (mediteranean	3/0.69	3.8
0.2%	Gherkins/pickled	0.5/0.36	3.5
0.2%	Tomatoes/juice	1.5/0.17	3.2
0.2%	Oat/boiled	4/0.75	2.7
0.2%	Barley/cooked	4/0.75	2.7
0.2%	Oat/milling (flakes)	4/0.75	2.3
0.1%	Rose hips/jam	3/0.69	2.1
0.1%	Wheat/milling (flour)	0.5/0.13	1.6
0.10%	Quinces/jam	2/0.48	1.5
0.09%	Ginger/jam	1.5/0.45	1.4
0.09%	Barley/milling (flour)	4/0.75	1.4
0.08%	Celeriacs/juice	0.3/0.08	1.2
0.06%	Guavas/juice	1.5/0.49	0.84
0.05%	Witloofs/boiled	0.06/0.03	0.79
0.05%	Wheat/milling	0.5/0.13	0.72
0.03%	Rye/boiled	0.5/0.13	0.47
0.03%	Rye/milling (wholemeal)-	0.5/0.13	0.46
0.02%	Shallots/boiled	0.07/0.05	0.35
0.01%	Coconuts/milk	0.04/0.02	0.17

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
22%	Celeries/boiled	30/16	324
9%	Escarioles/broad-leaved endives/	15/8.9	138
5%	Chards/beet leaves/boiled	15/8.9	79
5%	Spinaches/frozen; boiled	15/8.9	74
2%	Purslanes/boiled	15/8.9	37
2%	Cauliflowers/boiled	2/1.1	27
1%	Broccoli/boiled	2/1.1	22
1%	Wine grapes/wine	3/2.3	22
1%	Florence fennels/boiled	4/1.71	21
1%	Beetroots/boiled	1.5/1.04	17
1%	Apples/juice	2/0.48	16
1.0%	Pumpkins/boiled	0.6/0.36	14
0.9%	Wine grapes/juice	3/0.67	14
0.7%	Peaches/canned	2/1.7	10
0.6%	Salsifies/boiled	1.5/1.04	9.5
0.6%	Currants (red, black and white)/	3/0.69	8.8
0.4%	Elderberries/juice	3/0.69	6.3
0.4%	Courgettes/boiled	0.5/0.36	5.7
0.4%	Barley/beer	4/0.15	5.4
0.3%	Peas (with pods)/boiled	2/1.15	3.9
0.2%	Carrots/canned	1.5/0.45	3.7
0.09%	Table grapes/raisins	3/3.2	1.3
0.08%	Celeriacs/boiled	0.3/0.11	1.2
0.06%	Rose hips/jam	3/0.69	0.86
0.05%	Onions/boiled	0.3/0.1	0.72
0.04%	Witloofs/boiled	0.06/0.03	0.65
0.04%	Quinces/jam	2/0.48	0.60
0.04%	Wheat/bread/pizza	0.5/0.13	0.57
0.04%	Tomatoes/sauce/puree	1.5/0.17	0.56
0.04%	Ginger/jam	1.5/0.45	0.56
0.04%	Cranberries/dried	3/0.69	0.52
0.03%	Wheat/pasta	0.5/0.13	0.50
0.03%	Beans/canned	0.2/0.06	0.43
0.02%	Shallots/boiled	0.07/0.05	0.36
0.02%	Beans (without pods)/boiled	0.08/0.05	0.26
0.01%	Wheat/bread (wholemeal)	0.5/0.13	0.22
0.01%	Head cabbages/canned	0.7/0.03	0.16
0.01%	Peas (without pods)/boiled	0.08/0.05	0.16
0.00%	Coconuts/milk	0.04/0.02	0.07
0.00%	Peas/canned	0.1/0.01	0.05
0.00%	Turmeric (Curcuma)/boiled	1.5/1.04	0.02
0.00%	Valerian root/infusion	1.5/0	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 Cyprodinil (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; 2018/11/18

Pyraclostrobin (F)

LOQs (mg/kg) range from: 0.01 to: 0.10

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:

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)
29%	NL toddler	8.80	13%	Milk: Cattle	4%	Apples	2%	Pears	0.6%	
21%	ES adult	6.29	17%	Lettuces	1%	Milk: Cattle	0.6%	Barley	0.2%	
20%	SE general	5.94	13%	Lettuces	3%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	
20%	ES child	5.89	13%	Lettuces	3%	Milk: Cattle	0.5%	Apples	0.4%	
20%	IT adult	5.86	12%	Lettuces	5%	Other lettuce and other salad plants	0.4%	Tomatoes	0.1%	
19%	DE child	5.67	5%	Apples	4%	Milk: Cattle	2%	Lettuces	0.7%	
18%	GEMS/Food G10	5.29	10%	Lettuces	1%	Milk: Cattle	0.7%	Barley	0.3%	
17%	NL child	5.21	5%	Milk: Cattle	2%	Apples	2%	Lettuces	0.5%	
16%	IT toddler	4.71	9%	Lettuces	4%	Other lettuce and other salad plants	0.5%	Tomatoes	0.2%	
15%	GEMS/Food G07	4.63	8%	Lettuces	1%	Milk: Cattle	0.7%	Barley	0.4%	
15%	FR child 3–15 years	4.38	5%	Milk: Cattle	4%	Other lettuce and other salad plants	0.7%	Apples	0.5%	
14%	GEMS/Food G08	4.26	6%	Lettuces	1%	Milk: Cattle	1%	Barley	0.4%	
13%	UK infant	3.84	8%	Milk: Cattle	0.6%	Apples	0.5%	Carrots	0.5%	
13%	FR toddler 2–3 years	3.82	6%	Milk: Cattle	1%	Apples	0.9%	Other lettuce and other salad plants	0.4%	
13%	DK child	3.77	4%	Lettuces	3%	Milk: Cattle	0.9%	Apples	0.3%	
12%	DE women 14–50 years	3.47	4%	Lettuces	3%	Milk: Cattle	1%	Apples	0.2%	
11%	GEMS/Food G15	3.32	3%	Lettuces	2%	Milk: Cattle	0.9%	Barley	0.3%	
11%	DE general	3.30	3%	Lettuces	3%	Milk: Cattle	1.0%	Apples	0.2%	
11%	GEMS/Food G11	3.28	2%	Lettuces	2%	Milk: Cattle	0.9%	Barley	0.4%	
10%	GEMS/Food G06	3.11	3%	Lettuces	1%	Tomatoes	0.5%	Milk: Cattle	0.3%	
10%	IE adult	2.96	3%	Lettuces	0.9%	Milk: Cattle	0.4%	Other other small fruit & berries	0.6%	
10%	UK toddler	2.91	4%	Milk: Cattle	0.7%	Apples	0.6%	Lettuces	0.4%	
9%	FR adult	2.82	5%	Other lettuce and other salad plants	1.0%	Milk: Cattle	0.5%	Tea (dried leaves of Camellia sinens	0.2%	
9%	NL general	2.69	3%	Lettuces	2%	Milk: Cattle	0.6%	Apples	0.3%	
7%	UK vegetarian	2.16	4%	Lettuces	0.7%	Milk: Cattle	0.2%	Apples	0.2%	
7%	FR infant	2.07	4%	Milk: Cattle	0.7%	Apples	0.4%	Carrots	0.2%	
7%	FI adult	2.02	4%	Lettuces	0.6%	Coffee beans	0.2%	Apples	0.1%	
7%	RO general	1.97	2%	Milk: Cattle	0.6%	Tomatoes	0.6%	Apples	0.4%	
6%	UK adult	1.84	4%	Lettuces	0.6%	Milk: Cattle	0.2%	Tea (dried leaves of Camellia sinens	0.2%	
6%	DK adult	1.83	3%	Lettuces	1%	Milk: Cattle	0.4%	Apples	0.2%	
6%	PT general	1.82	3%	Lettuces	0.4%	Apples	0.4%	Potatoes	0.4%	
6%	FI 6 years	1.76	3%	Lettuces	0.4%	Raspberries (red and yellow)	0.4%	Oat	0.4%	
6%	FI 3 years	1.74	1%	Lettuces	0.7%	Oat	0.5%	Raspberries (red and yellow)	0.4%	
5%	LT adult	1.60	2%	Lettuces	0.9%	Milk: Cattle	0.7%	Apples	0.3%	
3%	PL general	0.85	0.8%	Apples	0.4%	Lettuces	0.3%	Tomatoes	0.3%	
2%	IE child	0.54	0.8%	Milk: Cattle	0.2%	Lettuces	0.1%	Apples	0.1%	

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	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acuterisk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): 9

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2500%	Lettuces	40/19.7	750
319%	Pears	0.7/0.69	96
248%	Apples	0.7/0.69	74
107%	Kaki/Japanese	0.02/0.69	32
103%	Kales	1.5/0.7	31
99%	Sweet peppers/bell peppers	0.5/0.5	30
94%	Lamb's lettuce/corn salads	10/10	28
92%	Raspberries (red and	3/3	28
92%	Mangoes	0.6/0.35	28
84%	Globe artichokes	2/1.44	25
82%	Strawberries	1.5/1.5	25
79%	Currants (red, black and	3/3	24
78%	Spring onions/green onions	1.5/1.5	24
76%	Celeries	1.5/0.61	23
75%	Chinese cabbages/pe-tsai	1.5/0.7	22
73%	Apricots	1/0.63	22
69%	Spinaches	1.5/0.91	21
65%	Roman rocket/rucola	10/7.2	19
64%	Cherries (sweet)	3/1.57	19
63%	Carrots	0.5/0.3	19
59%	Cucumbers	0.5/0.27	18
59%	Gooseberries (green, red	3/3	18

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
797%	Lettuces	40/19.7	239
127%	Red mustards	10/7.2	38
70%	Pears	0.7/0.69	21
66%	Currants (red, black and	3/3	20
65%	Apples	0.7/0.69	19
63%	Blueberries	4/2.08	19
63%	Lamb's lettuce/corn salads	10/10	19
62%	Globe artichokes	2/1.44	19
59%	Chinese cabbages/pe-tsai	1.5/0.7	18
54%	Raspberries (red and	3/3	16
52%	Cherries (sweet)	3/1.57	16
51%	Chards/beet leaves	1.5/0.81	15
51%	Kaki/Japanese persimmons	0.02/0.69	15
47%	Strawberries	1.5/1.5	14
45%	Gooseberries (green, red	3/3	14
45%	Kales	1.5/0.7	13
38%	Florence fennels	1.5/0.61	11
36%	Blackberries	3/1.3	11
35%	Quinces	0.7/0.69	10
34%	Swedes/rutabagas	0.5/0.3	10
33%	Celeries	1.5/0.61	9.8
31%	Head cabbages	0.2/0.22	9.3

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3046%	Lettuces	40/40	914
164%	Apricots	1/1	49
144%	Apples	0.7/0.7	43
138%	Pears	0.7/0.7	42
132%	Kales	1.5/1.5	40
122%	Cherries (sweet)	3/3	37
113%	Spinaches	1.5/1.5	34
112%	Celeries	1.5/1.5	34
107%	Blackberries	3/3	32
96%	Chinese cabbages/pe-tsai	1.5/1.5	29
94%	Mangoes	0.6/0.6	28
94%	Lamb's lettuce/corn salads	10/10	28
92%	Raspberries (red and	3/3	28
90%	Roman rocket/rucola	10/10	27
84%	Milk: Cattle	0.03/0.2	25
84%	Globe artichokes	2/2	25
82%	Strawberries	1.5/1.5	25
79%	Blueberries	4/4	24
79%	Currants (red, black and	3/3	24
76%	Melons	0.5/0.25	23
68%	Spring onions/green onions	1.5/1.5	21
68%	Plums	0.8/0.8	20

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
971%	Lettuces	40/40	291
158%	Wine grapes	2/2	47
122%	Blueberries	4/4	36
104%	Plums	0.8/0.8	31
100%	Cherries (sweet)	3/3	30
83%	Pears	0.7/0.7	25
82%	Blackberries	3/3	25
76%	Chinese cabbages/pe-tsai	1.5/1.5	23
76%	Red mustards	10/10	23
72%	Globe artichokes	2/2	22
70%	Apples	0.7/0.7	21
66%	Currants (red, black and white)	3/3	20
63%	Lamb's lettuce/corn salads	10/10	19
58%	Kales	1.5/1.5	17
54%	Raspberries (red and yellow)	3/3	16
48%	Celeries	1.5/1.5	14
47%	Mangoes	0.6/0.6	14
47%	Strawberries	1.5/1.5	14
45%	Gooseberries (green, red and	3/3	14
44%	Chards/beet leaves	1.5/1.5	13
43%	Apricots	1/1	13
40%	Florence fennels	1.5/1.5	12

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 6

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) 12

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): ---

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

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

IESTI

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
90%	Currants (red, black and wh	3/0.94	27
88%	Escaroles/broad-leaved end	0.4/0.4	27
86%	Oranges/juice	2/0.49	26
84%	Chards/beet leaves/boiled	1.5/0.81	25
64%	Kales/boiled	1.5/0.7	19
55%	Leeks/boiled	0.7/0.29	17
51%	Turnips/boiled	0.5/0.3	15
51%	Parsnips/boiled	0.5/0.3	15
50%	Elderberries/juice	3/0.94	15
50%	Broccoli/boiled	0.1/0.19	15
44%	Pumpkins/boiled	0.5/0.15	13
44%	Beetroots/boiled	0.5/0.3	13
44%	Cauliflowers/boiled	0.1/0.19	13
42%	Spinaches/frozen; boiled	1.5/0.91	13

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
69%	Celeries/boiled	1.5/0.61	21
40%	Currants (red, black and	3/0.94	12
39%	Florence fennels/boiled	1.5/0.61	12
34%	Chards/beet leaves/boiled	1.5/0.81	10
29%	Elderberries/juice	3/0.94	8.6
28%	Pumpkins/boiled	0.5/0.15	8.3
27%	Escaroles/broad-leaved	0.4/0.4	8.2
26%	Cauliflowers/boiled	0.1/0.19	7.9
25%	Spinaches/frozen; boiled	1.5/0.91	7.5
25%	Oranges/juice	2/0.49	7.4
22%	Beetroots/boiled	0.5/0.3	6.6
21%	Parsnips/boiled	0.5/0.3	6.4
21%	Courgettes/boiled	0.5/0.27	6.2
20%	Grapefruits/juice	1/0.54	5.9
19%	Onions/boiled	1.5/0.62	5.8

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
90%	Currants (red, black and	3/0.94	27
86%	Oranges/juice	2/0.49	26
55%	Florence fennels/boiled	1.5/0.61	17
53%	Escaroles/broad-leaved	0.4/0.4	16
50%	Elderberries/juice	3/0.94	15
42%	Spinaches/frozen; boiled	1.5/0.91	13
39%	Kales/boiled	1.5/0.7	12
36%	Chards/beet leaves/boiled	1.5/0.81	11
34%	Raspberries/juice	3/0.87	10
32%	Leeks/boiled	0.7/0.29	9.5
30%	Broccoli/boiled	0.1/0.19	9.0
27%	Pumpkins/boiled	0.5/0.15	8.0
26%	Cauliflowers/boiled	0.1/0.19	7.9
22%	Turnips/boiled	0.5/0.3	6.5
22%	Salsifies/boiled	0.5/0.3	6.5

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
41%	Celeries/boiled	1.5/0.61	12
40%	Currants (red, black and white)/	3/0.94	12
29%	Elderberries/juice	3/0.94	8.6
25%	Florence fennels/boiled	1.5/0.61	7.5
25%	Spinaches/frozen; boiled	1.5/0.91	7.5
25%	Oranges/juice	2/0.49	7.4
24%	Chards/beet leaves/boiled	1.5/0.81	7.1
21%	Escaroles/broad-leaved endives/	0.4/0.4	6.2
20%	Pumpkins/boiled	0.5/0.15	6.0
20%	Grapefruits/juice	1/0.54	5.9
17%	Beetroots/boiled	0.5/0.3	5.0
16%	Cauliflowers/boiled	0.1/0.19	4.7
15%	Onions/boiled	1.5/0.62	4.4
14%	Courgettes/boiled	0.5/0.27	4.3
13%	Apples/juice	0.7/0.12	4.0

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 6 commodities.

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

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Fludioxonil

LOQs (mg/kg) range from: 0.01 to: 0.01

Toxicological reference values

ADI (mg/kg bw per day):	0.37	ARfD (mg/kg bw):	0.37
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	75.31	7%	Apples	3%	Oranges	3%	Pears	0.0%	0.0%
	19%	DE child	70.60	8%	Apples	6%	Oranges	1%	Potatoes		0.0%
	11%	NL child	42.11	4%	Apples	2%	Oranges	1%	Potatoes	0.0%	0.0%
	11%	IE adult	40.50	4%	Sweet potatoes	1%	Oranges	1.0%	Grapefruits		0.0%
	9%	FR child 3–15 years	31.80	5%	Oranges	1%	Apples	0.6%	Potatoes	0.0%	0.0%
	8%	FR toddler 2–3 years	28.65	2%	Oranges	2%	Apples	1%	Mandarins	0.0%	0.0%
	7%	GEMS/Food G11	27.56	2%	Potatoes	1%	Oranges	1.0%	Apples		0.0%
	7%	GEMS/Food G07	26.29	2%	Oranges	2%	Potatoes	0.6%	Apples	0.0%	0.0%
	7%	ES child	26.10	3%	Oranges	0.9%	Lettuces	0.7%	Potatoes	0.0%	
	7%	SE general	25.88	2%	Potatoes	1%	Oranges	0.9%	Lettuces		0.0%
	7%	UK toddler	25.17	3%	Oranges	1%	Potatoes	1%	Apples	0.0%	
	7%	DE women 14–50 years	24.98	3%	Oranges	2%	Apples	0.4%	Potatoes	0.0%	0.0%
	6%	GEMS/Food G10	23.94	2%	Oranges	1%	Potatoes	0.7%	Lettuces	0.0%	0.0%
	6%	DE general	22.26	2%	Oranges	2%	Apples	0.5%	Potatoes	0.0%	0.0%
	6%	GEMS/Food G08	22.10	2%	Potatoes	0.8%	Apples	0.7%	Oranges		0.0%
	6%	GEMS/Food G06	22.00	1%	Oranges	0.8%	Potatoes	0.6%	Tomatoes	0.0%	0.0%
	6%	PT general	20.54	2%	Potatoes	0.9%	Oranges	0.7%	Apples		0.0%
	5%	ES adult	20.13	2%	Oranges	1%	Lettuces	0.5%	Apples	0.0%	
	5%	UK infant	19.91	2%	Oranges	1%	Potatoes	1.0%	Apples	0.0%	
	5%	GEMS/Food G15	19.53	1%	Potatoes	1.0%	Oranges	0.7%	Apples		0.0%
	5%	NL general	18.83	1%	Oranges	1.0%	Potatoes	0.9%	Apples	0.0%	0.0%
	5%	DK child	17.50	1%	Apples	1.0%	Potatoes	0.4%	Pears		
	5%	FI 3 years	17.07	2%	Potatoes	0.6%	Apples	0.6%	Mandarins		
	4%	RO general	15.68	2%	Potatoes	0.9%	Apples	0.4%	Oranges	0.0%	
	4%	IT toddler	15.63	0.7%	Oranges	0.7%	Lettuces	0.6%	Apples		0.0%
	4%	IT adult	14.99	0.8%	Lettuces	0.5%	Oranges	0.5%	Apples		0.0%
	4%	FI 6 years	14.20	2%	Potatoes	0.5%	Mandarins	0.4%	Apples		
	4%	FR infant	13.85	1%	Apples	0.8%	Potatoes	0.4%	Spinaches	0.0%	0.0%
	4%	PL general	13.57	1%	Potatoes	1%	Apples	0.2%	Pears		0.0%
	3%	UK vegetarian	12.57	1%	Oranges	0.6%	Potatoes	0.4%	Apples	0.0%	0.0%
	3%	LT adult	11.58	1%	Potatoes	1%	Apples	0.1%	Lettuces		
	3%	FR adult	11.44	0.8%	Oranges	0.5%	Apples	0.3%	Potatoes	0.0%	0.0%
	3%	UK adult	9.61	0.8%	Oranges	0.6%	Potatoes	0.3%	Lettuces	0.0%	0.0%
	3%	DK adult	9.49	0.6%	Apples	0.5%	Potatoes	0.2%	Oranges		
	2%	FI adult	9.09	0.6%	Oranges	0.5%	Potatoes	0.4%	Apples		
	0.8%	IE child	2.95	0.2%	Potatoes	0.2%	Apples	0.1%	Oranges		

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 12

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
412%	Lettuces	40/40	1523
358%	Oranges	10/10	1326
257%	Peaches	10/10	950
252%	Kiwi fruits (green, red,	15/15	933
217%	Escaroles/broad-leaved	20/20	803
212%	Grapefruits	10/10	785
208%	Potatoes	5/5	769
187%	Pears	5/5	692
183%	Spinaches	30/30	678
158%	Mandarins	10/10	583
146%	Apples	5/5	539
141%	Lemons	10/10	520
99%	Table grapes	5/5	365
84%	Kales	15/7.1	312
84%	Chards/beet leaves	20/20	312
84%	Yams	10/10	311
80%	Broccoli	15/7.1	295
79%	Celeries	15/7.8	292
77%	Pineapples	7/2.8	283
62%	Chinese cabbages/pe-tsai	15/7.1	228
59%	Spring onions/green onions	5/14	220
57%	Plums	5/5	211
54%	Limes	10/10	201
47%	Apricots	5/5	175
47%	Tomatoes	3/3	174
43%	Mangoes	2/2	157
33%	Quinces	5/5	123
30%	Granate	3/2	110
24%	Head cabbages	2/2	88
19%	Medlar	5/5	69
18%	Strawberries	4/4	65
17%	Carrots	1/1	63
17%	Cherries (sweet)	5/5	61
16%	Sweet peppers/bell peppers	1/1	60
15%	Lamb's lettuce/corn salads	20/20	56
15%	Roman rocket/rucola	20/20	54
14%	Blackberries	5/5	54
14%	Sweet potatoes	10/10	53
12%	Raspberries (red and	5/5	46
12%	Melons	0.3/0.3	46
12%	Beetroots	1/1	44
11%	Avocados	1.5/0.8	40
10%	Watermelons	0.3/0.3	37
10%	Parsnips	1/1	36
8%	Salsifies	1/1	31
7%	Leeks	0.8/0.47	28
7%	Cucumbers	0.4/0.4	26
7%	Chervil	20/20	26
7%	Florence fennels	1.5/1.5	24
6%	Parsley	20/20	22
6%	Onions	0.5/0.95	22
5%	Courgettes	0.4/0.4	19
4%	Chives	20/20	16
4%	Sage	20/20	15
4%	Basil and edible flowers	20/20	15
3%	Gooseberries (green, red	2/2	12
3%	Celeriacs/turnip rooted	0.2/0.2	11
3%	Currants (red, black and	3/1.4	11
3%	Aubergines/egg plants	0.4/0.4	10.0
2%	Beans (with pods)	1/1	8.8
2%	Pumpkins	0.3/0.3	8.0
2%	Radishes	0.3/0.3	7.4
2%	Blueberries	2/1.7	6.8
1%	Cranberries	2/2	5.2

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)
131%	Lettuces	40/40	486
109%	Escaroles/broad-leaved	20/20	403
83%	Oranges	10/10	307
77%	Yams	10/10	283
68%	Chards/beet leaves	20/20	250
56%	Kiwi fruits (green, red,	15/15	209
56%	Sweet potatoes	10/10	208
51%	Peaches	10/10	187
49%	Chinese cabbages/pe-tsai	15/7.1	180
49%	Mandarins	10/10	180
48%	Grapefruits	10/10	179
46%	Table grapes	5/5	170
46%	Broccoli	15/7.1	169
41%	Pears	5/5	153
40%	Potatoes	5/5	149
38%	Apples	5/5	140
37%	Kales	15/7.1	137
34%	Celeries	15/7.8	125
32%	Spinaches	30/30	120
29%	Red mustards	20/20	106
27%	Plums	5/5	99
26%	Wine grapes	4/4	95
24%	Lemons	10/10	90
23%	Head cabbages	2/2	84
22%	Pineapples	7/2.8	83
21%	Quinces	5/5	76
19%	Limes	10/10	70
17%	Spring onions/green onions	5/14	63
15%	Apricots	5/5	54
14%	Cherries (sweet)	5/5	50
13%	Tomatoes	3/3	48
11%	Mangoes	2/2	42
11%	Blackberries	5/5	41
10%	Purslanes	20/20	38
10%	Lamb's lettuce/corn salads	20/20	38
10%	Strawberries	4/4	37
10%	Granate	3/2	35
9%	Medlar	5/5	34
8%	Florence fennels	1.5/1.5	28
7%	Raspberries (red and	5/5	27
6%	Parsley	20/20	24
6%	Roman rocket/rucola	20/20	24
5%	Carrots	1/1	20
4%	Sweet peppers/bell peppers	1/1	16
4%	Blueberries	2/1.7	16
4%	Onions	0.5/0.95	14
4%	Parsnips	1/1	14
3%	Beetroots	1/1	12
3%	Watermelons	0.3/0.3	12
3%	Avocados	1.5/0.8	12
3%	Melons	0.3/0.3	12
3%	Cucumbers	0.4/0.4	11
3%	Salsifies	1/1	11
3%	Parsley roots/Hamburg	1/1	10
3%	Courgettes	0.4/0.4	9.3
2%	Currants (red, black and	3/1.4	9.2
2%	Gooseberries (green, red	2/2	9.0
2%	Aubergines/egg plants	0.4/0.4	8.8
2%	Horseradishes	1/1	7.3
2%	Leeks	0.8/0.47	6.2
1%	Pumpkins	0.3/0.3	4.4
1%	Sage	20/20	4.0
0.9%	Chives	20/20	3.4
0.9%	Guavas	0.5/0.19	3.4

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): 125

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
247%	Lettuces	40/40	914
5%	Salsifies	1/1	17
4%	Chives	20/20	16
4%	Cucumbers	0.4/0.4	16
4%	Parsnips	1/1	15
4%	Sage	20/20	15
4%	Basil and edible flowers	20/20	15
4%	Onions	0.5/1.4	14
3%	Gooseberries (green, red	2/2	12
3%	Florence fennels	1.5/1.5	10
2%	Beans	0.5/0.5	9.1
2%	Beans (with pods)	1/1	8.8
2%	Blueberries	2/2	8.0
2%	Courgettes	0.4/0.4	8.0
2%	Celeriacs/turnip rooted	0.2/0.2	6.6
2%	Aubergines/egg plants	0.4/0.4	6.0
1%	Cranberries	2/2	5.2
1%	Milk: Cattle	0.04/0.04	5.0
1%	Garlic	0.5/1.4	4.9
1%	Pumpkins	0.3/0.3	4.8
1%	Guavas	0.5/0.5	4.7
1%	Celery leaves	20/20	3.8
0.9%	Peas (with pods)	1/1	3.5
0.9%	Beans (without pods)	0.4/0.4	3.2
0.9%	Radishes	0.3/0.3	3.2
0.7%	Lentils	0.4/0.4	2.7
0.7%	Peas	0.4/0.4	2.6
0.7%	Peas (without pods)	0.3/0.3	2.5
0.5%	Parsley roots/Hamburg	1/1	1.9
0.4%	Bovine: Liver	0.2/0.2	1.6
0.3%	Equine: Muscle/meat	0.2/0.2	1.2
0.3%	Thyme	20/20	1.2
0.3%	Gherkins	0.4/0.4	1.1
0.3%	Milk: Goat	0.04/0.04	0.97
0.2%	Ginseng root	4/4	0.80
0.2%	Bovine: Kidney	0.2/0.2	0.75
0.2%	Eggs: Chicken	0.05/0.05	0.62
0.2%	Rosemary	20/20	0.60
0.1%	Soyabeans	0.2/0.2	0.46
0.1%	Shallots	0.5/1.4	0.43
0.1%	Bovine: Fat tissue	0.2/0.2	0.42
0.10%	Bovine: Edible offals (other	0.05/0.05	0.36
0.08%	Swine: Edible offals (other	0.1/0.1	0.30
0.08%	Bovine: Muscle/meat	0.04/0.04	0.29
0.08%	Lentils (fresh)	0.05/0.05	0.29
0.07%	Swine: Muscle/meat	0.02/0.02	0.24
0.05%	Laurel/bay leaves	20/20	0.20
0.05%	Sweet corn	0.01/0.01	0.19
0.05%	Horseradishes	1/1	0.18
0.05%	Poultry: Muscle/meat	0.01/0.01	0.17
0.04%	Sheep: Muscle/meat	0.04/0.04	0.17
0.04%	Wheat	0.01/0.01	0.14
0.04%	Milk: Sheep	0.04/0.04	0.14
0.04%	Asparagus	0.01/0.01	0.14
0.03%	Swine: Kidney	0.1/0.1	0.13
0.03%	Rice	0.01/0.01	0.13
0.03%	Swine: Liver	0.1/0.1	0.12
0.02%	Other farmed animals:	0.01/0.01	0.07
0.02%	Maize/corn	0.01/0.01	0.07
0.02%	Rye	0.01/0.01	0.06
0.02%	Pistachios	0.01/0.01	0.06
0.02%	Barley	0.01/0.01	0.06
0.01%	Poultry: Liver	0.05/0.05	0.06
0.01%	Buckwheat and other	0.01/0.01	0.05

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
127%	Oranges	10/10	469
89%	Mandarins	10/10	330
80%	Escaroles/broad-leaved endives	20/20	294
79%	Lettuces	40/40	291
78%	Broccoli	15/15	290
77%	Kiwi fruits (green, red, yellow)	15/15	286
74%	Yams	10/10	274
62%	Chinese cabbages/pe-tsai	15/15	228
57%	Grapefruits	10/10	210
55%	Peaches	10/10	204
53%	Plums	5/5	195
48%	Pears	5/5	178
48%	Chards/beet leaves	20/20	176
47%	Kales	15/15	173
42%	Potatoes	5/5	156
41%	Apples	5/5	150
39%	Celeries	15/15	144
34%	Pineapples	7/7	124
32%	Spinaches	30/30	120
29%	Sweet potatoes	10/10	106
27%	Table grapes	5/5	102
26%	Wine grapes	4/4	95
17%	Apricots	5/5	64
16%	Tomatoes	3/3	58
14%	Head cabbages	2/2	50
14%	Cherries (sweet)	5/5	50
13%	Spring onions/green onions and	5/14	47
13%	Mangoes	2/2	47
12%	Quinces	5/5	46
12%	Red mustards	20/20	46
11%	Blackberries	5/5	41
10%	Lemons	10/10	38
10%	Purslanes	20/20	38
10%	Lamb's lettuce/corn salads	20/20	38
10%	Strawberries	4/4	37
8%	Limes	10/10	30
8%	Granate apples/pomegranates	3/3	30
7%	Raspberries (red and yellow)	5/5	27
6%	Parsley	20/20	24
6%	Medlar	5/5	24
6%	Roman rocket/rucola	20/20	24
5%	Currants (red, black and white)	3/3	20
5%	Avocados	1.5/1.5	18
5%	Blueberries	2/2	18
3%	Florence fennels	1.5/1.5	12
3%	Carrots	1/1	12
2%	Gooseberries (green, red and	2/2	9.0
2%	Onions	0.5/1.4	8.9
2%	Parsnips	1/1	8.5
2%	Watermelons	0.3/0.3	7.3
2%	Melons	0.3/0.3	7.1
2%	Sweet peppers/bell peppers	1/1	7.0
2%	Cucumbers	0.4/0.4	6.7
1%	Beetroots	1/1	5.3
1%	Aubergines/egg plants	0.4/0.4	5.3
1%	Salsifies	1/1	4.9
1%	Courgettes	0.4/0.4	4.8
1%	Leeks	0.8/0.8	4.7
1%	Parsley roots/Hamburg roots	1/1	4.4
1%	Sage	20/20	4.0
1%	Guavas	0.5/0.5	3.8
0.9%	Chives	20/20	3.4
0.9%	Beans	0.5/0.5	3.3
0.9%	Peas (with pods)	1/1	3.2

1%	Celery leaves	20/20	3.8	0.7%	Celery leaves	20/20	2.6	0.01%	Sunflower seeds	0.01/0.01	0.03	0.7%	Pumpkins	0.3/0.3	2.6
0.9%	Peas (with pods)	1/1	3.5	0.7%	Shallots	0.5/0.95	2.5	0.01%	Turmeric/curcuma	1/1	0.02	0.7%	Celery leaves	20/20	2.6
0.9%	Garlic	0.5/0.95	3.4	0.7%	Gherkins	0.4/0.4	2.4	0.00%	Common millet/proso	0.01/0.01	0.01	0.7%	Lentils	0.4/0.4	2.5
0.9%	Beans (without pods)	0.4/0.4	3.2	0.6%	Ginseng root	4/4	2.4	0.00%	Rapeseeds/canola seeds	0.01/0.01	0.01	0.6%	Ginseng root	4/4	2.4
0.7%	Peas (without pods)	0.3/0.3	2.5	0.6%	Celeriacs/turnip rooted	0.2/0.2	2.4	0.00%	Oat	0.01/0.01	0.01	0.5%	Tarragon	20/20	2.0
0.4%	Bovine: Liver	0.2/0.2	1.6	0.5%	Tarragon	20/20	2.0	0.00%	Wine grapes	4/4	0.01	0.5%	Rosemary	20/20	2.0
0.3%	Thyme	20/20	1.2	0.5%	Rosemary	20/20	2.0	0.00%	Liquorice	1/1	0.01	0.5%	Rosemary	20/20	2.0
0.3%	Gherkins	0.4/0.4	1.1	0.5%	Rosemary	20/20	2.0	0.00%	Poultry: Fat tissue	0.05/0.05	0.01	0.5%	Rosemary	20/20	2.0
0.3%	Milk: Cattle	0.04/0.01	0.99	0.5%	Rosemary	20/20	2.0					0.5%	Rosemary	20/20	2.0
0.2%	Ginseng root	4/4	0.80	0.5%	Rosemary	20/20	2.0					0.4%	Chervil	20/20	1.6
0.2%	Bovine: Kidney	0.2/0.2	0.75	0.4%	Chervil	20/20	1.6					0.4%	Shallots	0.5/1.4	1.6
0.2%	Beans	0.5/0.04	0.73	0.4%	Beans (without pods)	0.4/0.4	1.6					0.4%	Beans (without pods)	0.4/0.4	1.6
0.2%	Eggs: Chicken	0.05/0.05	0.62	0.3%	Peas (without pods)	0.3/0.3	0.98					0.4%	Milk: Cattle	0.04/0.04	1.5
0.2%	Rosemary	20/20	0.60	0.2%	Bovine: Liver	0.2/0.2	0.80					0.4%	Celeriacs/turnip rooted celeries	0.2/0.2	1.4
0.1%	Sweet corn	0.01/0.01	0.43	0.2%	Garlic	0.5/0.95	0.61					0.4%	Radishes	0.3/0.3	1.3
0.1%	Bovine: Fat tissue	0.2/0.2	0.42	0.2%	Sheep: Liver	0.2/0.2	0.56					0.4%	Peas	0.4/0.4	1.3
0.1%	Horseradishes	1/1	0.41	0.1%	Bovine: Kidney	0.2/0.2	0.42					0.3%	Soyabeans	0.2/0.2	1.1
0.10%	Bovine: Edible offals (other	0.05/0.05	0.36	0.1%	Poultry: Edible offals (other	0.05/0.05	0.42					0.3%	Peas (without pods)	0.3/0.3	0.98
0.08%	Shallots	0.5/0.95	0.30	0.08%	Milk: Cattle	0.04/0.01	0.31					0.3%	Equine: Muscle/meat	0.2/0.2	0.96
0.08%	Bovine: Muscle/meat	0.04/0.04	0.29	0.07%	Beans	0.5/0.04	0.26					0.2%	Garlic	0.5/1.4	0.90
0.08%	Lentils (fresh)	0.05/0.05	0.29	0.07%	Lentils	0.4/0.04	0.25					0.2%	Bovine: Liver	0.2/0.2	0.80
0.07%	Swine: Edible offals (other	0.1/0.09	0.27	0.06%	Poultry: Liver	0.05/0.05	0.24					0.2%	Milk: Goat	0.04/0.04	0.74
0.07%	Lentils	0.4/0.04	0.27	0.06%	Swine: Edible offals (other	0.1/0.09	0.23					0.2%	Milk: Sheep	0.04/0.04	0.60
0.07%	Peas	0.4/0.04	0.26	0.06%	Bovine: Muscle	0.04/0.04	0.23					0.2%	Sheep: Liver	0.2/0.2	0.56
0.07%	Swine: Muscle/meat	0.02/0.02	0.24	0.06%	Eggs: Chicken	0.05/0.05	0.21					0.1%	Bovine: Kidney	0.2/0.2	0.42
0.05%	Laurel/bay leaves	20/20	0.20	0.05%	Swine: Kidney	0.1/0.09	0.20					0.1%	Poultry: Edible offals (other than	0.05/0.05	0.42
0.05%	Milk: Goat	0.04/0.01	0.19	0.05%	Bovine: Fat tissue	0.2/0.2	0.19					0.07%	Swine: Edible offals (other than	0.1/0.1	0.26
0.05%	Poultry: Muscle/meat	0.01/0.01	0.17	0.05%	Sheep: Muscle/meat	0.04/0.04	0.17					0.06%	Poultry: Liver	0.05/0.05	0.24
0.04%	Sheep: Muscle/meat	0.04/0.04	0.17	0.04%	Bovine: Edible offals (other	0.05/0.05	0.17					0.06%	Bovine: Muscle	0.04/0.04	0.23
0.04%	Wheat	0.01/0.01	0.14	0.04%	Lentils (fresh)	0.05/0.05	0.17					0.06%	Swine: Kidney	0.1/0.1	0.22
0.03%	Rice	0.01/0.01	0.13	0.04%	Sweet corn	0.01/0.01	0.16					0.06%	Eggs: Chicken	0.05/0.05	0.21
0.03%	Swine: Kidney	0.1/0.09	0.11	0.04%	Milk: Goat	0.04/0.01	0.15					0.05%	Bovine: Fat tissue	0.2/0.2	0.19
0.03%	Asparagus	0.01/0.01	0.11	0.04%	Peas	0.4/0.04	0.13					0.05%	Asparagus	0.01/0.01	0.18
0.03%	Swine: Liver	0.1/0.09	0.11	0.03%	Swine: Liver	0.1/0.09	0.13					0.05%	Sheep: Muscle/meat	0.04/0.04	0.17
0.02%	Ginger	1/1	0.08	0.03%	Milk: Sheep	0.04/0.01	0.12					0.04%	Bovine: Edible offals (other than	0.05/0.05	0.17
0.02%	Other farmed animals:	0.01/0.01	0.07	0.03%	Poultry: Muscle	0.01/0.01	0.12					0.04%	Lentils (fresh)	0.05/0.05	0.17
0.02%	Maize/corn	0.01/0.01	0.07	0.03%	Liquorice	1/1	0.10					0.04%	Swine: Liver	0.1/0.1	0.14
0.02%	Rye	0.01/0.01	0.06	0.03%	Liquorice	1/1	0.10					0.03%	Sweet corn	0.01/0.01	0.13
0.02%	Equine: Muscle/meat	0.2/0.01	0.06	0.02%	Swine: Muscle/meat	0.02/0.02	0.09					0.03%	Poultry: Muscle	0.01/0.01	0.12
0.02%	Pistachios	0.01/0.01	0.06	0.02%	Rice	0.01/0.01	0.09					0.03%	Liquorice	1/1	0.10
0.02%	Barley	0.01/0.01	0.06	0.02%	Wheat	0.01/0.01	0.08					0.03%	Liquorice	1/1	0.10
0.01%	Poultry: Liver	0.05/0.05	0.06	0.02%	Asparagus	0.01/0.01	0.08					0.02%	Swine: Muscle/meat	0.02/0.02	0.09
0.01%	Buckwheat and other	0.01/0.01	0.05	0.02%	Eggs: Quail	0.05/0.05	0.07					0.02%	Rice	0.01/0.01	0.09
0.01%	Sorghum	0.01/0.01	0.03	0.02%	Poultry: Kidney	0.05/0.05	0.06					0.02%	Wheat	0.01/0.01	0.08
0.01%	Sunflower seeds	0.01/0.01	0.03	0.02%	Goat: Muscle	0.04/0.04	0.06					0.02%	Eggs: Quail	0.05/0.05	0.07
0.01%	Milk: Sheep	0.04/0.01	0.03	0.02%	Other farmed animals:	0.01/0.01	0.06					0.02%	Poultry: Kidney	0.05/0.05	0.06
0.01%	Turmeric/curcuma	1/1	0.02	0.01%	Soyabeans	0.2/0.01	0.06					0.02%	Goat: Muscle	0.04/0.04	0.06
0.01%	Soyabeans	0.2/0.01	0.02	0.01%	Rye	0.01/0.01	0.05					0.02%	Other farmed animals:	0.01/0.01	0.06
0.01%	Swine: Fat tissue	0.02/0.01	0.02	0.01%	Barley	0.01/0.01	0.05					0.01%	Rye	0.01/0.01	0.05
0.00%	Common millet/proso	0.01/0.01	0.01	0.01%	Equine: Muscle/meat	0.2/0.01	0.05					0.01%	Barley	0.01/0.01	0.05
0.00%	Rapeseeds/canola seeds	0.01/0.01	0.01	0.01%	Buckwheat and other	0.01/0.01	0.03					0.01%	Swine: Fat tissue	0.02/0.02	0.04
0.00%	Oat	0.01/0.01	0.01	0.01%	Sheep: Edible offals (other	0.05/0.05	0.03					0.01%	Buckwheat and other pseudo-	0.01/0.01	0.03
0.00%	Wine grapes	4/4	0.01	0.01%	Pistachios	0.01/0.01	0.03					0.01%	Sheep: Edible offals (other than	0.05/0.05	0.03
0.00%	Liquorice	1/1	0.01	0.01%	Eggs: Goose	0.05/0.05	0.03					0.01%	Pistachios	0.01/0.01	0.03
0.00%	Poultry: Fat tissue	0.05/0.05	0.01	0.01%	Swine: Fat tissue	0.02/0.01	0.02					0.01%	Eggs: Goose	0.05/0.05	0.03
				0.01%	Maize/corn	0.01/0.01	0.02					0.01%	Maize/corn	0.01/0.01	0.02
				0.01%	Sheep: Kidney	0.2/0.2	0.02					0.01%	Sheep: Kidney	0.2/0.2	0.02
				0.00%	Poultry: Fat tissue	0.05/0.05	0.02					0.00%	Poultry: Fat tissue	0.05/0.05	0.02
				0.00%	Sunflower seeds	0.01/0.01	0.01					0.00%	Sunflower seeds	0.01/0.01	0.01
				0.00%	Common millet/proso millet	0.01/0.01	0.01					0.00%	Common millet/proso millet	0.01/0.01	0.01
				0.00%	Poppy seeds	0.01/0.01	0.01					0.00%	Poppy seeds	0.01/0.01	0.01
				0.00%	Oat	0.01/0.01	0.01					0.00%	Oat	0.01/0.01	0.01
				0.00%	Rapeseeds/canola seeds	0.01/0.01	0.01					0.00%	Rapeseeds/canola seeds	0.01/0.01	0.01
				0.00%	Sorghum	0.01/0.01	0.00					0.00%	Sorghum	0.01/0.01	0.00
				0.00%	Beans (with pods)	1/1	0.00					0.00%	Beans (with pods)	1/1	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 12

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

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 6

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
358%	Escaroles/broad-leaved end	20/20	1325
266%	Spinaches/frozen	30/30	983
168%	Chards/beet leaves/boiled	20/20	622
151%	Broccoli/boiled	15/7.1	559
136%	Sweet potatoes/boiled	10/10	504
126%	Potatoes/fried	5/5	467
76%	Oranges/juice	10/5.3	280
56%	Peaches/canned	10/10	207
35%	Kiwi fruits/juice	15/7.3	131
34%	Head cabbages/boiled	2/2	127
34%	Apples/juice	5/2.3	125
24%	Potatoes/dried (flakes)	5/6.9	89
20%	Pears/juice	5/2.3	75
18%	Florence fennels/boiled	1.5/1.5	68
16%	Peaches/juice	10/3.65	61

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)
110%	Escaroles/broad-leaved	20/20	409
71%	Celeries/boiled	15/7.8	263
68%	Chards/beet leaves/boiled	20/20	250
67%	Spinaches/frozen	30/30	248
46%	Broccoli/boiled	15/7.1	171
42%	Sweet potatoes/boiled	10/10	154
36%	Peaches/canned	10/10	135
22%	Purslanes/boiled	20/20	82
22%	Oranges/juice	10/5.3	80
21%	Apples/juice	5/2.3	77
16%	Grapefruits/juice	10/5.3	58
10%	Wine grapes/wine	4/4	38
10%	Pineapples/canned	7/2.8	37
8%	Florence fennels/boiled	1.5/1.5	29
6%	Beetroots/boiled	1/1	22

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 4

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
266%	Spinaches/frozen	30/30	983
215%	Escaroles/broad-leaved	20/20	795
192%	Broccoli/boiled	15/15	709
143%	Oranges/juice	10/10	527
80%	Potatoes/dried (flakes)	5/23	297
75%	Sweet potatoes/boiled	10/10	279
73%	Apples/juice	5/5	271
73%	Kiwi fruits/juice	15/15	269
72%	Chards/beet leaves/boiled	20/20	267
59%	Potatoes/fried	5/5	218
47%	Wine grapes/juice	4/4	175
45%	Peaches/juice	10/10	166
44%	Pears/juice	5/5	163
27%	Pineapples/juice	7/7	101
24%	Peaches/canned	10/10	89

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
84%	Escaroles/broad-leaved endives/	20/20	311
82%	Celeries/boiled	15/15	304
81%	Broccoli/boiled	15/15	301
67%	Spinaches/frozen	30/30	248
48%	Chards/beet leaves/boiled	20/20	176
45%	Apples/juice	5/5	167
41%	Oranges/juice	10/10	151
32%	Sweet potatoes/boiled	10/10	117
29%	Grapefruits/juice	10/10	109
22%	Wine grapes/juice	4/4	83
22%	Purslanes/boiled	20/20	82
17%	Pineapples/juice	7/7	62
16%	Peaches/canned	10/10	60
15%	Pineapples/canned	7/7	55
10%	Currants (red, black and white)/	3/3	38

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 12 commodities.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Mandipropamid

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.15	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA 2018	Source of ARfD:	EFSA 2018
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)
	5%	NL toddler	7.80	3%	Spinaches	0.9%	Escaroles/broad-leaved endives	0.5%	Table grapes		5%
	4%	SE general	5.67	2%	Lettuces	0.8%	Chinese cabbages/pe-tsai	0.5%	Head cabbages		4%
	4%	GEMS/Food G10	5.58	1%	Lettuces	0.6%	Chinese cabbages/pe-tsai	0.3%	Head cabbages		4%
	4%	IT adult	5.50	1%	Lettuces	0.6%	Other lettuce and other salad plants	0.4%	Spinaches		4%
	3%	GEMS/Food G06	4.75	0.8%	Tomatoes	0.4%	Lettuces	0.4%	Table grapes		3%
	3%	ES adult	4.66	2%	Lettuces	0.3%	Chards/beet leaves	0.3%	Spinaches		3%
	3%	IE adult	4.47	0.7%	Other leafy brassica	0.5%	Spinaches	0.4%	Wine grapes		3%
	3%	IT toddler	4.33	1%	Lettuces	0.4%	Other lettuce and other salad plants	0.3%	Tomatoes		3%
	3%	GEMS/Food G08	4.32	0.7%	Lettuces	0.4%	Head cabbages	0.4%	Wine grapes		3%
	3%	DE child	4.24	0.8%	Spinaches	0.5%	Table grapes	0.3%	Lettuces		3%
	3%	GEMS/Food G07	4.03	0.9%	Lettuces	0.5%	Wine grapes	0.2%	Tomatoes		3%
	3%	ES child	3.95	2%	Lettuces	0.3%	Spinaches	0.3%	Chards/beet leaves		3%
	3%	NL child	3.94	0.9%	Spinaches	0.4%	Escaroles/broad-leaved endives	0.4%	Table grapes		3%
	3%	GEMS/Food G11	3.89	0.5%	Celeries	0.3%	Spinaches	0.3%	Wine grapes		3%
	2%	RO general	3.73	1%	Head cabbages	0.6%	Wine grapes	0.4%	Tomatoes		2%
	2%	GEMS/Food G15	3.66	0.7%	Head cabbages	0.4%	Lettuces	0.3%	Wine grapes		2%
	2%	PT general	3.54	0.8%	Wine grapes	0.7%	Kales	0.4%	Lettuces		2%
	2%	NL general	3.40	0.6%	Spinaches	0.4%	Escaroles/broad-leaved endives	0.4%	Lettuces		2%
	2%	FR adult	3.07	0.8%	Wine grapes	0.6%	Other lettuce and other salad plants	0.2%	Spinaches		2%
	2%	FR child 3–15 years	2.56	0.4%	Other lettuce and other salad plants	0.4%	Spinaches	0.2%	Tomatoes		2%
	2%	DE women 14–50 years	2.42	0.4%	Lettuces	0.3%	Wine grapes	0.2%	Spinaches		2%
	2%	DE general	2.39	0.4%	Lettuces	0.3%	Wine grapes	0.2%	Spinaches		2%
	1%	UK vegetarian	2.18	0.5%	Lettuces	0.3%	Wine grapes	0.1%	Tomatoes		1%
	1%	FR infant	2.16	1%	Spinaches	0.1%	Chards/beet leaves	0.1%	Beans (with pods)		1%
	1%	FR toddler 2–3 years	2.01	0.6%	Spinaches	0.1%	Beans (with pods)	0.1%	Tomatoes		1%
	1%	UK adult	1.92	0.4%	Lettuces	0.4%	Wine grapes	0.1%	HOPS (dried)		1%
	1%	DK adult	1.58	0.3%	Lettuces	0.3%	Wine grapes	0.1%	Tomatoes		1%
	1%	FI adult	1.56	0.5%	Lettuces	0.1%	Tomatoes	0.1%	Wine grapes		1%
	1%	FI 6 years	1.51	0.3%	Lettuces	0.2%	Spinaches	0.1%	Chinese cabbages/pe-tsai		1%
	1.0%	DK child	1.43	0.5%	Lettuces	0.1%	Tomatoes	0.1%	Table grapes		1.0%
	0.9%	FI 3 years	1.34	0.2%	Spinaches	0.1%	Lettuces	0.1%	Tomatoes		0.9%
	0.9%	PL general	1.31	0.3%	Head cabbages	0.2%	Tomatoes	0.1%	Table grapes		0.9%
	0.8%	LT adult	1.15	0.3%	Head cabbages	0.2%	Lettuces	0.1%	Tomatoes		0.8%
	0.6%	UK toddler	0.97	0.1%	Tomatoes	0.1%	Spinaches	0.1%	Table grapes		0.6%
	0.3%	UK infant	0.51	0.1%	Tomatoes	0.1%	Head cabbages	0.0%	Spinaches		0.3%
	0.1%	IE child	0.21	0.0%	Lettuces	0.0%	Head cabbages	0.0%	Table grapes		0.1%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

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)	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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	**IESTI new**	**IESTI new**

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)	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

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Fluopyram (R)

LOQs (mg/kg) range from: 0.01 to: 0.80

Toxicological reference values

ADI (mg/kg bw per day):	0.012	ARfD (mg/kg bw):	0.5
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)
99%	NL toddler	11.88	21%	Apples	8%	Pears	8%	Bananas		99%
73%	DE child	8.72	24%	Apples	7%	Table grapes	5%	Oranges		73%
66%	NL child	7.98	11%	Apples	7%	Sugar beet roots	5%	Table grapes		66%
51%	GEMS/Food G07	6.11	5%	Lettuces	5%	Poultry: Muscle/meat	5%	Swine: Muscle/meat		51%
50%	FR child 3–15 years	6.04	6%	Bovine: Muscle/meat	6%	Swine: Muscle/meat	5%	Eggs: Chicken		50%
49%	IE adult	5.90	7%	Sheep: Liver	5%	Basil and edible flowers	3%	Other other small fruit & berries		49%
47%	ES child	5.69	9%	Lettuces	6%	Bovine: Muscle/meat	5%	Poultry: Muscle/meat		47%
47%	GEMS/Food G10	5.69	7%	Lettuces	6%	Poultry: Muscle/meat	4%	Bovine: Muscle/meat		47%
47%	SE general	5.65	19%	Bovine: Muscle/meat	9%	Lettuces	3%	Eggs: Chicken		47%
46%	DK child	5.47	9%	Swine: Muscle/meat	6%	Bovine: Muscle/meat	4%	Apples		46%
44%	GEMS/Food G08	5.26	8%	Swine: Muscle/meat	4%	Lettuces	4%	Poultry: Muscle/meat		44%
42%	GEMS/Food G15	4.99	6%	Swine: Muscle/meat	4%	Poultry: Muscle/meat	3%	Swine: Liver		42%
41%	GEMS/Food G06	4.86	6%	Tomatoes	5%	Table grapes	3%	Poultry: Muscle/meat		41%
39%	FR toddler 2–3 years	4.74	6%	Apples	5%	Bovine: Muscle/meat	5%	Swine: Muscle/meat		39%
39%	GEMS/Food G11	4.63	5%	Swine: Muscle/meat	4%	Poultry: Muscle/meat	3%	Apples		39%
35%	ES adult	4.19	12%	Lettuces	3%	Bovine: Muscle/meat	3%	Swine: Muscle/meat		35%
34%	DE women 14–50 years	4.04	5%	Apples	4%	Sugar beet roots	4%	Swine: Muscle/meat		34%
33%	DE general	3.96	5%	Swine: Muscle/meat	5%	Apples	4%	Sugar beet roots		33%
33%	UK toddler	3.93	5%	Bovine: Muscle/meat	3%	Eggs: Chicken	3%	Apples		33%
32%	UK infant	3.84	5%	Bovine: Muscle/meat	5%	Eggs: Chicken	3%	Apples		32%
30%	NL general	3.59	4%	Swine: Muscle/meat	3%	Bovine: Muscle/meat	3%	Apples		30%
29%	RO general	3.47	5%	Swine: Muscle/meat	3%	Poultry: Muscle/meat	3%	Tomatoes		29%
25%	FR adult	3.04	3%	Other lettuce and other salad plants	3%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		25%
23%	IT adult	2.71	8%	Lettuces	3%	Other lettuce and other salad plants	2%	Tomatoes		23%
22%	DK adult	2.62	4%	Swine: Muscle/meat	2%	Bovine: Muscle/meat	2%	Lettuces		22%
22%	IT toddler	2.62	6%	Lettuces	2%	Other lettuce and other salad plants	2%	Tomatoes		22%
19%	LT adult	2.32	4%	Swine: Muscle/meat	4%	Apples	1%	Lettuces		19%
17%	FI 3 years	2.06	2%	Bananas	2%	Apples	1%	Strawberries		17%
17%	UK adult	2.00	3%	Bovine: Muscle/meat	3%	Lettuces	2%	Poultry: Muscle/meat		17%
17%	PT general	1.99	2%	Lettuces	2%	Apples	1%	Tomatoes		17%
16%	FR infant	1.89	3%	Apples	2%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		16%
14%	UK vegetarian	1.72	3%	Lettuces	1%	Eggs: Chicken	1%	Apples		14%
13%	FI 6 years	1.62	2%	Lettuces	1%	Bananas	1%	Apples		13%
12%	FI adult	1.48	3%	Lettuces	2%	Coffee beans	1%	Apples		12%
12%	PL general	1.39	4%	Apples	2%	Table grapes	1%	Tomatoes		12%
6%	IE child	0.78	0.7%	Swine: Fat tissue	0.7%	Swine: Muscle/meat	0.6%	Apples		6%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
64%	Lettuces	15/8.45	322
36%	Sweet peppers/bell peppers	3/3	179
29%	Peaches	1.5/1.5	143
22%	Table grapes	1.5/1.5	109
16%	Oranges	0.6/0.6	80
16%	Bananas	0.8/0.8	78
14%	Pears	0.5/0.5	69
13%	Apples	0.6/0.6	65
13%	Bovine: Liver	8/8	65
12%	Melons	0.4/0.4	61
12%	Escaroles/broad-leaved	1.5/1.5	60
12%	Bovine: Edible offals (other	8/8	58
11%	Currants (red, black and	7/7	55
11%	Blackberries	5/5	54
10%	Apricots	1.5/1.5	52
10%	Basil and edible flowers	70/70	51
10%	Watermelons	0.4/0.4	49
9%	Raspberries (red and	5/5	46
8%	Lamb's lettuce/corn salads	15/15	42
8%	Leeks	0.7/0.7	41
8%	Gooseberries (green, red	7/7	41
8%	Roman rocket/rucola	15/15	40
7%	Tomatoes	0.9/0.63	37
7%	Mandarins	0.6/0.6	36
7%	Lemons	1/1	34
7%	Cucumbers	0.5/0.5	33
7%	Strawberries	2/2	33
6%	Grapefruits	0.4/0.4	31
6%	Spring onions/green onions	2/2	31
6%	Bovine: Kidney	8/8	30
6%	Blueberries	5/5	30
5%	Poultry: Muscle/meat	1.5/1.5	25
5%	Carrots	0.4/0.4	25
5%	Eggs: Chicken	2/2	25
5%	Swine: Edible offals (other	8/8	24
5%	Courgettes	0.5/0.5	23
5%	Potatoes	0.15/0.15	23
5%	Aubergines/egg plants	0.9/0.9	23
4%	Chinese cabbages/pe-tsai	0.7/0.7	22
4%	Plums	0.5/0.5	21
4%	Limes	1/1	20
4%	Rice	1.5/1.5	19
4%	Cherries (sweet)	1.5/1.5	18
4%	Swine: Muscle/meat	1.5/1.5	18
3%	Beetroots	0.3/0.3	17
3%	Celeriacs/turnip rooted	0.3/0.3	17
3%	Swedes/rutabagas	0.3/0.3	16
3%	Wine grapes	1.5/1.5	14
3%	Cranberries	3/3	13
3%	Head cabbages	0.3/0.3	13
3%	Wheat	0.9/0.9	13
2%	Broccoli	0.3/0.3	12
2%	Quinces	0.5/0.5	12
2%	Peas (with pods)	1.5/1.5	12
2%	Witloofs/Belgian endives	0.3/0.3	12
2%	Cauliflowers	0.2/0.2	12
2%	Beans (with pods)	1/1	11
2%	Parsnips	0.3/0.3	11
2%	Bovine: Muscle/meat	1.5/1.5	11
2%	Turnips	0.3/0.3	11
2%	Pumpkins	0.4/0.4	11
2%	Other farmed animals:	1.5/1.5	10
2%	Chervil	8/8	10
2%	Swine: Kidney	8/8	10
2%	Swine: Liver	8/8	9.8
2%	Salsifies	0.3/0.3	9.3

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)
21%	Lettuces	15/8.45	103
16%	Red mustards	15/15	80
10%	Table grapes	1.5/1.5	51
10%	Sweet peppers/bell peppers	3/3	49
9%	Currants (red, black and	7/7	46
9%	Blueberries	5/5	46
8%	Blackberries	5/5	41
8%	Purslanes	20/20	38
7%	Wine grapes	1.5/1.5	36
6%	Bovine: Liver	8/8	32
6%	Gooseberries (green, red	7/7	32
6%	Escaroles/broad-leaved	1.5/1.5	30
6%	Lamb's lettuce/corn salads	15/15	28
6%	Peaches	1.5/1.5	28
5%	Raspberries (red and	5/5	27
5%	Bovine: Edible offals (other	8/8	27
5%	Aubergines/egg plants	0.9/0.9	24
5%	Poultry: Liver	5/5	24
4%	Sheep: Liver	8/8	22
4%	Swine: Edible offals (other	8/8	21
4%	Strawberries	2/2	19
4%	Oranges	0.6/0.6	18
4%	Roman rocket/rucola	15/15	18
4%	Chinese cabbages/pe-tsai	0.7/0.7	18
4%	Poultry: Muscle	1.5/1.5	18
4%	Swine: Kidney	8/8	18
3%	Bananas	0.8/0.8	17
3%	Bovine: Kidney	8/8	17
3%	Apples	0.6/0.6	17
3%	Apricots	1.5/1.5	16
3%	Watermelons	0.4/0.4	16
3%	Melons	0.4/0.4	16
3%	Rose hips	7/7	15
3%	Pears	0.5/0.5	15
3%	Cherries (sweet)	1.5/1.5	15
3%	Cucumbers	0.5/0.5	14
3%	Rice	1.5/1.5	13
3%	Head cabbages	0.3/0.3	13
2%	Courgettes	0.5/0.5	12
2%	Swine: Liver	8/8	11
2%	Mandarins	0.6/0.6	11
2%	Swedes/rutabagas	0.3/0.3	10
2%	Tomatoes	0.9/0.63	10.0
2%	Parsley	8/8	9.6
2%	Leeks	0.7/0.7	9.2
2%	HOPS (dried)	50/50	9.1
2%	Spring onions/green onions	2/2	9.0
2%	Lemons	1/1	9.0
2%	Plums	0.5/0.5	8.9
2%	Basil and edible flowers	70/70	8.6
2%	Bovine: Muscle	1.5/1.5	8.5
2%	Eggs: Chicken	2/2	8.5
2%	Other farmed animals:	1.5/1.5	8.4
2%	Carrots	0.4/0.4	7.9
2%	Beans (with pods)	1/1	7.7
2%	Quinces	0.5/0.5	7.6
2%	Wheat	0.9/0.9	7.6
1%	Swine: Muscle/meat	1.5/1.5	7.3
1%	Dewberries	5/5	7.2
1%	Equine: Muscle/meat	1.5/1.5	7.2
1%	Grapefruits	0.4/0.4	7.2
1%	Broccoli	0.3/0.3	7.2
1%	Sheep: Muscle/meat	1.5/1.5	7.1
1%	Limes	1/1	7.0
1%	Eggs: Quail	5/5	7.0
1%	Beetroots	0.3/0.3	6.9

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
69%	Lettuces	15/15	343
16%	Peaches	1.5/1.5	81
15%	Sweet peppers/bell	3/3	77
15%	Apricots	1.5/1.5	74
13%	Table grapes	1.5/1.5	66
13%	Bovine: Liver	8/8	65
12%	Bovine: Edible offals (other	8/8	58
11%	Currants (red, black and	7/7	55
11%	Blackberries	5/5	54
10%	Basil and edible flowers	70/70	51
10%	Bananas	0.8/0.8	49
9%	Raspberries (red and	5/5	46
8%	Lamb's lettuce/corn salads	15/15	42
8%	Gooseberries (green, red	7/7	41
8%	Roman rocket/rucola	15/15	40
8%	Oranges	0.6/0.6	40
7%	Apples	0.6/0.6	37
7%	Melons	0.4/0.4	36
7%	Escaroles/broad-leaved	1.5/1.5	36
7%	Strawberries	2/2	33
6%	Bovine: Kidney	8/8	30
6%	Blueberries	5/5	30
6%	Pears	0.5/0.5	30
6%	Watermelons	0.4/0.4	29
5%	Spring onions/green onions	2/2	27
5%	Tomatoes	0.9/0.9	27
5%	Poultry: Muscle/meat	1.5/1.5	25
5%	Eggs: Chicken	2/2	25
5%	Swine: Edible offals (other	8/8	24
5%	Lemons	1/1	23
4%	Mandarins	0.6/0.6	22
4%	Cucumbers	0.5/0.5	20
4%	Rice	1.5/1.5	19
4%	Grapefruits	0.4/0.4	19
4%	Cherries (sweet)	1.5/1.5	18
4%	Swine: Muscle/meat	1.5/1.5	18
4%	Leeks	0.7/0.7	18
3%	Wine grapes	1.5/1.5	14
3%	Aubergines/egg plants	0.9/0.9	14
3%	Chinese cabbages/pe-tsai	0.7/0.7	13
3%	Cranberries	3/3	13
3%	Wheat	0.9/0.9	13
3%	Plums	0.5/0.5	13
3%	Peas (with pods)	1.5/1.5	12
3%	Beans (with pods)	1/1	11
2%	Carrots	0.4/0.4	11
2%	Bovine: Muscle/meat	1.5/1.5	11
2%	Other farmed animals:	1.5/1.5	10
2%	Chervil	8/8	10
2%	Swine: Kidney	8/8	10
2%	Courgettes	0.5/0.5	10.0
2%	Celeriacs/turnip rooted	0.3/0.3	10.0
2%	Witloofs/Belgian endives	0.3/0.3	9.9
2%	Potatoes	0.15/0.15	9.9
2%	Swine: Liver	8/8	9.8
2%	Swedes/rutabagas	0.3/0.3	9.3
2%	Equine: Muscle/meat	1.5/1.5	9.0
2%	Dewberries	5/5	8.8
2%	Parsley	8/8	8.8
2%	Limes	1/1	8.6
2%	Sheep: Muscle/meat	1.5/1.5	8.2
2%	Head cabbages	0.3/0.3	8.0
1%	Broccoli	0.3/0.3	7.5
1%	Quinces	0.5/0.5	7.4
1%	Beetroots	0.3/0.3	7.3
1%	Beans	0.4/0.4	7.3

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
22%	Lettuces	15/15	109
9%	Currants (red, black and white)	7/7	46
9%	Blueberries	5/5	46
8%	Blackberries	5/5	41
8%	Purslanes	20/20	38
7%	Wine grapes	1.5/1.5	36
7%	Red mustards	15/15	34
6%	Bovine: Liver	8/8	32
6%	Gooseberries (green, red and	7/7	32
6%	Peaches	1.5/1.5	31
6%	Table grapes	1.5/1.5	31
6%	Lamb's lettuce/corn salads	15/15	28
6%	Oranges	0.6/0.6	28
5%	Raspberries (red and yellow)	5/5	27
5%	Bovine: Edible offals (other than	8/8	27
5%	Poultry: Liver	5/5	24
4%	Sheep: Liver	8/8	22
4%	Bananas	0.8/0.8	22
4%	Escaroles/broad-leaved endives	1.5/1.5	22
4%	Sweet peppers/bell peppers	3/3	21
4%	Swine: Edible offals (other than	8/8	21
4%	Mandarins	0.6/0.6	20
4%	Plums	0.5/0.5	20
4%	Apricots	1.5/1.5	19
4%	Strawberries	2/2	19
4%	Apples	0.6/0.6	18
4%	Pears	0.5/0.5	18
4%	Roman rocket/rucola	15/15	18
4%	Poultry: Muscle	1.5/1.5	18
4%	Swine: Kidney	8/8	18
3%	Aubergines/egg plants	0.9/0.9	17
3%	Tomatoes	0.9/0.9	17
3%	Bovine: Kidney	8/8	17
3%	Cherries (sweet)	1.5/1.5	15
3%	Rice	1.5/1.5	13
2%	Swine: Liver	8/8	11
2%	Chinese cabbages/pe-tsai	0.7/0.7	11
2%	Watermelons	0.4/0.4	9.7
2%	Parsley	8/8	9.6
2%	Melons	0.4/0.4	9.4
2%	HOPS (dried)	50/50	9.1
2%	Basil and edible flowers	70/70	8.6
2%	Bovine: Muscle	1.5/1.5	8.5
2%	Eggs: Chicken	2/2	8.5
2%	Other farmed animals:	1.5/1.5	8.4
2%	Grapefruits	0.4/0.4	8.4
2%	Cucumbers	0.5/0.5	8.3
2%	Beans (with pods)	1/1	7.7
2%	Head cabbages	0.3/0.3	7.6
2%	Wheat	0.9/0.9	7.6
1%	Swine: Muscle/meat	1.5/1.5	7.3
1%	Dewberries	5/5	7.2
1%	Equine: Muscle/meat	1.5/1.5	7.2
1%	Sheep: Muscle/meat	1.5/1.5	7.1
1%	Eggs: Quail	5/5	7.0
1%	Spring onions/green onions and	2/2	6.7
1%	Poultry: Kidney	5/5	6.5
1%	Swedes/rutabagas	0.3/0.3	6.1
1%	Courgettes	0.5/0.5	6.0
1%	Broccoli	0.3/0.3	5.8
1%	Sheep: Edible offals (other than	8/8	5.5
1%	Globe artichokes	0.5/0.5	5.4
1%	Peas (with pods)	1.5/1.5	5.1
0.9%	Carrots	0.4/0.4	4.7
0.9%	Potatoes	0.15/0.15	4.7

2%	Equine: Muscle/meat	1.5/1.5	9.0	1%	Globe artichokes	0.5/0.5	6.5	1%	Cauliflowers	0.2/0.2	7.0	0.9%	Quinces	0.5/0.5	4.6
2%	Globe artichokes	0.5/0.5	8.8	1%	Poultry: Kidney	5/5	6.5	1%	Chives	8/8	6.6	0.9%	Rye	0.9/0.9	4.4
2%	Dewberries	5/5	8.8	1%	Pumpkins	0.4/0.4	5.9	1%	Pumpkins	0.4/0.4	6.4	0.8%	Leeks	0.7/0.7	4.1
2%	Parsley	8/8	8.8	1%	Witloofs/Belgian endives	0.3/0.3	5.5	1%	Globe artichokes	0.5/0.5	6.3	0.8%	Gherkins	0.5/0.5	4.0
2%	Sheep: Muscle/meat	1.5/1.5	8.2	1%	Sheep: Edible offals (other	8/8	5.5	1%	Sage	8/8	6.1	0.8%	Lemons	1/1	3.8
1%	Radishes	0.3/0.3	7.4	1%	Peas (with pods)	1.5/1.5	5.1	1%	Rye	0.9/0.9	5.7	0.8%	Witloofs/Belgian endives	0.3/0.3	3.8
1%	Beans	0.4/0.4	7.3	0.9%	Cauliflowers	0.2/0.2	4.6	1%	Poultry: Liver	5/5	5.5	0.7%	Pumpkins	0.4/0.4	3.5
1%	Medlar	0.5/0.5	6.9	0.9%	Potatoes	0.15/0.15	4.5	1%	Medlar	0.5/0.5	5.1	0.7%	Cranberries	3/3	3.4
1%	Chives	8/8	6.6	0.9%	Rye	0.9/0.9	4.4	1%	Salsifies	0.3/0.3	5.1	0.6%	Jerusalem artichokes	0.3/0.3	3.2
1%	Sage	8/8	6.1	0.8%	Parsnips	0.3/0.3	4.2	1.0%	Sorghum	1.5/1.5	4.8	0.6%	Beetroots	0.3/0.3	3.1
1%	Rye	0.9/0.9	5.7	0.8%	Chards/beet leaves	0.2/0.2	3.8	0.9%	Parsnips	0.3/0.3	4.6	0.6%	Swine: Fat tissue	1.5/1.5	3.0
1%	Poultry: Liver	5/5	5.5	0.7%	Celeriacs/turnip rooted	0.3/0.3	3.6	0.9%	Turnips	0.3/0.3	4.6	0.6%	Limes	1/1	3.0
1%	Kohlrabies	0.1/0.1	5.2	0.7%	Medlar	0.5/0.5	3.4	0.9%	Spinaches	0.2/0.2	4.5	0.6%	Cauliflowers	0.2/0.2	2.8
1.0%	Sorghum	1.5/1.5	4.8	0.7%	Cranberries	3/3	3.4	0.8%	Celery leaves	8/8	3.8	0.5%	Yams	0.1/0.1	2.7
0.9%	Spinaches	0.2/0.2	4.5	0.7%	Turnips	0.3/0.3	3.3	0.6%	Radishes	0.3/0.3	3.2	0.5%	Beans	0.4/0.4	2.6
0.9%	Kales	0.1/0.1	4.4	0.6%	Salsifies	0.3/0.3	3.2	0.6%	Bovine: Fat tissue	1.5/1.5	3.1	0.5%	Celery leaves	8/8	2.6
0.8%	Celery leaves	8/8	3.8	0.6%	Radishes	0.3/0.3	3.1	0.6%	Kohlrabies	0.1/0.1	3.1	0.5%	Parsnips	0.3/0.3	2.5
0.6%	Chards/beet leaves	0.2/0.2	3.1	0.6%	Parsley roots/Hamburg	0.3/0.3	3.1	0.5%	Lentils	0.4/0.4	2.7	0.5%	Lentils	0.4/0.4	2.5
0.6%	Bovine: Fat tissue	1.5/1.5	3.1	0.6%	Swine: Fat tissue	1.5/1.5	3.0	0.5%	Kales	0.1/0.1	2.6	0.5%	Medlar	0.5/0.5	2.4
0.6%	Yams	0.1/0.1	3.1	0.6%	Gherkins	0.5/0.5	3.0	0.5%	Peas	0.4/0.4	2.6	0.5%	Goat: Muscle	1.5/1.5	2.3
0.5%	Lentils	0.4/0.4	2.7	0.6%	Yams	0.1/0.1	2.8	0.5%	Swine: Fat tissue	1.5/1.5	2.6	0.4%	Celeriacs/turnip rooted celeries	0.3/0.3	2.1
0.5%	Peas	0.4/0.4	2.6	0.6%	Jerusalem artichokes	0.3/0.3	2.8	0.5%	Brussels sprouts	0.3/0.3	2.5	0.4%	Eggs: Goose	4/4	2.0
0.5%	Swine: Fat tissue	1.5/1.5	2.6	0.5%	Beans	0.4/0.4	2.6	0.4%	Sunflower seeds	0.7/0.7	2.2	0.4%	Brussels sprouts	0.3/0.3	1.8
0.5%	Brussels sprouts	0.3/0.3	2.5	0.5%	Celery leaves	8/8	2.6	0.4%	HOPS (dried)	50/50	2.1	0.4%	Chards/beet leaves	0.2/0.2	1.8
0.5%	Onions	0.1/0.1	2.3	0.5%	Lentils	0.4/0.4	2.5	0.4%	Yams	0.1/0.1	1.9	0.3%	Soyabeans	0.3/0.3	1.7
0.4%	Sunflower seeds	0.7/0.7	2.2	0.5%	Goat: Muscle	1.5/1.5	2.3	0.3%	Peas (without pods)	0.2/0.2	1.6	0.3%	Turnips	0.3/0.3	1.6
0.4%	HOPS (dried)	50/50	2.1	0.4%	Horseradishes	0.3/0.3	2.2	0.3%	Beans (without pods)	0.2/0.2	1.6	0.3%	Sage	8/8	1.6
0.3%	Peas (without pods)	0.2/0.2	1.6	0.4%	Sweet potatoes	0.1/0.1	2.1	0.3%	Gherkins	0.5/0.5	1.4	0.3%	Valerian root	2.5/2.5	1.5
0.3%	Beans (without pods)	0.2/0.2	1.6	0.4%	Eggs: Goose	4/4	2.0	0.3%	Rapeseeds/canola seeds	1/1	1.4	0.3%	Valerian root	2.5/2.5	1.5
0.3%	Gherkins	0.5/0.5	1.4	0.4%	Kales	0.1/0.1	1.9	0.3%	Chards/beet leaves	0.2/0.2	1.3	0.3%	Salsifies	0.3/0.3	1.5
0.3%	Rapeseeds/canola seeds	1/1	1.4	0.4%	Brussels sprouts	0.3/0.3	1.8	0.2%	Lentils (fresh)	0.2/0.2	1.2	0.3%	Bovine: Fat tissue	1.5/1.5	1.5
0.3%	Parsley roots/Hamburg	0.3/0.3	1.3	0.3%	Soyabeans	0.3/0.3	1.7	0.2%	Barley	0.2/0.2	1.1	0.3%	Chives	8/8	1.4
0.2%	Lentils (fresh)	0.2/0.2	1.2	0.3%	Sage	8/8	1.6	0.2%	Buckwheat and other	0.2/0.2	1.00	0.3%	Radishes	0.3/0.3	1.3
0.2%	Barley	0.2/0.2	1.1	0.3%	Valerian root	2.5/2.5	1.5	0.2%	Onions	0.1/0.1	0.97	0.3%	Peas	0.4/0.4	1.3
0.2%	Pineapples	0.01/0.01	1.0	0.3%	Valerian root	2.5/2.5	1.5	0.2%	Safflower seeds	0.3/0.3	0.92	0.3%	Parsley roots/Hamburg roots	0.3/0.3	1.3
0.2%	Buckwheat and other	0.2/0.2	1.00	0.3%	Onions	0.1/0.1	1.5	0.1%	Soyabeans	0.3/0.3	0.69	0.2%	Kales	0.1/0.1	1.2
0.2%	Safflower seeds	0.3/0.3	0.92	0.3%	Bovine: Fat tissue	1.5/1.5	1.5	0.1%	Pineapples	0.01/0.01	0.61	0.2%	Peas (without pods)	0.2/0.2	1.1
0.2%	Cassava roots/manioc	0.1/0.1	0.80	0.3%	Kohlrabies	0.1/0.1	1.4	0.1%	Peanuts/groundnuts	0.2/0.2	0.58	0.2%	Sweet potatoes	0.1/0.1	1.1
0.2%	Mangoes	0.01/0.01	0.79	0.3%	Chives	8/8	1.4	0.1%	Parsley roots/Hamburg	0.3/0.3	0.58	0.2%	Barley	0.2/0.2	0.97
0.1%	Soyabeans	0.3/0.3	0.69	0.3%	Peas	0.4/0.4	1.3	0.10%	Valerian root	2.5/2.5	0.50	0.2%	Horseradishes	0.3/0.3	0.94
0.1%	Kiwi fruits (green, red,	0.01/0.01	0.62	0.2%	Peas (without pods)	0.2/0.2	1.1	0.10%	Valerian root	2.5/2.5	0.50	0.2%	Kohlrabies	0.1/0.1	0.85
0.1%	Peanuts/groundnuts	0.2/0.2	0.58	0.2%	Barley	0.2/0.2	0.97	0.10%	Thyme	8/8	0.48	0.2%	Spinaches	0.2/0.2	0.80
0.1%	Coconuts	0.04/0.04	0.58	0.2%	Spinaches	0.2/0.2	0.80	0.10%	Cassava roots/manioc	0.1/0.1	0.48	0.2%	Rosemary	8/8	0.80
0.1%	Granate	0.01/0.01	0.55	0.2%	Rosemary	8/8	0.80	0.09%	Mangoes	0.01/0.01	0.47	0.2%	Rosemary	8/8	0.80
0.1%	Sweet potatoes	0.1/0.1	0.53	0.2%	Rosemary	8/8	0.80	0.09%	Sesame seeds	0.3/0.3	0.44	0.2%	Rosemary	8/8	0.80
0.1%	Avocados	0.01/0.01	0.50	0.2%	Rosemary	8/8	0.80	0.09%	Pumpkin seeds	0.3/0.3	0.44	0.2%	Rosemary	8/8	0.80
0.10%	Valerian root	2.5/2.5	0.50	0.2%	Rosemary	8/8	0.80	0.08%	Kiwi fruits (green, red,	0.01/0.01	0.40	0.2%	Rosemary	8/8	0.80
0.10%	Valerian root	2.5/2.5	0.50	0.2%	Rosemary	8/8	0.80	0.08%	Carobs/Staint John's bread	0.05/0.05	0.39	0.2%	Beans (without pods)	0.2/0.2	0.79
0.10%	Thyme	8/8	0.48	0.2%	Beans (without pods)	0.2/0.2	0.79	0.07%	Garlic	0.1/0.1	0.35	0.1%	Sunflower seeds	0.7/0.7	0.70
0.09%	Kaki/Japanese	0.01/0.01	0.47	0.1%	Sunflower seeds	0.7/0.7	0.70	0.07%	Coconuts	0.04/0.04	0.35	0.1%	Buckwheat and other pseudo-	0.2/0.2	0.69
0.09%	Sesame seeds	0.3/0.3	0.44	0.1%	Buckwheat and other	0.2/0.2	0.69	0.06%	Linseeds	0.3/0.3	0.32	0.1%	Lentils (fresh)	0.2/0.2	0.66
0.09%	Pumpkin seeds	0.3/0.3	0.44	0.1%	Lentils (fresh)	0.2/0.2	0.66	0.06%	Mustard seeds	0.3/0.3	0.31	0.1%	Chervil	8/8	0.64
0.09%	Sweet corn	0.01/0.01	0.43	0.1%	Chervil	8/8	0.64	0.06%	Pistachios	0.05/0.05	0.29	0.1%	Onions	0.1/0.1	0.64
0.08%	Papayas	0.01/0.01	0.42	0.1%	Rapeseeds/canola seeds	1/1	0.53	0.05%	Cultivated fungi	0.01/0.01	0.25	0.1%	Rapeseeds/canola seeds	1/1	0.53
0.08%	Carobs/Staint John's bread	0.05/0.05	0.39	0.10%	Pumpkin seeds	0.3/0.3	0.48	0.05%	Rosemary	8/8	0.24	0.10%	Pumpkin seeds	0.3/0.3	0.48
0.08%	Carambolas	0.01/0.01	0.39	0.09%	Peanuts/groundnuts	0.2/0.2	0.46	0.05%	Granate	0.01/0.01	0.24	0.09%	Peanuts/groundnuts	0.2/0.2	0.46
0.07%	Celeries	0.01/0.01	0.37	0.09%	Sorghum	1.5/1.5	0.45	0.05%	Sweet potatoes	0.1/0.1	0.23	0.09%	Sorghum	1.5/1.5	0.45
0.07%	Rhubarbs	0.01/0.01	0.37	0.07%	Coconuts	0.04/0.04	0.34	0.04%	Celeries	0.01/0.01	0.22	0.06%	Poultry: Fat tissue	1/1	0.30
0.07%	Garlic	0.1/0.1	0.35	0.06%	Cassava roots/manioc	0.1/0.1	0.30	0.04%	Oat	0.2/0.2	0.22	0.05%	Kaki/Japanese persimmons	0.01/0.01	0.27
0.06%	Linseeds	0.3/0.3	0.32	0.06%	Poultry: Fat tissue	1/1	0.30	0.04%	Avocados	0.01/0.01	0.22	0.05%	Mangoes	0.01/0.01	0.23
0.06%	Mustard seeds	0.3/0.3	0.31	0.06%	Pineapples	0.01/0.01	0.30	0.04%	Chestnuts	0.05/0.05	0.21	0.05%	Chestnuts	0.05/0.05	0.23
0.06%	Pistachios	0.05/0.05	0.29	0.05%	Shallots	0.1/0.1	0.27	0.04%	Kaki/Japanese	0.01/0.01	0.20	0.04%	Poppy seeds	0.3/0.3	0.21
0.05%	Rosemary	8/8	0.24	0.05%	Mangoes	0.01/0.01	0.26	0.04%	Asparagus	0.01/0.01	0.20	0.04%	Poppy seeds	0.3/0.3	0.21
0.04%	Prickly pears/cactus fruits	0.01/0.01	0.22	0.05%	Chestnuts	0.05/0.05	0.23	0.04%	Sweet corn	0.01/0.01	0.19	0.04%	Sesame seeds	0.3/0.3	0.21
0.04%	Oat	0.2/0.2	0.22	0.04%	Kaki/Japanese persimmons	0.01/0.01	0.22	0.04%	Papayas	0.01/0.01	0.18	0.04%	Coconuts	0.04/0.04	0.21
0.04%	Guavas	0.01/0.01	0.22	0.04%	Poppy seeds	0.3/0.3	0.21	0.04%	Honey and other apiculture	0.05/0.05	0.18	0.04%	Figs	0.01/0.01	0.20
0.04%	Chestnuts	0.05/0.05	0.21	0.04%	Poppy seeds	0.3/0.3	0.21	0.03%	Rhubarbs	0.01/0.01	0.17	0.04%	Kiwi fruits (green, red, yellow)	0.01/0.01	0.19
0.04%	Asparagus	0.01/0.01	0.19	0.04%	Sesame seeds	0.3/0.3	0.21	0.03%	Walnuts	0.05/0.05	0.17	0.04%	Cassava roots/manioc	0.1/0.1	0.18
0.04%	Honey and other apiculture	0.05/0.05	0.18	0.04%	Florence fennels	0.01/0.01	0.19	0.03%	Carambolas	0.01/0.01	0.17	0.04%	Pineapples	0.01/0.01	0.18
0.03%	Cultivated fungi	0.01/0.01	0.17	0.04%	Guavas	0.01/0.01	0.18	0.03%	Hazelnuts/cobnuts	0.05/0.05	0.16	0.04%	Asparagus	0.01/0.01	0.18
0.03%	Walnuts	0.05/0.05	0.17	0.04%	Granate	0.01/0.01	0.18	0.03%	Cocoa beans	0.05/0.05	0.16	0.03%	Borage seeds	0.3/0.3	0.15
0.03%	Hazelnuts/cobnuts	0.05/0.05	0.16	0.03%	Carambolas	0.01/0.01	0.16	0.03%	Almonds	0.05/0.05	0.14	0.03%	Linseeds	0.3/0.3	0.14
0.03%	Florence fennels	0.01/0.01	0.16	0.03%	Celeries	0.01/0.01	0.16	0.03%	Pecans	0.05/0.05	0.14	0.03%	Pistachios	0.05/0.05	0.13
0.03%	Cocoa beans	0.05/0.05	0.16	0.03%	Sweet corn	0.01/0.01	0.16	0.03%	Maize/corn	0.02/0.02	0.13	0.03%	Oat	0.2/0.2	0.13
0.03%	Cherimoyas	0.01/0.01	0.15	0.03%	Avocados	0.01/0.01	0.15	0.03%	Cashew nuts	0.05/0.05	0.13	0.03%	Sweet corn	0.01/0.01	0.13
0.03%	Almonds	0.05/0.05	0.14	0.03%	Borage seeds	0.3/0.3	0.15	0.02%	Litchis/lychees	0.01/0.01	0.12	0.02%	Safflower seeds	0.3/0.3	0.12
0.03%	Pecans	0.05/0.05	0.14	0.03%	Linseeds	0.3/0.3	0.14	0.02%	Poultry: Fat tissue	1/1	0.10	0.02%	Avocados	0.01/0.01	0.12
0.03%	Maize/corn	0.02/0.02	0.13	0.03%	Papayas	0.01/0.01	0.14	0.02%	Figs	0.01/0.01	0.10	0.02%	Watercress	0.1/0.1	0.12
0.03%	Cashew nuts	0.05/0.05	0.13	0.03%	Kiwi fruits (green, red,	0.01/0.01	0.14	0.02%	Prickly pears/cactus fruits	0.01/0.01	0.10	0.02%	Shallots	0.1/0.1	0.11
0.02%	Horseradishes	0.3/0.3	0.12	0.03%	Pistachios	0.05/0.05	0.13	0.02%	Guavas	0.01/0.01	0.09	0.02%	Pecans	0.05/0.05	0.11
0.02%	Litchis/lychees	0.01/0.01	0.12	0.03%	Oat	0.2/0.2	0.13	0.02%	Passionfruits/maracujas	0.01/0.01	0.09	0.02%	Walnuts	0.05/0.05	0.11
0.02%	Figs	0.01/0.01	0.12	0.02%	Safflower seeds	0.3/0.3	0.12	0.02%	Cherimoyas	0.01/0.01	0.09	0.02%	Macadamia	0.05/0.05	0.11
0.02%	Poultry: Fat tissue	1/1	0.10	0.02%	Watercress	0.1/0.1	0.12	0.02%	Laurel/bay leaves	8/8	0.08	0.02%	Granate apples/pomegranates	0.01/0.01	0.10
0.02%	Laurel/bay leaves	8/8	0.08	0.02%	Pecans	0.05/0.05	0.11	0.02%	Tea (dried leaves of	0.05/0.05	0.08	0.02%	Celeries	0.01/0.01	0.10
0.02%	Tea (dried leaves of	0.05/0.05	0.08	0.02%	Figs	0.01/0.01	0.11	0.01%	Florence fennels	0.01/0.01	0.07	0.02%	Cashew nuts	0.05/0.05	0.09
0.01%	Passionfruits/maracujas	0.01/0.01	0.07	0.02%	Walnuts	0.05/0.05	0.11	0.01%	Horseradishes	0.3/0.3	0.05	0.02%	Cocoa beans	0.05/0.05	0.08
0.01%	Ginger	0.3/0.72	0.06	0.02%	Cherimoyas	0.01/0.01	0.11	0.01%	Watercress	0.1/0.1	0.05	0.02%	Cultivated fungi	0.01/0.01	0.08
0.01%	Watercress	0.1/0.1	0.05	0.02%	Macadamia	0.05/0.05	0.11	0.01%	Brazil nuts	0.05/0.05	0.04	0.02%	Florence fennels	0.01/0.01	0.08
0.01%	Brazil nuts	0.05/0.05	0.04	0.02%	Cardoons	0.01/0.01	0.10	0.01%	Fennel seed	0.05/0.05	0.04	0.02%	Guavas	0.01/0.01	0.08
0.01%	Fennel seed	0.05/0.05	0.04	0.02%	Prickly pears/cactus fruits	0.01/0.01	0.09	0.01%	Coffee beans	0.05/0.05	0.04	0.02%	Papayas	0.01/0.01	0.08
0.01%	Coffee beans	0.05/0.05	0.04	0.02%	Rhubarbs	0.01/0.01	0.09	0.01%	Table olives	0.01/0.01	0.03	0.01%	Rhubarbs	0.01/0.01	0.07
0.01%	Table olives	0.01/0.01	0.03	0.02%	Cashew nuts	0.05/0.05	0.09	0.01%	Oil palm kernels	0.02/0.02	0.03	0.01%	Almonds	0.05/0.05	0.07
0.01%	Oil palm kernels	0.02/0.02	0.03	0.02%	Cocoa beans	0.05/0.05	0.08	0.01%	Dates	0.01/0.01	0.03	0.01%	Carambolas	0.01/0.01	0.07

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
20%	Escaroles/broad-leaved end	1.5/1.5	99	16%	Purslanes/boiled	20/20	82	12%	Escaroles/broad-leaved	1.5/1.5	60	16%	Purslanes/boiled	20/20	82
8%	Leeks/boiled	0.7/0.7	40	6%	Escaroles/broad-leaved	1.5/1.5	31	7%	Currants (red, black and	7/1.15	33	5%	Escaroles/broad-leaved endives/	1.5/1.5	23
8%	Peaches/canned	1/1.5	39	4%	Pumpkins/boiled	0.4/0.4	22	6%	Peaches/canned	1/1.5	29	3%	Pumpkins/boiled	0.4/0.4	16
7%	Pumpkins/boiled	0.4/0.4	35	3%	Currants (red, black and	7/1.15	15	5%	Leeks/boiled	0.7/0.7	23	3%	Currants (red, black and white)/	7/1.15	15
7%	Currants (red, black and wh	7/1.15	33	3%	Wine grapes/wine	1.5/1.5	14	4%	Pumpkins/boiled	0.4/0.4	21	3%	Wine grapes/wine	1.5/1.5	14
5%	Witloofs/boiled	0.3/0.3	26	2%	Leeks/boiled	0.7/0.7	12	4%	Elderberries/juice	7/1.15	18	2%	Peaches/canned	1.5/1.5	12
5%	Broccoli/boiled	0.3/0.3	24	2%	Peaches/canned	1.5/1.5	12	3%	Broccoli/boiled	0.3/0.3	14	2%	Elderberries/juice	7/1.15	11
4%	Elderberries/juice	7/1.15	18	2%	Courgettes/boiled	0.5/0.5	11	3%	Witloofs/boiled	0.3/0.3	14	2%	Leeks/boiled	0.7/0.7	9.5
4%	Courgettes/boiled	0.5/0.5	18	2%	Elderberries/juice	7/1.15	11	3%	Beans (with pods)/boiled	1/1	13	2%	Table grapes/raisins	1.5/7.05	8.6
3%	Turnips/boiled	0.3/0.3	15	2%	Table grapes/raisins	1.5/7.05	8.6	3%	Apples/juice	0.6/0.23	13	2%	Courgettes/boiled	0.5/0.5	8.0
3%	Parsnips/boiled	0.3/0.3	15	2%	Cauliflowers/boiled	0.2/0.2	8.3	2%	Sugar beets (root)/sugar	0.1/1.2	11	2%	Apples/juice	0.6/0.23	7.7
3%	Potatoes/fried	0.15/0.15	14	2%	Apples/juice	0.6/0.23	7.7	2%	Courgettes/boiled	0.5/0.5	11	1%	Witloofs/boiled	0.3/0.3	6.5
3%	Cauliflowers/boiled	0.2/0.2	14	1%	Broccoli/boiled	0.3/0.3	7.2	2%	Raspberries/juice	5/0.83	9.7	1%	Broccoli/boiled	0.3/0.3	6.0
3%	Beetroots/boiled	0.3/0.3	13	1%	Beetroots/boiled	0.3/0.3	6.6	2%	Cauliflowers/boiled	0.2/0.2	8.4	1%	Peas (with pods)/boiled	1.5/1.5	5.1
3%	Beans (with pods)/boiled	1/1	13	1%	Parsnips/boiled	0.3/0.3	6.4	2%	Oranges/juice	0.6/0.15	7.9	1%	Beetroots/boiled	0.3/0.3	5.0
Expand/collapse list															

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Fluopyram (R) 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; 2018/11/18

Sulfoxaflor

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):	0.25
Source of ADI:	Reg. (EU)	Source of ARfD:	Reg. (EU) 2015/1295
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:

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)
34%	NL toddler	13.76	21%	Milk: Cattle	3%	Apples	2%	Spinaches	0.6%	
18%	DE child	7.30	7%	Milk: Cattle	3%	Apples	3%	Oranges	0.2%	
18%	UK infant	7.12	14%	Milk: Cattle	1.0%	Oranges	0.6%	Rice	0.1%	
16%	NL child	6.60	9%	Milk: Cattle	2%	Apples	1%	Oranges	0.4%	
16%	FR toddler 2–3 years	6.53	10%	Milk: Cattle	1%	Oranges	0.9%	Apples	0.2%	
15%	FR child 3–15 years	6.12	8%	Milk: Cattle	3%	Oranges	0.6%	Bovine: Muscle/meat	0.3%	
12%	UK toddler	4.87	7%	Milk: Cattle	1%	Oranges	0.6%	Rice	0.1%	
11%	ES child	4.28	4%	Milk: Cattle	2%	Oranges	0.6%	Lettuces	0.2%	
10%	SE general	4.16	4%	Milk: Cattle	2%	Bovine: Muscle/meat	0.6%	Lettuces	0.1%	
9%	DK child	3.66	4%	Milk: Cattle	0.9%	Swine: Muscle/meat	0.7%	Apples	0.0%	
9%	DE women 14–50 years	3.65	4%	Milk: Cattle	1%	Oranges	0.7%	Apples	0.2%	
9%	DE general	3.52	4%	Milk: Cattle	1%	Oranges	0.7%	Apples	0.2%	
9%	GEMS/Food G10	3.44	2%	Milk: Cattle	1%	Rice	0.9%	Oranges	0.2%	
9%	FR infant	3.42	6%	Milk: Cattle	0.9%	Spinaches	0.5%	Apples	0.1%	
8%	GEMS/Food G07	3.33	2%	Milk: Cattle	1%	Oranges	0.5%	Wine grapes	0.2%	
8%	RO general	3.32	4%	Milk: Cattle	0.6%	Wine grapes	0.5%	Swine: Muscle/meat	0.1%	
8%	GEMS/Food G11	3.14	3%	Milk: Cattle	0.6%	Oranges	0.5%	Swine: Muscle/meat	0.2%	
8%	GEMS/Food G15	3.04	2%	Milk: Cattle	0.6%	Swine: Muscle/meat	0.5%	Oranges	0.2%	
7%	GEMS/Food G06	2.93	2%	Rice	0.9%	Milk: Cattle	0.8%	Oranges	0.2%	
7%	NL general	2.89	3%	Milk: Cattle	0.8%	Oranges	0.5%	Spinaches	0.2%	
7%	GEMS/Food G08	2.85	2%	Milk: Cattle	0.8%	Swine: Muscle/meat	0.4%	Wine grapes	0.2%	
7%	IE adult	2.67	2%	Milk: Cattle	0.8%	Oranges	0.4%	Wine grapes	0.2%	
6%	ES adult	2.51	2%	Milk: Cattle	1.0%	Oranges	0.8%	Lettuces	0.1%	
5%	FR adult	2.00	2%	Milk: Cattle	0.8%	Wine grapes	0.4%	Oranges	0.1%	
4%	DK adult	1.72	2%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.3%	Wine grapes	0.0%	
4%	PT general	1.59	0.9%	Wine grapes	0.8%	Rice	0.5%	Oranges	0.1%	
4%	UK vegetarian	1.49	1%	Milk: Cattle	0.7%	Oranges	0.4%	Rice	0.0%	
4%	LT adult	1.44	1%	Milk: Cattle	0.5%	Apples	0.4%	Swine: Muscle/meat	0.0%	
4%	UK adult	1.42	1%	Milk: Cattle	0.4%	Oranges	0.4%	Wine grapes	0.0%	
3%	IT toddler	1.16	0.4%	Lettuces	0.4%	Wheat	0.4%	Oranges	0.1%	
3%	FI 3 years	1.08	0.5%	Rice	0.3%	Mandarins	0.3%	Apples	0.1%	
3%	IT adult	1.08	0.6%	Lettuces	0.3%	Spinaches	0.3%	Oranges	0.0%	
2%	FI 6 years	0.91	0.4%	Rice	0.2%	Mandarins	0.2%	Spinaches	0.1%	
2%	FI adult	0.91	0.7%	Coffee beans	0.3%	Oranges	0.2%	Lettuces	0.7%	
2%	IE child	0.85	1%	Milk: Cattle	0.3%	Rice	0.1%	Apples	0.0%	
2%	PL general	0.61	0.6%	Apples	0.2%	Potatoes	0.1%	Tomatoes	0.0%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
61%	Lettuces	4/4	152
58%	Table grapes	2/2	146
54%	Spinaches	6/6	136
50%	Broccoli	3/3	125
42%	Oranges	0.8/0.8	106
30%	Melons	0.5/0.5	76
26%	Chinese cabbages/pe-tsai	2/2	64
24%	Watermelons	0.5/0.5	61
22%	Celeries	1.5/1.5	56
22%	Pears	0.4/0.4	55
19%	Peaches	0.5/0.5	48
19%	Mandarins	0.8/0.8	47
17%	Apples	0.4/0.4	43
13%	Cucumbers	0.5/0.5	33
10%	Sweet peppers/bell peppers	0.4/0.4	24

Expand/collapse list

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

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)
29%	Broccoli	3/3	72
27%	Table grapes	2/2	68
20%	Chinese cabbages/pe-tsai	2/2	51
19%	Lettuces	4/4	49
19%	Wine grapes	2/2	47
10%	Oranges	0.8/0.8	25
10%	Spinaches	6/6	24
10%	Celeries	1.5/1.5	24
8%	Watermelons	0.5/0.5	20
8%	Melons	0.5/0.5	20
7%	Head cabbages	0.4/0.4	17
6%	Cherries (sweet)	1.5/1.5	15
6%	Mandarins	0.8/0.8	14
6%	Cucumbers	0.5/0.5	14
5%	Pears	0.4/0.4	12

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
54%	Spinaches	6/6	136
37%	Lettuces	4/4	91
35%	Table grapes	2/2	88
30%	Broccoli	3/3	75
21%	Oranges	0.8/0.8	53
18%	Melons	0.5/0.5	46
15%	Chinese cabbages/pe-tsai	2/2	39
15%	Watermelons	0.5/0.5	37
13%	Celeries	1.5/1.5	34
12%	Mandarins	0.8/0.8	30
11%	Peaches	0.5/0.5	27
10%	Milk: Cattle	0.2/0.2	25
10%	Apples	0.4/0.4	25
10%	Apricots	0.5/0.5	25
9%	Pears	0.4/0.4	24

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
23%	Broccoli	3/3	58
19%	Wine grapes	2/2	47
16%	Table grapes	2/2	41
15%	Oranges	0.8/0.8	37
12%	Chinese cabbages/pe-tsai	2/2	30
12%	Lettuces	4/4	29
11%	Mandarins	0.8/0.8	26
10%	Spinaches	6/6	24
8%	Plums	0.5/0.5	20
6%	Cherries (sweet)	1.5/1.5	15
6%	Celeries	1.5/1.5	14
6%	Pears	0.4/0.4	14
5%	Rice	1.5/1.5	13
5%	Watermelons	0.5/0.5	12
5%	Apples	0.4/0.4	12

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)
95%	Broccoli/boiled	3/3	236
33%	Spinaches/frozen; boiled	6/6	83
18%	Pumpkins/boiled	0.5/0.5	44
7%	Courgettes/boiled	0.5/0.5	18
6%	Oranges/juice	0.8/0.3	16
5%	Peaches/canned	1/0.5	13
5%	Gherkins/pickled	0.5/0.5	11
2%	Wine grapes/juice	2/0.14	6.1
2%	Apples/juice	0.4/0.11	6.1
1%	Pears/juice	0.4/0.11	3.6
1%	Potatoes/fried	0.03/0.03	2.8
1%	Cauliflowers/boiled	0.04/0.04	2.8
1.0%	Peaches/juice	0.5/0.15	2.5
1.0%	Rice/milling (polishing)	1.5/0.16	2.4
0.6%	Turnips/boiled	0.03/0.03	1.5

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)
29%	Broccoli/boiled	3/3	72
20%	Celeries/boiled	1.5/1.5	51
20%	Spinaches/frozen; boiled	6/6	50
11%	Pumpkins/boiled	0.5/0.5	28
8%	Wine grapes/wine	2/2	19
5%	Table grapes/raisins	2/9.4	12
5%	Courgettes/boiled	0.5/0.5	11
2%	Oranges/juice	0.8/0.3	4.6
2%	Peaches/canned	0.5/0.5	4.0
1%	Apples/juice	0.4/0.11	3.7
1%	Wine grapes/juice	2/0.14	2.9
0.7%	Cauliflowers/boiled	0.04/0.04	1.7
0.7%	Grape leaves/canned	2/2	1.7
0.6%	Rice/milling (polishing)	1.5/0.16	1.5
0.4%	Head cabbages/canned	0.4/0.1	0.93

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
57%	Broccoli/boiled	3/3	142
33%	Spinaches/frozen; boiled	6/6	83
11%	Pumpkins/boiled	0.5/0.5	27
6%	Oranges/juice	0.8/0.3	16
4%	Courgettes/boiled	0.5/0.5	11
4%	Peaches/canned	1/0.5	9.7
2%	Wine grapes/juice	2/0.14	6.1
2%	Apples/juice	0.4/0.11	6.1
2%	Gherkins/pickled	0.5/0.5	4.9
1%	Pears/juice	0.4/0.11	3.6
1.0%	Peaches/juice	0.5/0.15	2.5
1.0%	Rice/milling (polishing)	1.5/0.16	2.4
0.7%	Cauliflowers/boiled	0.04/0.04	1.7
0.5%	Potatoes/fried	0.03/0.03	1.3
0.5%	Tomatoes/juice	0.3/0.06	1.2

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Broccoli/boiled	3/3	60
20%	Spinaches/frozen; boiled	6/6	50
12%	Celeries/boiled	1.5/1.5	30
8%	Pumpkins/boiled	0.5/0.5	20
8%	Wine grapes/wine	2/2	19
5%	Table grapes/raisins	2/9.4	12
3%	Courgettes/boiled	0.5/0.5	8.0
2%	Oranges/juice	0.8/0.3	4.6
2%	Peaches/canned	0.5/0.5	4.1
1%	Apples/juice	0.4/0.11	3.7
1%	Wine grapes/juice	2/0.14	2.9
0.7%	Grape leaves/canned	2/2	1.7
0.6%	Rice/milling (polishing)	1.5/0.16	1.5
0.4%	Cauliflowers/boiled	0.04/0.04	1.00
0.4%	Head cabbages/canned	0.4/0.1	0.93

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Sulfoxaflor 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; 2018/11/18

Chlorfenapyr (F)

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):	0.015
Source of ADI:	ECCO	Source of ARfD:	ECCO
Year of evaluation:	1999	Year of evaluation:	1999

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 : ---

	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)	28%	NL toddler	4.16	17%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat	5%	
	20%	UK infant	3.06	11%	Milk: Cattle	5%	Tea (dried leaves of Camellia sinensis)	2%	Bovine: Muscle/meat	1%	
	19%	IE adult	2.80	11%	Tea (dried leaves of Camellia sinensis)	2%	Other farmed animals: Muscle/meat	1%	Milk: Cattle	2%	
	18%	FR child 3–15 years	2.64	6%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat	2%	
	17%	FR adult	2.55	11%	Tea (dried leaves of Camellia sinensis)	1%	Milk: Cattle	1.0%	Swine: Muscle/meat	1%	
	16%	NL child	2.38	7%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Bovine: Muscle/meat	3%	
	15%	FR toddler 2–3 years	2.29	8%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat	2%	
	14%	GEMS/Food G07	2.06	4%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	Swine: Muscle/meat	2%	
	14%	GEMS/Food G11	2.06	3%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	Swine: Muscle/meat	2%	
	13%	UK toddler	1.96	6%	Milk: Cattle	2%	Tea (dried leaves of Camellia sinensis)	2%	Bovine: Muscle/meat	1%	
	13%	GEMS/Food G08	1.91	3%	Swine: Muscle/meat	2%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	
	12%	SE general	1.81	6%	Bovine: Muscle/meat	4%	Milk: Cattle	0.4%	Wheat	1%	
	12%	DK child	1.80	4%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Bovine: Muscle/meat	2%	
	12%	GEMS/Food G15	1.78	2%	Swine: Muscle/meat	2%	Milk: Cattle	2%	Swine: Fat tissue	2%	
	12%	DE child	1.73	6%	Milk: Cattle	0.9%	Swine: Muscle/meat	0.8%	Apples	3%	
	11%	ES child	1.71	4%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat	1%	
	11%	GEMS/Food G10	1.67	2%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	1%	Bovine: Muscle/meat	2%	
	11%	DE general	1.66	3%	Milk: Cattle	2%	Tea (dried leaves of Camellia sinensis)	2%	Swine: Muscle/meat	1%	
	11%	GEMS/Food G06	1.59	4%	Tea (dried leaves of Camellia sinensis)	2%	Tomatoes	1.0%	Wheat	2%	
	10%	DE women 14–50 years	1.57	4%	Milk: Cattle	2%	Tea (dried leaves of Camellia sinensis)	1%	Swine: Muscle/meat	1%	
	10%	NL general	1.49	3%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	1%	Swine: Muscle/meat	1%	
	9%	RO general	1.30	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.8%	Tomatoes	2%	
	7%	UK adult	1.11	4%	Tea (dried leaves of Camellia sinensis)	1.0%	Bovine: Muscle/meat	0.8%	Milk: Cattle	0.6%	
	7%	DK adult	1.10	1%	Milk: Cattle	1%	Swine: Fat tissue	1%	Swine: Muscle/meat	0.6%	
	7%	FR infant	1.07	5%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.5%	Bovine: Muscle/meat	0.7%	
	6%	ES adult	0.94	1%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Swine: Muscle/meat	0.9%	
	6%	UK vegetarian	0.94	4%	Tea (dried leaves of Camellia sinensis)	0.9%	Milk: Cattle	0.3%	Wheat	0.7%	
	5%	LT adult	0.76	1%	Swine: Muscle/meat	1%	Milk: Cattle	0.9%	Swine: Fat tissue	0.6%	
	3%	IE child	0.43	1%	Milk: Cattle	0.9%	Swine: Fat tissue	0.3%	Swine: Muscle/meat	0.3%	
	3%	FI adult	0.40	2%	Coffee beans	0.2%	Tomatoes	0.1%	Rye	2%	
	2%	IT toddler	0.33	0.9%	Wheat	0.6%	Tomatoes	0.2%	Other cereals	1%	
	2%	PT general	0.33	0.5%	Wheat	0.4%	Tomatoes	0.4%	Potatoes	1%	
	2%	FI 3 years	0.25	0.3%	Potatoes	0.2%	Tomatoes	0.2%	Wheat	1%	
	2%	IT adult	0.24	0.6%	Wheat	0.5%	Tomatoes	0.1%	Other cereals	1%	
	1%	FI 6 years	0.20	0.3%	Potatoes	0.2%	Tomatoes	0.1%	Wheat	0.8%	
	1%	PL general	0.15	0.4%	Tomatoes	0.2%	Potatoes	0.1%	Apples	0.4%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results of IESTI calculation for all crops

Unprocessed commodities

Results for children	Results for adults	IESTI new Results for children	IESTI new Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1	No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 2	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
122%	Tea (dried leaves of	60/11.99	18
74%	Tomatoes	0.4/0.19	11
60%	Sweet peppers/bell peppers	0.3/0.15	8.9
49%	Papayas	0.3/0.17	7.3
35%	Milk: Cattle	0.03/0.04	5.3
29%	Bovine: Liver	0.05/0.54	4.4
26%	Bovine: Edible offals (other	0.05/0.54	3.9
19%	Oranges	1.5/0.02	2.8
18%	Swine: Muscle/meat	#VALUE!	2.7
14%	Bovine: Fat tissue	0.6/1	2.1
12%	Bovine: Kidney	0.05/0.48	1.8
11%	Swine: Fat tissue	0.6/1	1.7
11%	Swine: Edible offals (other	0.05/0.54	1.6
11%	Bovine: Muscle/meat	#VALUE!	1.6
10%	Potatoes	0.01/0.01	1.5

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
40%	Tea (dried leaves of	60/11.99	6.0
20%	Tomatoes	0.4/0.19	3.0
16%	Sweet peppers/bell peppers	0.3/0.15	2.4
16%	Papayas	0.3/0.17	2.4
14%	Bovine: Liver	0.05/0.54	2.2
14%	Swine: Fat tissue	0.6/1	2.0
12%	Bovine: Edible offals (other	0.05/0.54	1.8
12%	Swine: Other products	0.05/0.54	1.8
11%	Milk: Cattle	0.03/0.04	1.6
10%	Sheep: Liver	0.05/0.54	1.5
9%	Swine: Edible offals (other	0.05/0.54	1.4
8%	Bovine: Muscle	#VALUE!	1.3
7%	Bovine: Other products	0.05/0.54	1.1
7%	Swine: Muscle/meat	#VALUE!	1.1
7%	Equine: Muscle/meat	#VALUE!	1.1

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
716%	Tea (dried leaves of	60/70.2	107
243%	Melons	0.4/0.4	36
81%	Tomatoes	0.4/0.4	12
62%	Milk: Cattle	0.03/0.08	9.3
52%	Papayas	0.3/0.43	7.9
51%	Sweet peppers/bell	0.3/0.3	7.7
16%	Oranges	1.5/0.04	2.5
14%	Kumquats	0.8/1.15	2.1
12%	Milk: Goat	0.03/0.08	1.8
10%	Swine: Muscle/meat	#VALUE!	1.5
8%	Bovine: Fat tissue	0.6/0.6	1.2
7%	Swine: Fat tissue	0.6/0.6	1.0
6%	Bovine: Muscle/meat	#VALUE!	0.87
5%	Watermelons	0.01/0.01	0.73
5%	Equine: Muscle/meat	#VALUE!	0.72

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
234%	Tea (dried leaves of Camellia	60/70.2	35
63%	Melons	0.4/0.4	9.4
51%	Tomatoes	0.4/0.4	7.7
22%	Papayas	0.3/0.43	3.3
19%	Milk: Cattle	0.03/0.08	2.9
14%	Sweet peppers/bell peppers	0.3/0.3	2.1
11%	Oranges	1.5/0.04	1.7
9%	Milk: Goat	0.03/0.08	1.4
8%	Swine: Fat tissue	0.6/0.6	1.2
8%	Milk: Sheep	0.03/0.08	1.1
5%	Bovine: Muscle	#VALUE!	0.68
4%	Bovine: Fat tissue	0.6/0.6	0.58
4%	Swine: Muscle/meat	#VALUE!	0.58
4%	Equine: Muscle/meat	#VALUE!	0.58
4%	Sheep: Muscle/meat	#VALUE!	0.57

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) 2	
1			

Processed commodities

Results for children	Results for adults	Results for children	Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1	No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 1	No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
223%	Oranges/juice	1.5/0.63	33
28%	Tea (dried leaves of Camelli	60/0.12	4.2
8%	Tomatoes/juice	0.4/0.07	1.2
7%	Sugar beets (root)/sugar	0.01/0.12	1.1
6%	Potatoes/fried	0.01/0.01	0.93
6%	Pumpkins/boiled	0.01/0.01	0.89
6%	Witloofs/boiled	0.01/0.01	0.87
5%	Broccoli/boiled	0.01/0.01	0.79
5%	Lemons/jam	0.8/0.23	0.70
5%	Cauliflowers/boiled	0.01/0.01	0.70
4%	Escaroles/broad-leaved end	0.01/0.01	0.66
4%	Tomatoes/sauce/puree	0.4/0.07	0.62
4%	Potatoes/dried (flakes)	0.01/0.05	0.59
4%	Leeks/boiled	0.01/0.01	0.57
4%	Apples/juice	0.01/0.01	0.54

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
64%	Oranges/juice	1.5/0.63	9.6
16%	Tea (dried leaves of	60/0.12	2.4
4%	Pumpkins/boiled	0.01/0.01	0.55
4%	Tomatoes/sauce/puree	0.4/0.07	0.53
3%	Sugar beets (root)/sugar	0.01/0.12	0.44
3%	Lemons/juice	0.8/0.23	0.44
3%	Cauliflowers/boiled	0.01/0.01	0.42
2%	Celeries/boiled	0.01/0.01	0.34
2%	Apples/juice	0.01/0.01	0.33
2%	Maize/oil	0.02/0.5	0.25
2%	Broccoli/boiled	0.01/0.01	0.24
2%	Coffee beans/extraction	0.05/0.01	0.24
2%	Courgettes/boiled	0.01/0.01	0.23
1%	Beetroots/boiled	0.01/0.01	0.22
1%	Parsnips/boiled	0.01/0.01	0.21

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
223%	Oranges/juice	1.5/0.63	33
28%	Tea (dried leaves of	60/0.12	4.2
8%	Tomatoes/juice	0.4/0.07	1.2
7%	Sugar beets (root)/sugar	0.01/0.12	1.1
5%	Lemons/jam	0.8/0.23	0.70
4%	Tomatoes/sauce/puree	0.4/0.07	0.62
4%	Potatoes/dried (flakes)	0.01/0.05	0.59
4%	Apples/juice	0.01/0.01	0.54
4%	Pumpkins/boiled	0.01/0.01	0.53
3%	Broccoli/boiled	0.01/0.01	0.47
3%	Witloofs/boiled	0.01/0.01	0.47
3%	Maize/oil	0.02/0.5	0.47
3%	Potatoes/fried	0.01/0.01	0.44
3%	Wine grapes/juice	0.01/0.01	0.44
3%	Cauliflowers/boiled	0.01/0.01	0.42

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
64%	Oranges/juice	1.5/0.63	9.6
16%	Tea (dried leaves of Camellia	60/0.12	2.4
4%	Tomatoes/sauce/puree	0.4/0.07	0.53
3%	Sugar beets (root)/sugar	0.01/0.12	0.44
3%	Lemons/juice	0.8/0.23	0.44
3%	Pumpkins/boiled	0.01/0.01	0.40
2%	Apples/juice	0.01/0.01	0.33
2%	Maize/oil	0.02/0.5	0.25
2%	Cauliflowers/boiled	0.01/0.01	0.25
2%	Coffee beans/extraction	0.05/0.01	0.24
1%	Witloofs/boiled	0.01/0.01	0.22
1%	Wine grapes/juice	0.01/0.01	0.21
1%	Celeries/boiled	0.01/0.01	0.20
1%	Broccoli/boiled	0.01/0.01	0.20
1%	Rhubarbs/sauce/puree	0.01/0.01	0.19

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Fluxapyroxad

LOQs (mg/kg) range from:	0.01	to:	1.00
Toxicological reference values			
ADI (mg/kg bw per day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EFSA 12	Source of ARfD:	EFSA 12
Year of evaluation:	2012	Year of evaluation:	2012

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 : ---

	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)	89%	NL toddler	17.83	16%	Apples	8%	Wheat	7%	Pears	0.5%	
	66%	DE child	13.26	19%	Apples	8%	Wheat	7%	Oranges	0.1%	
	60%	GEMS/Food G06	12.08	14%	Wheat	11%	Tomatoes	7%	Rice	0.1%	
	56%	NL child	11.23	9%	Apples	8%	Wheat	6%	Sugar beet roots	0.1%	
	52%	GEMS/Food G10	10.33	8%	Wheat	6%	Barley	5%	Rice	0.1%	
	51%	GEMS/Food G08	10.19	9%	Barley	8%	Wheat	3%	Tomatoes	0.1%	
	50%	GEMS/Food G07	9.90	8%	Wheat	6%	Barley	3%	Wine grapes	0.1%	
	49%	GEMS/Food G15	9.86	9%	Wheat	8%	Barley	4%	Tomatoes	0.1%	
	48%	GEMS/Food G11	9.64	8%	Barley	7%	Wheat	3%	Soyabeans	0.1%	
	43%	FR child 3–15 years	8.63	9%	Wheat	6%	Oranges	3%	Sugar beet roots	0.1%	
	42%	DK child	8.30	11%	Rye	9%	Wheat	4%	Oat	0.0%	
	40%	RO general	8.06	10%	Wheat	6%	Tomatoes	4%	Wine grapes	0.1%	
	39%	IE adult	7.83	5%	Wheat	3%	Wine grapes	2%	Peaches	0.1%	
	36%	FR toddler 2–3 years	7.25	6%	Wheat	5%	Apples	3%	Milk: Cattle	0.1%	
	34%	PT general	6.79	8%	Wheat	6%	Wine grapes	3%	Rice	0.0%	
	34%	DE general	6.72	5%	Barley	4%	Wheat	4%	Apples	0.0%	
	33%	SE general	6.54	6%	Wheat	4%	Chinese cabbages/pe-tsai	2%	Tomatoes	0.0%	
	33%	DE women 14–50 years	6.51	4%	Wheat	4%	Apples	3%	Sugar beet roots	0.1%	
	32%	UK toddler	6.39	8%	Wheat	3%	Oranges	3%	Apples	0.0%	
	31%	IT toddler	6.12	13%	Wheat	4%	Tomatoes	3%	Peaches	0.1%	
	31%	NL general	6.10	4%	Wheat	3%	Barley	2%	Apples	0.0%	
	30%	ES child	6.07	9%	Wheat	4%	Oranges	3%	Tomatoes	0.1%	
	30%	UK infant	5.91	5%	Wheat	4%	Milk: Cattle	3%	Rice	0.1%	
	28%	FI 3 years	5.51	6%	Oat	2%	Rice	2%	Wheat	0.0%	
	26%	ES adult	5.18	5%	Barley	5%	Wheat	2%	Tomatoes	0.1%	
	24%	IT adult	4.87	8%	Wheat	3%	Tomatoes	3%	Peaches	0.0%	
	23%	FR adult	4.69	5%	Wine grapes	4%	Wheat	1%	Tomatoes	0.0%	
	21%	FI 6 years	4.17	3%	Oat	2%	Wheat	2%	Potatoes	0.0%	
	19%	UK vegetarian	3.71	4%	Wheat	2%	Wine grapes	2%	Tomatoes	0.0%	
	16%	LT adult	3.23	3%	Apples	2%	Rye	2%	Wheat	0.0%	
	16%	FR infant	3.21	3%	Apples	2%	Milk: Cattle	2%	Wheat	0.0%	
	15%	UK adult	3.06	3%	Wheat	3%	Wine grapes	2%	Rice	0.0%	
	15%	DK adult	2.96	2%	Wheat	2%	Wine grapes	2%	Tomatoes	0.0%	
	13%	FI adult	2.62	2%	Tomatoes	1%	Rye	1%	Oat	0.0%	
	13%	PL general	2.51	3%	Apples	3%	Tomatoes	2%	Potatoes	0.0%	
	7%	IE child	1.31	2%	Wheat	1%	Rice	0.5%	Apples	0.0%	

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.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
88%	Table grapes	3/3	219
77%	Celeries	9/5.15	193
77%	Rhubarbs	9/5.15	192
62%	Bananas	3/1.6	155
59%	Witloofs/Belgian endives	6/3.7	147
57%	Peaches	1.5/1.5	143
51%	Chinese cabbages/pe-tsai	4/4	129
50%	Pears	0.9/0.9	125
39%	Apples	0.9/0.9	97
33%	Florence fennels	9/5.15	84
31%	Oranges	1/0.58	77
29%	Escaroles/broad-leaved	4/1.8	72
27%	Lettuces	4/1.8	69
27%	Spinaches	3/3	68
25%	Plums	1.5/1.5	63

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
41%	Table grapes	3/3	102
41%	Chinese cabbages/pe-tsai	4/4	101
38%	Florence fennels	9/5.15	96
33%	Celeries	9/5.15	82
28%	Wine grapes	3/3	71
27%	Witloofs/Belgian endives	6/3.7	68
23%	Chards/beet leaves	3/3	57
21%	Cardoons	9/5.15	53
19%	Rhubarbs	9/5.15	48
15%	Escaroles/broad-leaved	4/1.8	36
14%	Blueberries	7/3.77	34
14%	Bananas	3/1.6	34
12%	Broccoli	2/1.27	30
11%	Peaches	1.5/1.5	28
11%	Pears	0.9/0.9	27

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
81%	Celeries	9/9	202
79%	Witloofs/Belgian endives	6/6	199
74%	Bananas	3/3	184
62%	Rhubarbs	9/9	155
53%	Table grapes	3/3	131
39%	Escaroles/broad-leaved	4/4	96
37%	Lettuces	4/4	91
32%	Peaches	1.5/1.5	81
31%	Chinese cabbages/pe-tsai	4/4	77
27%	Spinaches	3/3	68
27%	Oranges	1/1	67
26%	Strawberries	4/4	65
25%	Rice	5/5	63
25%	Florence fennels	9/9	63
22%	Apples	0.9/0.9	55

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
35%	Celeries	9/9	86
33%	Bananas	3/3	84
30%	Witloofs/Belgian endives	6/6	76
29%	Florence fennels	9/9	72
28%	Wine grapes	3/3	71
26%	Rhubarbs	9/9	66
26%	Blueberries	7/7	64
24%	Table grapes	3/3	61
24%	Chinese cabbages/pe-tsai	4/4	61
24%	Escaroles/broad-leaved endives	4/4	59
23%	Plums	1.5/1.5	59
19%	Oranges	1/1	47
17%	Rice	5/5	43
16%	Cardoons	9/9	40
15%	Broccoli	2/2	39

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
129%	Witloofs/boiled	6/3.7	323
93%	Florence fennels/boiled	9/5.15	233
77%	Rhubarbs/sauce/puree	9/5.15	192
48%	Escaroles/broad-leaved end	4/1.8	119
40%	Broccoli/boiled	2/1.27	100
37%	Chards/beet leaves/boiled	3/3	93
17%	Spinaches/frozen; boiled	3/3	42
16%	Peaches/canned	1/1.5	39
14%	Leeks/boiled	0.6/0.6	34
10%	Beans (with pods)/boiled	2/2	25
10%	Peaches/juice	1.5/1.5	25
8%	Wine grapes/juice	3/0.47	21
7%	Oranges/juice	1/0.33	17
7%	Sugar beets (root)/sugar	0.15/1.8	17
6%	Apples/juice	0.9/0.3	16

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
70%	Celeries/boiled	9/5.15	174
40%	Florence fennels/boiled	9/5.15	100
30%	Rhubarbs/sauce/puree	9/5.15	75
27%	Witloofs/boiled	6/3.7	68
25%	Cardoons/boiled	9/5.15	63
15%	Chards/beet leaves/boiled	3/3	38
15%	Escaroles/broad-leaved	4/1.8	37
12%	Broccoli/boiled	2/1.27	31
11%	Wine grapes/wine	3/3	28
10%	Spinaches/frozen; boiled	3/3	25
7%	Table grapes/raisins	3/14.1	17
6%	Barley/beer	2/0.4	14
5%	Purslanes/boiled	3/3	12
5%	Peaches/canned	1.5/1.5	12
4%	Leeks/boiled	0.6/0.6	10

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
70%	Witloofs/boiled	6/3.7	175
56%	Florence fennels/boiled	9/5.15	140
50%	Rhubarbs/sauce/puree	9/5.15	126
29%	Escaroles/broad-leaved	4/1.8	72
24%	Broccoli/boiled	2/1.27	60
17%	Spinaches/frozen; boiled	3/3	42
16%	Chards/beet leaves/boiled	3/3	40
12%	Peaches/canned	1/1.5	29
10%	Beans (with pods)/boiled	2/2	25
10%	Peaches/juice	1.5/1.5	25
8%	Wine grapes/juice	3/0.47	21
8%	Leeks/boiled	0.6/0.6	20
7%	Oranges/juice	1/0.33	17
7%	Sugar beets (root)/sugar	0.15/1.8	17
6%	Apples/juice	0.9/0.3	16

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
42%	Celeries/boiled	9/5.15	104
40%	Rhubarbs/sauce/puree	9/5.15	100
32%	Witloofs/boiled	6/3.7	80
25%	Florence fennels/boiled	9/5.15	64
19%	Cardoons/boiled	9/5.15	47
11%	Wine grapes/wine	3/3	28
11%	Escaroles/broad-leaved endives/	4/1.8	28
11%	Chards/beet leaves/boiled	3/3	26
11%	Broccoli/boiled	2/1.27	25
10%	Spinaches/frozen; boiled	3/3	25
7%	Table grapes/raisins	3/14.1	17
6%	Barley/beer	2/0.4	14
5%	Purslanes/boiled	3/3	12
5%	Peaches/canned	1.5/1.5	12
4%	Apples/juice	0.9/0.3	10.0

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, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

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:	EC	Source of ARfD:	EC
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:

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)	16%	NL toddler	7.92	4%	Apples	3%	Table grapes	2%	Tomatoes	2%	0.0%
	13%	GEMS/Food G06	6.74	6%	Tomatoes	2%	Table grapes	1%	Wheat	0.3%	0.0%
	13%	DE child	6.55	5%	Apples	3%	Table grapes	2%	Tomatoes	0.8%	0.0%
	11%	GEMS/Food G15	5.63	2%	Barley	2%	Tomatoes	2%	Wine grapes	0.4%	0.0%
	11%	GEMS/Food G08	5.59	3%	Barley	2%	Wine grapes	2%	Tomatoes	0.4%	0.0%
	11%	GEMS/Food G07	5.39	3%	Wine grapes	2%	Tomatoes	2%	Barley	0.4%	0.0%
	11%	RO general	5.38	3%	Tomatoes	3%	Wine grapes	1%	Wheat	0.4%	0.0%
	10%	GEMS/Food G11	5.18	2%	Barley	2%	Wine grapes	2%	Tomatoes	0.4%	0.0%
	9%	PT general	4.74	5%	Wine grapes	2%	Tomatoes	0.8%	Wheat	0.1%	0.0%
	9%	GEMS/Food G10	4.52	2%	Tomatoes	2%	Barley	0.8%	Wine grapes	0.4%	0.0%
	8%	NL child	4.23	2%	Apples	2%	Table grapes	1%	Tomatoes	1.0%	0.0%
	8%	DE general	3.87	2%	Wine grapes	2%	Barley	1%	Tomatoes	0.5%	0.0%
	7%	DE women 14–50 years	3.59	2%	Wine grapes	1%	Tomatoes	1%	Apples	0.5%	0.0%
	7%	FR adult	3.58	5%	Wine grapes	0.8%	Tomatoes	0.4%	Wheat	0.2%	0.0%
	7%	DK child	3.49	1%	Oat	1%	Rye	1.0%	Tomatoes	0.4%	0.0%
	7%	IE adult	3.47	3%	Wine grapes	0.7%	Tomatoes	0.5%	Oat	0.4%	0.0%
	6%	FR child 3–15 years	3.05	2%	Tomatoes	0.9%	Wheat	0.7%	Wine grapes	0.9%	0.0%
	5%	ES adult	2.73	1%	Barley	1%	Tomatoes	0.8%	Wine grapes	0.3%	0.0%
	5%	NL general	2.69	1%	Wine grapes	0.9%	Barley	0.8%	Tomatoes	0.4%	0.0%
	5%	IT toddler	2.56	3%	Tomatoes	1%	Wheat	0.4%	Apples	0.1%	0.0%
	5%	FI 3 years	2.48	2%	Oat	1%	Tomatoes	0.5%	Table grapes	0.1%	0.0%
	5%	FR toddler 2–3 years	2.33	1%	Apples	0.9%	Tomatoes	0.6%	Wheat	0.9%	0.0%
	5%	FI adult	2.32	2%	Coffee beans	1%	Tomatoes	0.6%	Wine grapes	0.1%	0.0%
	5%	DK adult	2.29	2%	Wine grapes	0.9%	Tomatoes	0.4%	Apples	0.2%	0.0%
	4%	ES child	2.18	2%	Tomatoes	0.9%	Wheat	0.5%	Apples	0.5%	0.0%
	4%	UK toddler	2.14	1%	Tomatoes	0.8%	Wheat	0.7%	Apples	0.7%	0.0%
	4%	UK vegetarian	2.13	2%	Wine grapes	1%	Tomatoes	0.4%	Wheat	0.2%	0.0%
	4%	IT adult	2.06	2%	Tomatoes	0.8%	Wheat	0.3%	Apples	0.1%	0.0%
	4%	UK infant	2.03	0.8%	Milk: Cattle	0.8%	Oat	0.7%	Tomatoes	1%	0.0%
	4%	UK adult	2.02	2%	Wine grapes	0.8%	Tomatoes	0.3%	Wheat	0.2%	0.0%
	4%	SE general	1.97	1%	Tomatoes	0.6%	Wheat	0.4%	Apples	0.5%	
	4%	PL general	1.77	2%	Tomatoes	0.8%	Apples	0.6%	Table grapes	0.1%	0.0%
	4%	FI 6 years	1.76	1.0%	Oat	0.8%	Tomatoes	0.3%	Table grapes	0.1%	0.0%
	3%	LT adult	1.64	1%	Tomatoes	0.7%	Apples	0.3%	Oat	0.1%	
	2%	FR infant	0.93	0.7%	Apples	0.3%	Milk: Cattle	0.2%	Tomatoes	0.5%	0.0%
	0.8%	IE child	0.40	0.2%	Wheat	0.1%	Apples	0.1%	Table grapes	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 Benzovindiflupyr is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
0.2%	Beans	0.2/0.01	0.20
0.07%	Lentils	0.2/0.01	0.07
0.07%	Peas	0.2/0.01	0.07

Expand/collapse list

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

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)
0.07%	Beans	0.2/0.01	0.07
0.07%	Lentils	0.2/0.01	0.07
0.04%	Peas	0.2/0.01	0.04

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Beans	0.2/0.2	3.7
1%	Lentils	0.2/0.2	1.3
1%	Peas	0.2/0.2	1.3

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Beans	0.2/0.2	1.3
1%	Lentils	0.2/0.2	1.2
0.7%	Peas	0.2/0.2	0.66

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)
2%	Lentils/boiled	0.2/0.2	1.6
1%	Peas/canned	0.2/0.08	1.4

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)
1%	Beans/canned	0.2/0.2	1.4
0.5%	Peas/canned	0.2/0.08	0.53

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Lentils/boiled	0.2/0.2	1.6
1%	Peas/canned	0.2/0.08	1.4

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Beans/canned	0.2/0.2	1.4
0.5%	Peas/canned	0.2/0.08	0.53

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; 2018/11/18

Cyantraniliprole

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):	not necessary
Source of ADI:	Reg. 2016/1414	Source of ARfD:	Reg. 2016/1414
Year of evaluation:	2016	Year of evaluation:	2016

Input values | Details–chronic risk assessment | Supplementary results–chronic risk assessment | Details–acute risk | Details–acute risk

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

	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)	152%	NL toddler	15.20	96%	Milk: Cattle	17%	Apples	7%	Pears		152%
	79%	DE child	7.94	32%	Milk: Cattle	20%	Apples	6%	Oranges		79%
	75%	UK infant	7.49	62%	Milk: Cattle	3%	Apples	2%	Oranges		75%
	71%	NL child	7.10	39%	Milk: Cattle	9%	Apples	3%	Table grapes		71%
	66%	FR toddler 2-3 years	6.59	47%	Milk: Cattle	5%	Apples	2%	Oranges		66%
	59%	FR child 3–15 years	5.88	37%	Milk: Cattle	5%	Oranges	3%	Apples		59%
	48%	UK toddler	4.81	33%	Milk: Cattle	3%	Oranges	3%	Apples		48%
	47%	ES child	4.68	20%	Milk: Cattle	11%	Olives for oil production	3%	Oranges		47%
	44%	RO general	4.40	19%	Milk: Cattle	8%	Head cabbages	5%	Wine grapes		44%
	43%	GEMS/Food G08	4.32	12%	Olives for oil production	9%	Milk: Cattle	3%	Wine grapes		43%
	42%	DE women 14–50 years	4.17	20%	Milk: Cattle	4%	Apples	3%	Oranges		42%
	40%	DE general	3.98	20%	Milk: Cattle	4%	Apples	3%	Wine grapes		40%
	39%	GEMS/Food G11	3.94	12%	Milk: Cattle	6%	Celeries	4%	Olives for oil production		39%
	38%	GEMS/Food G07	3.82	10%	Milk: Cattle	5%	Wine grapes	4%	Olives for oil production		38%
	38%	GEMS/Food G15	3.82	11%	Milk: Cattle	5%	Head cabbages	3%	Wine grapes		38%
	38%	SE general	3.80	20%	Milk: Cattle	4%	Head cabbages	3%	Lettuces		38%
	38%	FR infant	3.75	27%	Milk: Cattle	3%	Apples	1%	Cauliflowers		38%
	35%	GEMS/Food G10	3.47	9%	Milk: Cattle	6%	Olives for oil production	3%	Lettuces		35%
	33%	GEMS/Food G06	3.32	6%	Tomatoes	5%	Olives for oil production	4%	Milk: Cattle		33%
	33%	DK child	3.26	20%	Milk: Cattle	4%	Apples	1%	Lettuces		33%
	32%	IE adult	3.19	7%	Milk: Cattle	4%	Wine grapes	3%	Celeries		32%
	29%	ES adult	2.93	8%	Milk: Cattle	6%	Olives for oil production	4%	Lettuces		29%
	29%	NL general	2.92	14%	Milk: Cattle	2%	Apples	2%	Wine grapes		29%
	24%	FR adult	2.40	7%	Wine grapes	7%	Milk: Cattle	1%	Apples		24%
	22%	PT general	2.18	8%	Wine grapes	4%	Olives for oil production	2%	Apples		22%
	19%	DK adult	1.86	8%	Milk: Cattle	3%	Wine grapes	2%	Apples		19%
	17%	UK vegetarian	1.72	5%	Milk: Cattle	3%	Wine grapes	1%	Oranges		17%
	15%	LT adult	1.50	6%	Milk: Cattle	3%	Apples	2%	Head cabbages		15%
	15%	UK adult	1.48	5%	Milk: Cattle	3%	Wine grapes	0.9%	Lettuces		15%
	13%	IT toddler	1.27	2%	Tomatoes	2%	Lettuces	1%	Apples		13%
	12%	IT adult	1.23	3%	Lettuces	2%	Tomatoes	1%	Peaches		12%
	11%	FI 3 years	1.15	2%	Strawberries	2%	Apples	1.0%	Tomatoes		11%
	11%	PL general	1.14	3%	Apples	2%	Head cabbages	2%	Tomatoes		11%
	9%	FI 6 years	0.87	1%	Strawberries	0.9%	Apples	0.7%	Tomatoes		9%
	9%	FI adult	0.85	1%	Lettuces	1.0%	Wine grapes	0.9%	Tomatoes		9%
	8%	IE child	0.82	6%	Milk: Cattle	0.5%	Apples	0.3%	Broccoli		8%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0–152 % of the ADI.
For 1 diet(s), the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

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

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)	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; 2018/11/18

Cyazofamid

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.17	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC 03/23	Source of ARfD:	EC 03/23
Year of evaluation:	2003	Year of evaluation:	2003

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 : ---

	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)	1%	NL toddler	2.12	0.4%	Milk: Cattle	0.3%	Table grapes	0.1%	Leeks	0.7%	
	0.8%	DE child	1.33	0.3%	Table grapes	0.1%	Milk: Cattle	0.1%	Apples	0.3%	
	0.7%	NL child	1.21	0.2%	Table grapes	0.1%	Milk: Cattle	0.1%	Leeks	0.3%	
	0.7%	GEMS/Food G06	1.16	0.2%	Table grapes	0.1%	Tomatoes	0.1%	Wheat	0.2%	
	0.7%	GEMS/Food G11	1.13	0.2%	Leeks	0.1%	Table grapes	0.0%	Milk: Cattle	0.2%	
	0.6%	FR child 3–15 years	1.08	0.2%	Leeks	0.1%	Milk: Cattle	0.1%	Table grapes	0.3%	
	0.6%	FR toddler 2–3 years	1.04	0.2%	Leeks	0.2%	Milk: Cattle	0.0%	Wheat	0.3%	
	0.5%	GEMS/Food G08	0.80	0.1%	Leeks	0.1%	Table grapes	0.0%	Wheat	0.2%	
	0.5%	GEMS/Food G07	0.78	0.1%	Table grapes	0.1%	Leeks	0.0%	Wheat	0.2%	
	0.4%	IE adult	0.75	0.1%	Leeks	0.1%	Table grapes	0.0%	Spring onions/green onions and We	0.2%	
	0.4%	GEMS/Food G15	0.73	0.1%	Table grapes	0.1%	Wheat	0.0%	Milk: Cattle	0.2%	
	0.4%	FR infant	0.72	0.2%	Leeks	0.1%	Milk: Cattle	0.0%	Potatoes	0.1%	
	0.4%	DK child	0.71	0.1%	Milk: Cattle	0.1%	Rye	0.1%	Wheat	0.2%	
	0.4%	GEMS/Food G10	0.71	0.1%	Table grapes	0.0%	Wheat	0.0%	Tomatoes	0.2%	
	0.4%	UK infant	0.69	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	
	0.4%	RO general	0.68	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Tomatoes	0.2%	
	0.4%	DE women 14–50 years	0.68	0.1%	Milk: Cattle	0.1%	Leeks	0.1%	Table grapes	0.2%	
	0.4%	DE general	0.67	0.1%	Milk: Cattle	0.1%	Leeks	0.0%	Table grapes	0.2%	
	0.4%	NL general	0.66	0.1%	Leeks	0.0%	Milk: Cattle	0.0%	Table grapes	0.2%	
	0.4%	UK toddler	0.64	0.1%	Milk: Cattle	0.0%	Table grapes	0.0%	Wheat	0.2%	
	0.3%	SE general	0.56	0.1%	Milk: Cattle	0.0%	Leeks	0.0%	Wheat	0.2%	
	0.3%	FR adult	0.55	0.1%	Leeks	0.0%	Wine grapes	0.0%	Milk: Cattle	0.1%	
	0.3%	ES child	0.55	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Tomatoes	0.2%	
	0.3%	PT general	0.47	0.1%	Table grapes	0.0%	Wheat	0.0%	Wine grapes	0.1%	
	0.3%	FI adult	0.46	0.2%	Coffee beans	0.0%	Tomatoes	0.0%	Table grapes	0.2%	
	0.2%	FI 3 years	0.40	0.0%	Table grapes	0.0%	Leeks	0.0%	Potatoes	0.1%	
	0.2%	IT toddler	0.37	0.1%	Wheat	0.0%	Tomatoes	0.0%	Table grapes	0.1%	
	0.2%	ES adult	0.36	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Leeks	0.1%	
	0.2%	UK vegetarian	0.34	0.0%	Leeks	0.0%	Wheat	0.0%	Milk: Cattle	0.1%	
	0.2%	DK adult	0.33	0.0%	Table grapes	0.0%	Milk: Cattle	0.0%	Leeks	0.1%	
	0.2%	PL general	0.32	0.1%	Table grapes	0.0%	Leeks	0.0%	Tomatoes	0.0%	
	0.2%	FI 6 years	0.31	0.0%	Table grapes	0.0%	Potatoes	0.0%	Leeks	0.1%	
	0.2%	UK adult	0.29	0.0%	Wheat	0.0%	Wine grapes	0.0%	HOPS (dried)	0.1%	
	0.2%	IT adult	0.29	0.0%	Wheat	0.0%	Tomatoes	0.0%	Table grapes	0.1%	
	0.1%	LT adult	0.23	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Tomatoes	0.1%	
	0.1%	IE child	0.12	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Table grapes	0.0%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

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)	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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	**IESTI new**	**IESTI new**

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)	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; 2018/11/18

Lufenuron

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):	not necessary
Source of ADI:	Dir 09/77	Source of ARfD:	
Year of evaluation:	2009	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 : ---

	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)	83%	NL toddler	12.42	47%	Milk: Cattle	21%	Apples	8%	Pears		83%
	47%	DE child	7.02	24%	Apples	15%	Milk: Cattle	2%	Oranges		47%
	39%	NL child	5.84	19%	Milk: Cattle	11%	Apples	2%	Pears		39%
	37%	UK infant	5.60	30%	Milk: Cattle	3%	Apples	2%	Bovine: Muscle/meat		37%
	36%	FR toddler 2–3 years	5.37	23%	Milk: Cattle	6%	Apples	2%	Bovine: Muscle/meat		36%
	31%	FR child 3–15 years	4.68	18%	Milk: Cattle	3%	Apples	2%	Bovine: Muscle/meat		31%
	25%	UK toddler	3.70	16%	Milk: Cattle	3%	Apples	2%	Bovine: Muscle/meat		25%
	23%	DK child	3.52	10%	Milk: Cattle	4%	Apples	4%	Swine: Muscle/meat		23%
	23%	SE general	3.41	10%	Milk: Cattle	7%	Bovine: Muscle/meat	2%	Apples		23%
	23%	ES child	3.39	10%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Apples		23%
	20%	DE women 14–50 years	3.04	10%	Milk: Cattle	5%	Apples	1%	Swine: Muscle/meat		20%
	20%	DE general	3.02	10%	Milk: Cattle	5%	Apples	2%	Swine: Muscle/meat		20%
	19%	FR infant	2.82	13%	Milk: Cattle	3%	Apples	0.6%	Swine: Muscle/meat		19%
	17%	RO general	2.58	9%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat		17%
	17%	GEMS/Food G11	2.58	6%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat		17%
	17%	GEMS/Food G15	2.53	5%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Apples		17%
	16%	GEMS/Food G08	2.37	4%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Apples		16%
	15%	GEMS/Food G07	2.30	5%	Milk: Cattle	2%	Apples	2%	Swine: Muscle/meat		15%
	15%	NL general	2.18	7%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat		15%
	14%	GEMS/Food G10	2.10	4%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Apples		14%
	13%	ES adult	1.97	4%	Milk: Cattle	2%	Lettuces	1%	Apples		13%
	12%	DK adult	1.81	4%	Milk: Cattle	2%	Apples	1%	Swine: Muscle/meat		12%
	12%	IE adult	1.77	3%	Milk: Cattle	2%	Other farmed animals: Muscle/meat	1%	Apples		12%
	11%	LT adult	1.64	4%	Apples	3%	Milk: Cattle	2%	Swine: Muscle/meat		11%
	10%	GEMS/Food G06	1.53	2%	Milk: Cattle	2%	Tomatoes	2%	Apples		10%
	9%	FR adult	1.40	4%	Milk: Cattle	1%	Apples	1%	Swine: Muscle/meat		9%
	6%	UK adult	0.87	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.8%	Apples		6%
	6%	UK vegetarian	0.85	3%	Milk: Cattle	1%	Apples	0.5%	Oranges		6%
	5%	PL general	0.81	4%	Apples	0.5%	Pears	0.5%	Tomatoes		5%
	5%	IE child	0.76	3%	Milk: Cattle	1.0%	Swine: Fat tissue	0.6%	Apples		5%
	5%	PT general	0.73	2%	Apples	0.7%	Pears	0.5%	Tomatoes		5%
	5%	IT toddler	0.72	2%	Apples	1.0%	Lettuces	0.8%	Tomatoes		5%
	5%	IT adult	0.68	2%	Apples	1%	Lettuces	0.6%	Tomatoes		5%
	3%	FI 3 years	0.52	2%	Apples	0.3%	Pears	0.3%	Potatoes		3%
	3%	FI 6 years	0.41	1%	Apples	0.3%	Pears	0.3%	Lettuces		3%
	2%	FI adult	0.37	1%	Apples	0.5%	Lettuces	0.3%	Tomatoes		2%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

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)	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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	**IESTI new**	**IESTI new**

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)	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; 2018/11/18

Isofetamid

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):	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:

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)	27%	NL toddler	5.36	7%	Apples	5%	Table grapes	3%	Milk: Cattle	5%	22%
	24%	DE child	4.83	8%	Apples	5%	Table grapes	2%	Cherries (sweet)	2%	22%
	16%	NL child	3.14	4%	Apples	4%	Table grapes	1%	Milk: Cattle	3%	13%
	14%	PT general	2.81	9%	Wine grapes	1%	Peaches	1.0%	Table grapes	0.8%	13%
	13%	RO general	2.60	6%	Wine grapes	1%	Sweet peppers/bell peppers	1.0%	Apples	2%	11%
	12%	IE adult	2.44	4%	Wine grapes	1%	Peaches	0.9%	Table grapes	1%	11%
	12%	FR adult	2.35	8%	Wine grapes	0.5%	Peaches	0.5%	Apples	0.9%	11%
	12%	GEMS/Food G06	2.33	4%	Table grapes	1%	Sweet peppers/bell peppers	1%	Peaches	2%	10%
	11%	GEMS/Food G15	2.27	4%	Wine grapes	2%	Sweet peppers/bell peppers	1%	Table grapes	2%	10%
	11%	GEMS/Food G07	2.21	5%	Wine grapes	1%	Table grapes	0.7%	Apples	2%	9%
	11%	GEMS/Food G08	2.14	4%	Wine grapes	1%	Table grapes	0.9%	Peaches	2%	9%
	10%	DE women 14–50 years	2.10	3%	Wine grapes	2%	Apples	1%	Table grapes	2%	9%
	10%	DE general	1.96	3%	Wine grapes	2%	Apples	0.9%	Table grapes	2%	8%
	10%	GEMS/Food G11	1.94	4%	Wine grapes	1%	Table grapes	1%	Apples	2%	8%
	9%	FR child 3–15 years	1.79	1%	Wine grapes	1%	Table grapes	1%	Milk: Cattle	3%	6%
	8%	GEMS/Food G10	1.53	1%	Wine grapes	1%	Table grapes	0.7%	Peaches	2%	6%
	7%	DK child	1.44	2%	Apples	1%	Cucumbers	0.6%	Table grapes	2%	5%
	7%	FR toddler 2–3 years	1.43	2%	Apples	1%	Milk: Cattle	0.8%	Wine grapes	3%	5%
	7%	NL general	1.39	2%	Wine grapes	1.0%	Apples	0.9%	Table grapes	1%	6%
	7%	DK adult	1.32	3%	Wine grapes	0.6%	Apples	0.6%	Table grapes	0.7%	6%
	6%	UK infant	1.24	2%	Milk: Cattle	1%	Apples	0.5%	Strawberries	3%	3%
	6%	UK toddler	1.22	1%	Apples	1%	Milk: Cattle	0.9%	Table grapes	2%	4%
	6%	FI 3 years	1.15	0.9%	Strawberries	0.8%	Table grapes	0.7%	Cucumbers	0.7%	5%
	6%	ES adult	1.14	1%	Wine grapes	0.9%	Peaches	0.5%	Apples	0.9%	5%
	6%	UK adult	1.11	4%	Wine grapes	0.3%	Apples	0.2%	Table grapes	0.6%	5%
	6%	SE general	1.11	0.7%	Apples	0.6%	Milk: Cattle	0.6%	Peaches	2%	4%
	5%	IT toddler	1.07	1%	Peaches	0.6%	Apples	0.5%	Cherries (sweet)	0.7%	5%
	5%	ES child	1.06	0.8%	Peaches	0.8%	Apples	0.6%	Milk: Cattle	2%	4%
	5%	UK vegetarian	1.05	3%	Wine grapes	0.4%	Apples	0.3%	Table grapes	0.6%	5%
	5%	IT adult	1.01	2%	Peaches	0.5%	Apples	0.5%	Table grapes	0.4%	5%
	5%	FI adult	0.92	1%	Coffee beans	1%	Wine grapes	0.4%	Apples	2%	3%
	4%	PL general	0.88	1%	Apples	1%	Table grapes	0.5%	Cherries (sweet)	0.3%	4%
	4%	FI 6 years	0.86	0.7%	Strawberries	0.6%	Table grapes	0.5%	Cucumbers	0.6%	4%
	4%	FR infant	0.80	1%	Apples	0.8%	Milk: Cattle	0.4%	Strawberries	1%	3%
	3%	LT adult	0.56	1%	Apples	0.3%	Cucumbers	0.2%	Milk: Cattle	0.7%	2%
	1%	IE child	0.21	0.2%	Apples	0.2%	Table grapes	0.2%	Milk: Cattle	0.4%	0.7%

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	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
45%	Witloofs/Belgian endives	0.01/11.38	452
43%	Lettuces	20/11.38	433
26%	Spinaches	20/11.38	257
23%	Table grapes	4/3.13	228
18%	Peaches	3/1.87	178
18%	Chards/beet leaves	20/11.38	178
10%	Sweet peppers/bell peppers	3/1.66	99
7%	Apricots	3/1.87	65
6%	Pears	0.6/0.42	58
5%	Strawberries	4/3.16	52
5%	Apples	0.6/0.42	45
4%	Cherries (sweet)	4/3.4	42
4%	Cucumbers	1/0.56	37
3%	Wine grapes	4/3.13	29
3%	Courgettes	1/0.56	26

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
22%	Chards/beet leaves	20/11.38	215
21%	Witloofs/Belgian endives	0.01/11.38	209
14%	Lettuces	20/11.38	138
11%	Table grapes	4/3.13	106
7%	Wine grapes	4/3.13	74
5%	Spinaches	20/11.38	46
4%	Peaches	3/1.87	35
3%	Cherries (sweet)	4/3.4	34
3%	Strawberries	4/3.16	29
3%	Blueberries	5/3	27
3%	Sweet peppers/bell peppers	3/1.66	27
3%	Aubergines/egg plants	1.5/0.94	25
2%	Purslanes	20/11.38	22
2%	Apricots	3/1.87	20
2%	Currants (red, black and	5/3	20

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
46%	Lettuces	20/20	457
45%	Spinaches	20/20	452
18%	Peaches	3/3.3	178
18%	Table grapes	4/4	175
16%	Apricots	3/3.3	162
13%	Chards/beet leaves	20/20	134
8%	Sweet peppers/bell peppers	3/3	77
7%	Strawberries	4/4.08	67
5%	Cherries (sweet)	4/4	49
4%	Currants (red, black and	5/5	39
4%	Cucumbers	1/1	39
4%	Wine grapes	4/4	37
4%	Apples	0.6/0.6	37
4%	Pears	0.6/0.6	36
3%	Blackberries	3/3	32

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Chards/beet leaves	20/20	176
15%	Lettuces	20/20	146
9%	Wine grapes	4/4	95
8%	Table grapes	4/4	81
8%	Spinaches	20/20	80
7%	Peaches	3/3.3	67
5%	Blueberries	5/5	46
4%	Apricots	3/3.3	42
4%	Cherries (sweet)	4/4	40
4%	Strawberries	4/4.08	38
4%	Purslanes	20/20	38
3%	Plums	0.8/0.88	34
3%	Currants (red, black and white)	5/5	33
3%	Aubergines/egg plants	1.5/1.5	29
2%	Blackberries	3/3	25

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
99%	Witloofs/boiled	0.01/11.38	993
35%	Chards/beet leaves/boiled	20/11.38	354
16%	Spinaches/frozen; boiled	20/11.38	158
5%	Peaches/canned	1/1.87	49
3%	Wine grapes/juice	4/0.71	31
2%	Courgettes/boiled	1/0.56	20
1%	Peaches/juice	3/0.84	14
1%	Gherkins/pickled	1/0.56	13
0.9%	Currants (red, black and whil	5/0.31	8.9
0.8%	Raspberries/juice	3/0.68	8.0
0.7%	Apples/juice	0.6/0.14	7.3
0.5%	Beans (with pods)/boiled	0.6/0.36	4.5
0.4%	Pears/juice	0.6/0.14	4.4
0.3%	Cranberries/juice	4/0.5	2.9
0.2%	Plums/juice	0.8/0.19	1.8

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Witloofs/boiled	0.01/11.38	210
14%	Chards/beet leaves/boiled	20/11.38	142
9%	Spinaches/frozen; boiled	20/11.38	94
5%	Purslanes/boiled	20/11.38	47
3%	Wine grapes/wine	4/3.13	30
2%	Table grapes/raisins	4/14.71	18
1%	Peaches/canned	3/1.87	15
1%	Wine grapes/juice	4/0.71	15
1%	Courgettes/boiled	1/0.56	13
0.9%	Grape leaves/canned	0.01/11.38	9.5
0.4%	Apples/juice	0.6/0.14	4.5
0.4%	Currants (red, black and	5/0.31	4.0
0.3%	Okra, lady's fingers/boiled	3/1.66	2.7
0.1%	Peas (with pods)/boiled	0.6/0.36	1.2
0.06%	Pumpkins/boiled	0.01/0.01	0.55

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
54%	Witloofs/boiled	0.01/11.38	538
16%	Spinaches/frozen; boiled	20/11.38	158
15%	Chards/beet leaves/boiled	20/11.38	152
4%	Peaches/canned	1/1.87	36
3%	Wine grapes/juice	4/0.71	31
1%	Peaches/juice	3/0.84	14
1%	Courgettes/boiled	1/0.56	12
0.9%	Currants (red, black and	5/0.31	8.9
0.8%	Raspberries/juice	3/0.68	8.0
0.7%	Apples/juice	0.6/0.14	7.3
0.6%	Gherkins/pickled	1/0.56	5.5
0.5%	Beans (with pods)/boiled	0.6/0.36	4.5
0.4%	Pears/juice	0.6/0.14	4.4
0.3%	Cranberries/juice	4/0.5	2.9
0.2%	Plums/juice	0.8/0.19	1.8

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
25%	Witloofs/boiled	0.01/11.38	245
10%	Chards/beet leaves/boiled	20/11.38	100
9%	Spinaches/frozen; boiled	20/11.38	94
5%	Purslanes/boiled	20/11.38	47
3%	Wine grapes/wine	4/3.13	30
2%	Table grapes/raisins	4/14.71	18
2%	Peaches/canned	3/1.87	15
1%	Wine grapes/juice	4/0.71	15
0.9%	Grape leaves/canned	0.01/11.38	9.5
0.9%	Courgettes/boiled	1/0.56	8.9
0.4%	Apples/juice	0.6/0.14	4.5
0.4%	Currants (red, black and white)/	5/0.31	4.0
0.3%	Okra, lady's fingers/boiled	3/1.66	2.7
0.1%	Peas (with pods)/boiled	0.6/0.36	1.2
0.04%	Sugar beets (root)/sugar	0.01/0.12	0.44

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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Oxathiapiprolin

LOQs (mg/kg) range from: 0.01 to: 10.0

Toxicological reference values

ADI (mg/kg bw per day):	0.14	ARfD (mg/kg bw):	n.a.
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	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	4.12	0.8%	Table grapes	0.6%	Maize/corn	0.4%	Milk: Cattle	0.8%	
3%	PT general	3.68	1%	Wine grapes	0.4%	Potatoes	0.4%	Kales	0.1%	
2%	IE adult	3.24	0.6%	Wine grapes	0.4%	Other leafy brassica	0.3%	Sweet potatoes	0.1%	
2%	GEMS/Food G06	3.07	0.5%	Table grapes	0.5%	Tomatoes	0.2%	Potatoes	0.2%	
2%	DE child	2.95	0.7%	Table grapes	0.3%	Grape leaves and similar species	0.2%	Potatoes	0.4%	
2%	GEMS/Food G10	2.90	0.4%	Soyabeans	0.4%	Chinese cabbages/pe-tsai	0.2%	Potatoes	0.2%	
2%	GEMS/Food G07	2.85	0.7%	Wine grapes	0.3%	Potatoes	0.2%	Soyabeans	0.2%	
2%	GEMS/Food G11	2.84	0.5%	Wine grapes	0.5%	Soyabeans	0.3%	Potatoes	0.2%	
2%	RO general	2.69	0.8%	Wine grapes	0.3%	Potatoes	0.3%	Tomatoes	0.2%	
2%	GEMS/Food G08	2.58	0.5%	Wine grapes	0.3%	Potatoes	0.2%	Soyabeans	0.2%	
2%	GEMS/Food G15	2.47	0.5%	Wine grapes	0.3%	Potatoes	0.2%	Soyabeans	0.2%	
2%	NL child	2.35	0.5%	Table grapes	0.3%	Potatoes	0.2%	Milk: Cattle	0.4%	
2%	FR adult	2.19	1%	Wine grapes	0.1%	Tomatoes	0.1%	Potatoes	0.1%	
1%	SE general	2.08	0.5%	Chinese cabbages/pe-tsai	0.3%	Potatoes	0.1%	Kales	0.2%	
1%	FR child 3–15 years	1.71	0.2%	Wine grapes	0.2%	Table grapes	0.2%	Milk: Cattle	0.3%	
1%	DE women 14–50 years	1.69	0.4%	Wine grapes	0.2%	Table grapes	0.1%	Tomatoes	0.2%	
1%	DE general	1.63	0.4%	Wine grapes	0.1%	Table grapes	0.1%	Potatoes	0.2%	
1%	NL general	1.62	0.3%	Wine grapes	0.2%	Potatoes	0.1%	Kales	0.2%	
0.9%	DK adult	1.28	0.5%	Wine grapes	0.1%	Potatoes	0.1%	Table grapes	0.1%	
0.9%	UK toddler	1.26	0.3%	Potatoes	0.1%	Milk: Cattle	0.1%	Table grapes	0.3%	
0.9%	UK adult	1.24	0.5%	Wine grapes	0.1%	Potatoes	0.1%	Tomatoes	0.1%	
0.9%	UK infant	1.23	0.3%	Milk: Cattle	0.3%	Potatoes	0.1%	Maize/corn	0.4%	
0.9%	FR toddler 2–3 years	1.22	0.2%	Milk: Cattle	0.2%	Potatoes	0.1%	Wine grapes	0.4%	
0.8%	UK vegetarian	1.17	0.4%	Wine grapes	0.1%	Potatoes	0.1%	Tomatoes	0.1%	
0.8%	DK child	1.16	0.2%	Potatoes	0.1%	Cucumbers	0.1%	Table grapes	0.3%	
0.8%	FI 3 years	1.15	0.4%	Potatoes	0.1%	Table grapes	0.1%	Tomatoes	0.1%	
0.8%	ES child	1.11	0.2%	Potatoes	0.1%	Tomatoes	0.1%	Lettuces	0.2%	
0.8%	ES adult	1.08	0.2%	Wine grapes	0.1%	Lettuces	0.1%	Tomatoes	0.1%	
0.7%	FI adult	1.02	0.2%	Coffee beans	0.2%	Wine grapes	0.1%	Potatoes	0.2%	
0.7%	FI 6 years	0.99	0.3%	Potatoes	0.1%	Table grapes	0.1%	Chinese cabbages/pe-tsai	0.1%	
0.7%	PL general	0.94	0.3%	Potatoes	0.2%	Table grapes	0.1%	Tomatoes	0.0%	
0.6%	IT toddler	0.85	0.2%	Tomatoes	0.1%	Potatoes	0.1%	Lettuces	0.1%	
0.6%	IT adult	0.80	0.2%	Tomatoes	0.1%	Lettuces	0.1%	Other leafy brassica	0.1%	
0.5%	LT adult	0.70	0.3%	Potatoes	0.1%	Tomatoes	0.0%	Milk: Cattle	0.1%	
0.4%	FR infant	0.61	0.2%	Potatoes	0.1%	Milk: Cattle	0.0%	Courgettes	0.2%	
0.1%	IE child	0.20	0.1%	Potatoes	0.0%	Table grapes	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 Oxathiapiprolin is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 1				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
197%	Kales/boiled	10/10	276	24%	Grape leaves/canned	40/40	33	118%	Kales/boiled	10/10	165	24%	Grape leaves/canned	40/40	33
22%	Wine grapes/juice	0.7/0.7	31	10%	Wine grapes/juice	0.7/0.7	15	22%	Wine grapes/juice	0.7/0.7	31	10%	Wine grapes/juice	0.7/0.7	15
5%	Potatoes/dried (flakes)	0.04/0.53	6.9	5%	Wine grapes/wine	0.7/0.7	6.6	5%	Potatoes/dried (flakes)	0.04/0.53	6.9	5%	Wine grapes/wine	0.7/0.7	6.6
3%	Tomatoes/juice	0.2/0.2	3.8	3%	Table grapes/raisins	0.7/3.29	4.0	3%	Tomatoes/juice	0.2/0.2	3.8	3%	Table grapes/raisins	0.7/3.29	4.0
3%	Potatoes/fried	0.04/0.04	3.7	2%	Courgettes/boiled	0.1/0.1	2.3	2%	Oranges/juice	0.05/0.06	3.0	1%	Tomatoes/sauce/puree	0.2/0.2	1.6
3%	Courgettes/boiled	0.1/0.1	3.5	1%	Tomatoes/sauce/puree	0.2/0.2	1.6	2%	Maize/oil	0.01/2.8	2.6	1%	Courgettes/boiled	0.1/0.1	1.6
2%	Oranges/juice	0.05/0.06	3.0	1%	Maize/oil	0.01/2.8	1.4	2%	Courgettes/boiled	0.1/0.1	2.1	1%	Maize/oil	0.01/2.8	1.4
2%	Maize/oil	0.01/2.8	2.6	0.7%	Potatoes/chips	0.04/0.12	0.98	1%	Tomatoes/sauce/puree	0.2/0.2	1.9	0.7%	Potatoes/chips	0.04/0.12	0.98
2%	Gherkins/pickled	0.1/0.1	2.3	0.6%	Oranges/juice	0.05/0.06	0.85	1%	Potatoes/fried	0.04/0.04	1.7	0.6%	Oranges/juice	0.05/0.06	0.85
1%	Sweet potatoes/boiled	0.04/0.04	2.0	0.5%	Cassava roots/boiled	0.04/0.04	0.76	0.8%	Sweet potatoes/boiled	0.04/0.04	1.1	0.5%	Potatoes/dried (flakes)	0.04/0.53	0.67
1%	Tomatoes/sauce/puree	0.2/0.2	1.9	0.5%	Potatoes/dried (flakes)	0.04/0.53	0.67	0.8%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.4%	Grapefruits/juice	0.05/0.06	0.61
0.8%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.4%	Sweet potatoes/boiled	0.04/0.04	0.62	0.7%	Gherkins/pickled	0.1/0.1	0.99	0.3%	Sweet potatoes/boiled	0.04/0.04	0.47
0.6%	Pumpkins/boiled	0.01/0.01	0.89	0.4%	Grapefruits/juice	0.05/0.06	0.61	0.5%	Soyabeans/soy milk	0.01/0.18	0.74	0.3%	Cassava roots/boiled	0.04/0.04	0.46
0.6%	Witloofs/boiled	0.01/0.01	0.87	0.4%	Pumpkins/boiled	0.01/0.01	0.55	0.5%	Raspberries/juice	0.5/0.06	0.66	0.3%	Sugar beets (root)/sugar	0.01/0.12	0.44
0.6%	Broccoli/boiled	0.01/0.01	0.79	0.3%	Sugar beets (root)/sugar	0.01/0.12	0.44	0.4%	Apples/juice	0.01/0.01	0.54	0.3%	Pumpkins/boiled	0.01/0.01	0.40
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Oxathiapiprolin 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; 2018/11/18

Ethiprole

LOQs (mg/kg) range from:	0.01	to:	0.15
Toxicological reference values			
ADI (mg/kg bw per day):	0.005	ARfD (mg/kg bw):	0.005
Source of ADI:	JMPR	Source of ARfD:	JMPR
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 : ---

	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)	29%	NL toddler	1.46	13%	Milk: Cattle	2%	Apples	2%	Rice	12%	
	16%	UK infant	0.81	9%	Milk: Cattle	2%	Rice	0.9%	Bovine: Muscle/meat	4%	
	16%	NL child	0.79	5%	Milk: Cattle	2%	Sugar beet roots	1%	Apples	7%	
	15%	FR child 3–15 years	0.75	5%	Milk: Cattle	1%	Rice	1%	Bovine: Muscle/meat	5%	
	15%	FR toddler 2–3 years	0.74	6%	Milk: Cattle	2%	Rice	0.9%	Bovine: Muscle/meat	4%	
	14%	DE child	0.72	4%	Milk: Cattle	2%	Apples	0.8%	Wheat	8%	
	12%	GEMS/Food G10	0.61	4%	Rice	1%	Milk: Cattle	0.8%	Wheat	5%	
	12%	UK toddler	0.61	5%	Milk: Cattle	2%	Rice	0.9%	Bovine: Muscle/meat	4%	
	12%	GEMS/Food G06	0.61	4%	Rice	1%	Wheat	0.7%	Tomatoes	6%	
	12%	DK child	0.58	3%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Rye	5%	
	11%	SE general	0.57	3%	Bovine: Muscle/meat	3%	Milk: Cattle	1%	Rice	4%	
	11%	ES child	0.55	3%	Milk: Cattle	1%	Rice	1%	Bovine: Muscle/meat	3%	
	11%	GEMS/Food G11	0.54	2%	Milk: Cattle	0.9%	Swine: Muscle/meat	0.8%	Rice	6%	
	10%	GEMS/Food G07	0.52	1%	Milk: Cattle	1.0%	Rice	0.8%	Wheat	5%	
	10%	GEMS/Food G15	0.52	2%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat	5%	
	10%	GEMS/Food G08	0.51	1%	Swine: Muscle/meat	1%	Milk: Cattle	0.8%	Wheat	5%	
	10%	RO general	0.48	3%	Milk: Cattle	1%	Wheat	0.8%	Swine: Muscle/meat	5%	
	9%	IE adult	0.44	1.0%	Milk: Cattle	0.7%	Sweet potatoes	0.6%	Rice	5%	
	8%	DE general	0.41	3%	Milk: Cattle	0.8%	Sugar beet roots	0.8%	Swine: Muscle/meat	4%	
	8%	DE women 14–50 years	0.41	3%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat	4%	
	8%	NL general	0.38	2%	Milk: Cattle	0.7%	Swine: Muscle/meat	0.6%	Sugar beet roots	3%	
	7%	FR infant	0.35	4%	Milk: Cattle	0.4%	Potatoes	0.3%	Apples	2%	
	6%	PT general	0.31	2%	Rice	1%	Potatoes	0.8%	Wheat	4%	
	6%	ES adult	0.31	1%	Milk: Cattle	0.7%	Rice	0.5%	Bovine: Muscle/meat	2%	
	6%	FR adult	0.29	1.0%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.5%	Wine grapes	2%	
	5%	DK adult	0.25	1%	Milk: Cattle	0.6%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat	2%	
	5%	LT adult	0.25	0.9%	Milk: Cattle	0.7%	Swine: Muscle/meat	0.6%	Potatoes	2%	
	5%	FI 3 years	0.24	2%	Rice	0.9%	Potatoes	0.3%	Bananas	3%	
	4%	FI adult	0.22	3%	Coffee beans	0.4%	Rice	0.2%	Potatoes	1%	
	4%	UK adult	0.22	1%	Rice	0.7%	Milk: Cattle	0.5%	Bovine: Muscle/meat	2%	
	4%	UK vegetarian	0.21	1%	Rice	0.7%	Milk: Cattle	0.4%	Wheat	2%	
	4%	IT toddler	0.19	1%	Wheat	0.5%	Rice	0.3%	Other cereals	3%	
	4%	FI 6 years	0.19	1%	Rice	0.8%	Potatoes	0.2%	Wheat	3%	
	3%	IE child	0.15	0.8%	Rice	0.8%	Milk: Cattle	0.3%	Swine: Fat tissue	0.7%	
	3%	IT adult	0.14	0.8%	Wheat	0.5%	Rice	0.2%	Tomatoes	2%	
	2%	PL general	0.10	0.7%	Potatoes	0.4%	Apples	0.2%	Tomatoes	2%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): 1				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): 1			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
35%	Rice	1.5/0.14	1.8	24%	Rice	1.5/0.14	1.2	378%	Rice	1.5/1.5	19	256%	Rice	1.5/1.5	13
31%	Potatoes	0.01/0.01	1.5	8%	Milk: Cattle	0.02/0.01	0.42	37%	Milk: Cattle	0.02/0.02	1.9	17%	Other farmed animals:	0.02/0.15	0.84
30%	Melons	0.01/0.01	1.5	8%	Head cabbages	0.01/0.01	0.42	21%	Other farmed animals:	0.02/0.15	1.0	12%	Milk: Cattle	0.02/0.02	0.58
28%	Pears	0.01/0.01	1.4	8%	Watermelons	0.01/0.01	0.41	18%	Melons	0.01/0.01	0.91	9%	Oranges	0.01/0.01	0.47
27%	Milk: Cattle	0.02/0.01	1.4	8%	Melons	0.01/0.01	0.39	16%	Bovine: Liver	0.1/0.1	0.81	8%	Bovine: Liver	0.1/0.1	0.40
27%	Oranges	0.01/0.01	1.3	7%	Swedes/rutabagas	0.01/0.01	0.34	15%	Watermelons	0.01/0.01	0.73	8%	Plums	0.01/0.01	0.39
24%	Watermelons	0.01/0.01	1.2	7%	Table grapes	0.01/0.01	0.34	15%	Bovine: Edible offals (other	0.1/0.1	0.73	7%	Pears	0.01/0.01	0.36
22%	Apples	0.01/0.01	1.1	6%	Bovine: Liver	0.1/0.08	0.32	13%	Oranges	0.01/0.01	0.67	7%	Bovine: Edible offals (other than	0.1/0.1	0.33
20%	Pineapples	0.01/0.01	1.0	6%	Oranges	0.01/0.01	0.31	13%	Potatoes	0.01/0.01	0.66	7%	Mandarins	0.01/0.01	0.33
19%	Bananas	0.01/0.01	0.97	6%	Pears	0.01/0.01	0.31	12%	Eggs: Chicken	0.05/0.05	0.62	6%	Potatoes	0.01/0.01	0.31
19%	Peaches	0.01/0.01	0.95	6%	Potatoes	0.01/0.01	0.30	12%	Apples	0.01/0.01	0.62	6%	Swine: Fat tissue	0.15/0.15	0.30
16%	Mangoes	0.01/0.01	0.79	6%	Pineapples	0.01/0.01	0.30	12%	Bananas	0.01/0.01	0.61	6%	Apples	0.01/0.01	0.30
16%	Grapefruits	0.01/0.01	0.79	6%	Yams	0.01/0.01	0.28	12%	Pineapples	0.01/0.01	0.61	6%	Sheep: Liver	0.1/0.1	0.28
15%	Table grapes	0.01/0.01	0.73	6%	Apples	0.01/0.01	0.28	12%	Pears	0.01/0.01	0.59	6%	Bananas	0.01/0.01	0.28
13%	Cucumbers	0.01/0.01	0.66	6%	Cucumbers	0.01/0.01	0.28	11%	Peaches	0.01/0.01	0.54	6%	Milk: Goat	0.02/0.02	0.28
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
22%	Sugar beets (root)/sugar	0.01/0.12	1.1	11%	Pumpkins/boiled	0.01/0.01	0.55	22%	Sugar beets (root)/sugar	0.01/0.12	1.1	11%	Rice/milling (polishing)	1.5/0.06	0.54
19%	Potatoes/fried	0.01/0.01	0.93	11%	Rice/milling (polishing)	1.5/0.06	0.54	17%	Rice/milling (polishing)	1.5/0.06	0.86	9%	Sugar beets (root)/sugar	0.01/0.12	0.44
18%	Pumpkins/boiled	0.01/0.01	0.89	9%	Sugar beets (root)/sugar	0.01/0.12	0.44	12%	Potatoes/dried (flakes)	0.01/0.05	0.59	8%	Pumpkins/boiled	0.01/0.01	0.40
17%	Witloofs/boiled	0.01/0.01	0.87	8%	Cauliflowers/boiled	0.01/0.01	0.42	11%	Apples/juice	0.01/0.01	0.54	7%	Apples/juice	0.01/0.01	0.33
17%	Rice/milling (polishing)	1.5/0.06	0.86	7%	Celeries/boiled	0.01/0.01	0.34	11%	Pumpkins/boiled	0.01/0.01	0.53	5%	Cauliflowers/boiled	0.01/0.01	0.25
16%	Broccoli/boiled	0.01/0.01	0.79	7%	Apples/juice	0.01/0.01	0.33	11%	Oranges/juice	0.01/0.01	0.53	4%	Witloofs/boiled	0.01/0.01	0.22
14%	Cauliflowers/boiled	0.01/0.01	0.70	5%	Broccoli/boiled	0.01/0.01	0.24	9%	Broccoli/boiled	0.01/0.01	0.47	4%	Wine grapes/juice	0.01/0.01	0.21
13%	Escaroles/broad-leaved	0.01/0.01	0.66	5%	Courgettes/boiled	0.01/0.01	0.23	9%	Witloofs/boiled	0.01/0.01	0.47	4%	Celeries/boiled	0.01/0.01	0.20
12%	Potatoes/dried (flakes)	0.01/0.05	0.59	4%	Beetroots/boiled	0.01/0.01	0.22	9%	Potatoes/fried	0.01/0.01	0.44	4%	Broccoli/boiled	0.01/0.01	0.20
11%	Leeks/boiled	0.01/0.01	0.57	4%	Parsnips/boiled	0.01/0.01	0.21	9%	Wine grapes/juice	0.01/0.01	0.44	4%	Rhubarbs/sauce/puree	0.01/0.01	0.19
11%	Apples/juice	0.01/0.01	0.54	4%	Kohlrabies/boiled	0.01/0.01	0.21	8%	Cauliflowers/boiled	0.01/0.01	0.42	3%	Beetroots/boiled	0.01/0.01	0.17
11%	Oranges/juice	0.01/0.01	0.53	4%	Wine grapes/juice	0.01/0.01	0.21	8%	Escaroles/broad-leaved	0.01/0.01	0.40	3%	Courgettes/boiled	0.01/0.01	0.16
10%	Turnips/boiled	0.01/0.01	0.51	4%	Escaroles/broad-leaved	0.01/0.01	0.20	7%	Carrots/juice	0.01/0.01	0.36	3%	Escaroles/broad-leaved endives/	0.01/0.01	0.16
10%	Parsnips/boiled	0.01/0.01	0.51	4%	Florence fennels/boiled	0.01/0.01	0.19	7%	Leeks/boiled	0.01/0.01	0.33	3%	Oranges/juice	0.01/0.01	0.15
10%	Sweet potatoes/boiled	0.01/0.01	0.50	4%	Turnips/boiled	0.01/0.01	0.19	7%	Pears/juice	0.01/0.01	0.33	3%	Leeks/boiled	0.01/0.01	0.14
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Ethiorole 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; 2018/11/18

Fluazinam (F) (F)

LOQs (mg/kg) range from: 0.01 to: 0.10

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.07
Source of ADI:	08/108	Source of ARfD:	08/108
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:

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)	84%	PT general	8.44	75%	Wine grapes	3%	Apples	3%	Tomatoes	2%	
	76%	FR adult	7.63	70%	Wine grapes	2%	Apples	1%	Tomatoes	2%	
	65%	RO general	6.55	50%	Wine grapes	6%	Tomatoes	4%	Apples	3%	
	62%	NL toddler	6.19	32%	Apples	13%	Pears	6%	Milk: Cattle	12%	
	56%	GEMS/Food G07	5.61	44%	Wine grapes	3%	Tomatoes	3%	Apples	4%	
	49%	DE child	4.94	37%	Apples	3%	Tomatoes	2%	Milk: Cattle	6%	
	46%	IE adult	4.60	38%	Wine grapes	2%	Apples	1%	Pears	3%	
	44%	GEMS/Food G08	4.37	31%	Wine grapes	4%	Apples	3%	Tomatoes	4%	
	44%	GEMS/Food G11	4.37	31%	Wine grapes	5%	Apples	3%	Tomatoes	4%	
	43%	GEMS/Food G15	4.26	30%	Wine grapes	4%	Tomatoes	3%	Apples	4%	
	40%	DE women 14–50 years	3.99	25%	Wine grapes	8%	Apples	2%	Tomatoes	4%	
	39%	DE general	3.90	25%	Wine grapes	7%	Apples	2%	Tomatoes	4%	
	37%	UK adult	3.69	32%	Wine grapes	1%	Tomatoes	1%	Apples	1%	
	36%	DK adult	3.58	29%	Wine grapes	3%	Apples	2%	Tomatoes	1%	
	30%	NL child	3.01	17%	Apples	4%	Pears	2%	Milk: Cattle	6%	
	30%	UK vegetarian	3.01	24%	Wine grapes	2%	Tomatoes	2%	Apples	1%	
	27%	NL general	2.75	18%	Wine grapes	4%	Apples	1%	Tomatoes	3%	
	26%	FR child 3–15 years	2.55	11%	Wine grapes	5%	Apples	3%	Tomatoes	6%	
	25%	FR toddler 2–3 years	2.49	10%	Apples	7%	Wine grapes	3%	Milk: Cattle	6%	
	25%	GEMS/Food G10	2.47	13%	Wine grapes	4%	Tomatoes	2%	Apples	4%	
	21%	GEMS/Food G06	2.09	11%	Tomatoes	3%	Apples	2%	Wine grapes	4%	
	21%	ES adult	2.06	12%	Wine grapes	2%	Tomatoes	2%	Apples	2%	
	19%	FI adult	1.93	9%	Wine grapes	6%	Coffee beans	2%	Apples	6%	
	16%	DK child	1.58	7%	Apples	2%	Pears	2%	Tomatoes	5%	
	14%	UK infant	1.39	5%	Apples	4%	Milk: Cattle	1%	Tomatoes	6%	
	14%	UK toddler	1.37	5%	Apples	2%	Milk: Cattle	2%	Tomatoes	4%	
	13%	ES child	1.25	3%	Apples	3%	Tomatoes	1%	Pears	4%	
	11%	SE general	1.13	3%	Apples	2%	Tomatoes	1%	Milk: Cattle	3%	
	11%	PL general	1.09	6%	Apples	3%	Tomatoes	0.8%	Pears	0.3%	
	10%	IT toddler	1.04	4%	Tomatoes	3%	Apples	1%	Wheat	2%	
	10%	FR infant	1.01	5%	Apples	2%	Milk: Cattle	1%	Wine grapes	3%	
	10%	LT adult	0.99	6%	Apples	2%	Tomatoes	0.6%	Potatoes	1%	
	8%	IT adult	0.82	3%	Tomatoes	2%	Apples	0.8%	Wheat	1%	
	8%	FI 3 years	0.78	3%	Apples	2%	Tomatoes	0.9%	Potatoes	2%	
	6%	FI 6 years	0.59	2%	Apples	1%	Tomatoes	0.8%	Potatoes	1%	
	2%	IE child	0.22	1.0%	Apples	0.4%	Milk: Cattle	0.2%	Wheat	0.8%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
59%	Pears	0.3/0.3	42
46%	Apples	0.3/0.3	32
40%	Wine grapes	3/3	28
26%	Blueberries	3/3	18
25%	Tomatoes	0.3/0.3	17
4%	Potatoes	0.02/0.02	3.1
2%	Melons	0.01/0.01	1.5
2%	Onions	0.06/0.06	1.4
2%	Oranges	0.01/0.01	1.3
2%	Milk: Cattle	0.01/0.01	1.2
2%	Watermelons	0.01/0.01	1.2
1%	Pineapples	0.01/0.01	1.0
1%	Bananas	0.01/0.01	0.97
1%	Peaches	0.01/0.01	0.95
1%	Mangoes	0.01/0.01	0.79

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
102%	Wine grapes	3/3	71
39%	Blueberries	3/3	27
13%	Pears	0.3/0.3	9.2
12%	Apples	0.3/0.3	8.4
7%	Tomatoes	0.3/0.3	4.8
3%	Valerian root	3/3	1.8
3%	Valerian root	3/3	1.8
1%	Onions	0.06/0.06	0.89
0.9%	Potatoes	0.02/0.02	0.60
0.6%	Head cabbages	0.01/0.01	0.42
0.6%	Watermelons	0.01/0.01	0.41
0.6%	Melons	0.01/0.01	0.39
0.6%	Milk: Cattle	0.01/0.01	0.39
0.5%	Swedes/rutabagas	0.01/0.01	0.34
0.5%	Table grapes	0.01/0.01	0.34

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
40%	Wine grapes	3/3	28
26%	Apples	0.3/0.3	18
26%	Blueberries	3/3	18
25%	Pears	0.3/0.3	18
13%	Tomatoes	0.3/0.3	9.1
2%	Potatoes	0.02/0.02	1.3
2%	Milk: Cattle	0.01/0.01	1.2
1%	Melons	0.01/0.01	0.91
1%	Carobs/Staint John's bread	0.1/0.1	0.79
1%	Watermelons	0.01/0.01	0.73
1.0%	Oranges	0.01/0.01	0.67
0.9%	Bananas	0.01/0.01	0.61
0.9%	Pineapples	0.01/0.01	0.61
0.9%	Valerian root	3/3	0.60
0.9%	Valerian root	3/3	0.60

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
102%	Wine grapes	3/3	71
39%	Blueberries	3/3	27
15%	Pears	0.3/0.3	11
13%	Apples	0.3/0.3	9.0
8%	Tomatoes	0.3/0.3	5.8
3%	Valerian root	3/3	1.8
3%	Valerian root	3/3	1.8
0.9%	Potatoes	0.02/0.02	0.62
0.7%	Oranges	0.01/0.01	0.47
0.6%	Plums	0.01/0.01	0.39
0.6%	Milk: Cattle	0.01/0.01	0.39
0.5%	Onions	0.06/0.06	0.38
0.5%	Mandarins	0.01/0.01	0.33
0.4%	Bananas	0.01/0.01	0.28
0.4%	Yams	0.01/0.01	0.27

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

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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 1	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
187%	Wine grapes/juice	3/3	131
23%	Apples/juice	0.3/0.3	16
14%	Pears/juice	0.3/0.3	9.8
8%	Tomatoes/juice	0.3/0.3	5.7
4%	Tomatoes/sauce/puree	0.3/0.3	2.9
3%	Potatoes/fried	0.02/0.02	1.9
2%	Potatoes/dried (flakes)	0.02/0.09	1.2
2%	Sugar beets (root)/sugar	0.01/0.12	1.1
1%	Shallots/boiled	0.06/0.06	0.97
1%	Pumpkins/boiled	0.01/0.01	0.89
1%	Witloofs/boiled	0.01/0.01	0.87
1%	Broccoli/boiled	0.01/0.01	0.79
1.0%	Cauliflowers/boiled	0.01/0.01	0.70
0.9%	Escaroles/broad-leaved end	0.01/0.01	0.66
0.8%	Leeks/boiled	0.01/0.01	0.57

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
89%	Wine grapes/juice	3/3	62
41%	Wine grapes/wine	3/3	28
14%	Apples/juice	0.3/0.3	10.0
4%	Tomatoes/sauce/puree	0.3/0.3	2.5
0.8%	Onions/boiled	0.06/0.06	0.56
0.8%	Pumpkins/boiled	0.01/0.01	0.55
0.7%	Coffee beans/extraction	0.1/0.02	0.48
0.6%	Sugar beets (root)/sugar	0.01/0.12	0.44
0.6%	Cauliflowers/boiled	0.01/0.01	0.42
0.5%	Shallots/boiled	0.06/0.06	0.37
0.5%	Celeries/boiled	0.01/0.01	0.34
0.4%	Maize/oil	0.02/0.5	0.25
0.3%	Broccoli/boiled	0.01/0.01	0.24
0.3%	Courgettes/boiled	0.01/0.01	0.23
0.3%	Beetroots/boiled	0.01/0.01	0.22

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
187%	Wine grapes/juice	3/3	131
23%	Apples/juice	0.3/0.3	16
14%	Pears/juice	0.3/0.3	9.8
8%	Tomatoes/juice	0.3/0.3	5.7
4%	Tomatoes/sauce/puree	0.3/0.3	2.9
2%	Potatoes/dried (flakes)	0.02/0.09	1.2
2%	Sugar beets (root)/sugar	0.01/0.12	1.1
1%	Potatoes/fried	0.02/0.02	0.87
0.8%	Pumpkins/boiled	0.01/0.01	0.53
0.8%	Oranges/juice	0.01/0.01	0.53
0.7%	Broccoli/boiled	0.01/0.01	0.47
0.7%	Witloofs/boiled	0.01/0.01	0.47
0.7%	Maize/oil	0.02/0.5	0.47
0.6%	Shallots/boiled	0.06/0.06	0.45
0.6%	Cauliflowers/boiled	0.01/0.01	0.42

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
89%	Wine grapes/juice	3/3	62
41%	Wine grapes/wine	3/3	28
14%	Apples/juice	0.3/0.3	10.0
4%	Tomatoes/sauce/puree	0.3/0.3	2.5
0.7%	Coffee beans/extraction	0.1/0.02	0.48
0.6%	Sugar beets (root)/sugar	0.01/0.12	0.44
0.6%	Onions/boiled	0.06/0.06	0.43
0.6%	Shallots/boiled	0.06/0.06	0.43
0.6%	Pumpkins/boiled	0.01/0.01	0.40
0.4%	Maize/oil	0.02/0.5	0.25
0.4%	Cauliflowers/boiled	0.01/0.01	0.25
0.3%	Witloofs/boiled	0.01/0.01	0.22
0.3%	Celeries/boiled	0.01/0.01	0.20
0.3%	Broccoli/boiled	0.01/0.01	0.20
0.3%	Rhubarbs/sauce/puree	0.01/0.01	0.19

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

For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2018/11/18

Fenpicoxamid (F) (R) (F)

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):	1.8
Source of ADI:	2018/1265	Source of ARfD:	2018/1265
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 : ---

	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)	1.0%	DK child	0.48	0.5%	Rye	0.4%	Wheat	0.0%	Bananas	0.0%	1.0%
	0.7%	GEMS/Food G06	0.35	0.7%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.7%
	0.6%	IT toddler	0.32	0.6%	Wheat	0.0%	Bananas				0.6%
	0.5%	NL toddler	0.26	0.4%	Wheat	0.1%	Bananas	0.0%	Rye	0.0%	0.5%
	0.5%	DE child	0.25	0.4%	Wheat	0.1%	Rye	0.0%	Bananas		0.5%
	0.5%	RO general	0.24	0.5%	Wheat	0.0%	Bananas				0.5%
	0.5%	GEMS/Food G15	0.23	0.4%	Wheat	0.0%	Rye	0.0%	Bananas	0.0%	0.5%
	0.4%	GEMS/Food G08	0.22	0.4%	Wheat	0.1%	Rye	0.0%	Bananas	0.0%	0.4%
	0.4%	FR child 3–15 years	0.22	0.4%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.4%
	0.4%	NL child	0.22	0.4%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.4%
	0.4%	ES child	0.22	0.4%	Wheat	0.0%	Bananas	0.0%	Bovine: Liver	0.0%	0.4%
	0.4%	GEMS/Food G07	0.21	0.4%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.4%
	0.4%	IT adult	0.20	0.4%	Wheat	0.0%	Bananas				0.4%
	0.4%	UK toddler	0.20	0.4%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.4%
	0.4%	PT general	0.19	0.4%	Wheat	0.0%	Rye	0.0%	Bananas		0.4%
	0.4%	GEMS/Food G10	0.19	0.4%	Wheat	0.0%	Rye	0.0%	Bananas	0.0%	0.4%
	0.4%	SE general	0.18	0.3%	Wheat	0.0%	Bananas	0.0%	Rye		0.4%
	0.3%	GEMS/Food G11	0.17	0.3%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.3%
	0.3%	FR toddler 2–3 years	0.15	0.3%	Wheat	0.0%	Bananas	0.0%	Bovine: Liver	0.0%	0.3%
	0.3%	UK infant	0.14	0.2%	Wheat	0.0%	Bananas	0.0%	Bovine: Liver	0.0%	0.3%
	0.3%	IE adult	0.13	0.2%	Wheat	0.0%	Bananas	0.0%	Rye		0.3%
	0.3%	DE women 14–50 years	0.13	0.2%	Wheat	0.0%	Rye	0.0%	Bananas	0.0%	0.3%
	0.2%	DE general	0.12	0.2%	Wheat	0.1%	Rye	0.0%	Bananas	0.0%	0.2%
	0.2%	ES adult	0.11	0.2%	Wheat	0.0%	Bananas	0.0%	Bovine: Liver	0.0%	0.2%
	0.2%	FR adult	0.11	0.2%	Wheat	0.0%	Bananas	0.0%	Bovine: Liver	0.0%	0.2%
	0.2%	UK vegetarian	0.10	0.2%	Wheat	0.0%	Bananas	0.0%	Rye		0.2%
	0.2%	LT adult	0.10	0.1%	Rye	0.1%	Wheat	0.0%	Bananas	0.0%	0.2%
	0.2%	FI 3 years	0.10	0.1%	Wheat	0.1%	Rye	0.0%	Bananas		0.2%
	0.2%	NL general	0.10	0.2%	Wheat	0.0%	Rye	0.0%	Bananas	0.0%	0.2%
	0.2%	UK adult	0.08	0.2%	Wheat	0.0%	Bananas	0.0%	Rye	0.0%	0.2%
	0.2%	DK adult	0.08	0.1%	Wheat	0.0%	Rye	0.0%	Bananas	0.0%	0.2%
	0.2%	FI 6 years	0.08	0.1%	Wheat	0.1%	Rye	0.0%	Bananas		0.2%
	0.1%	IE child	0.06	0.1%	Wheat	0.0%	Bananas				0.1%
	0.1%	FI adult	0.05	0.1%	Rye	0.0%	Wheat	0.0%	Bananas		0.1%
	0.1%	FR infant	0.04	0.1%	Wheat	0.0%	Bananas	0.0%	Sheep: Liver	0.0%	0.1%
	0.0%	PL general	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 Fenpicoxamid (F) (R) (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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)
0.05%	Bananas	0.15/0.01	0.97	0.02%	Wheat	0.6/0.05	0.39	0.5%	Bananas	0.15/0.15	9.2	0.3%	Wheat	0.6/0.6	5.0
0.04%	Wheat	0.6/0.05	0.68	0.01%	Rye	0.6/0.05	0.23	0.5%	Wheat	0.6/0.6	8.7	0.2%	Bananas	0.15/0.15	4.2
0.02%	Rye	0.6/0.05	0.30	0.01%	Bananas	0.15/0.01	0.21	0.2%	Rye	0.6/0.6	3.8	0.2%	Rye	0.6/0.6	2.9
0.00%	Bovine: Liver	0.01/0.01	0.08	0.00%	Sheep: Liver	0.02/0.02	0.04	0.00%	Bovine: Liver	0.01/0.01	0.08	0.00%	Sheep: Liver	0.02/0.02	0.06
0.00%	Bovine: Kidney	0.02/0.02	0.06	0.00%	Bovine: Liver	0.01/0.01	0.04	0.00%	Bovine: Kidney	0.02/0.02	0.08	0.00%	Bovine: Kidney	0.02/0.02	0.04
				0.00%	Bovine: Kidney	0.02/0.02	0.03					0.00%	Bovine: Liver	0.01/0.01	0.04
				0.00%	Sheep: Kidney	0.02/0.02	0.00					0.00%	Sheep: Kidney	0.02/0.02	0.00
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
0.0%	Wheat/milling (flour)	0.6/0.05	0.57	0.0%	Wheat/bread/pizza	0.6/0.05	0.21	0.03%	Wheat/milling (flour)	0.6/0.05	0.57	0.01%	Wheat/bread/pizza	0.6/0.05	0.21
0.0%	Wheat/milling (wholemeal)-l	0.6/0.05	0.26	0.01%	Wheat/pasta	0.6/0.05	0.18	0.01%	Wheat/milling	0.6/0.05	0.26	0.01%	Wheat/pasta	0.6/0.05	0.18
0.0%	Rye/boiled	0.6/0.05	0.17	0.01%	Wheat/bread (wholemeal)	0.6/0.05	0.16	0.01%	Rye/boiled	0.6/0.05	0.17	0.01%	Wheat/bread (wholemeal)	0.6/0.05	0.16
0.0%	Rye/milling (wholemeal)-bal	0.6/0.05	0.17					0.01%	Rye/milling (wholemeal)-	0.6/0.05	0.17				
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fenpicoxamid (F) (R) (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; 2018/11/18

Mandestrobin

LOQs (mg/kg) range from:	0.01	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.19	ARfD (mg/kg bw):	n.a.
Source of ADI:	Reg. (EU)	Source of ARfD:	Reg. (EU) 2015/2085
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:

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)	2%	DE child	3.13	0.6%	Cherries (sweet)	0.4%	Apricots	0.3%	Peaches	0.3%	
	1%	NL toddler	2.46	0.3%	Milk: Cattle	0.3%	Peaches	0.3%	Apricots	0.6%	
	0.9%	NL child	1.66	0.2%	Peaches	0.2%	Apricots	0.1%	Milk: Cattle	0.3%	
	0.8%	GEMS/Food G06	1.49	0.3%	Peaches	0.2%	Cherries (sweet)	0.1%	Apricots	0.2%	
	0.7%	IT toddler	1.36	0.4%	Peaches	0.1%	Cherries (sweet)	0.1%	Apricots	0.1%	
	0.7%	IE adult	1.36	0.3%	Peaches	0.1%	Apricots	0.1%	Plums	0.2%	
	0.7%	IT adult	1.31	0.4%	Peaches	0.1%	Apricots	0.1%	Cherries (sweet)	0.1%	
	0.7%	DE women 14–50 years	1.27	0.2%	Cherries (sweet)	0.2%	Peaches	0.1%	Apricots	0.2%	
	0.6%	RO general	1.20	0.2%	Cherries (sweet)	0.1%	Peaches	0.1%	Apricots	0.2%	
	0.6%	FR child 3–15 years	1.17	0.2%	Peaches	0.1%	Milk: Cattle	0.1%	Apricots	0.3%	
	0.6%	GEMS/Food G15	1.17	0.2%	Cherries (sweet)	0.1%	Peaches	0.1%	Plums	0.2%	
	0.6%	UK infant	1.17	0.2%	Milk: Cattle	0.1%	Apricots	0.1%	Cherries (sweet)	0.3%	
	0.6%	GEMS/Food G08	1.16	0.2%	Peaches	0.1%	Cherries (sweet)	0.1%	Apricots	0.2%	
	0.6%	DE general	1.14	0.2%	Cherries (sweet)	0.1%	Peaches	0.1%	Apricots	0.2%	
	0.6%	ES child	1.12	0.2%	Peaches	0.1%	Cherries (sweet)	0.1%	Milk: Cattle	0.2%	
	0.6%	PT general	1.07	0.4%	Peaches	0.1%	Cherries (sweet)	0.0%	Potatoes	0.1%	
	0.5%	GEMS/Food G10	0.97	0.2%	Peaches	0.1%	Cherries (sweet)	0.1%	Apricots	0.2%	
	0.5%	GEMS/Food G07	0.93	0.2%	Peaches	0.1%	Apricots	0.0%	Cherries (sweet)	0.2%	
	0.5%	ES adult	0.90	0.2%	Peaches	0.1%	Cherries (sweet)	0.0%	Apricots	0.1%	
	0.4%	SE general	0.80	0.2%	Peaches	0.1%	Milk: Cattle	0.0%	Apricots	0.2%	
	0.4%	DK child	0.72	0.1%	Peaches	0.1%	Milk: Cattle	0.0%	Rye	0.2%	
	0.4%	GEMS/Food G11	0.70	0.1%	Peaches	0.0%	Milk: Cattle	0.0%	Cherries (sweet)	0.2%	
	0.4%	FR toddler 2–3 years	0.69	0.2%	Milk: Cattle	0.0%	Apricots	0.0%	Peaches	0.3%	
	0.3%	UK toddler	0.66	0.1%	Milk: Cattle	0.1%	Peaches	0.0%	Wheat	0.2%	
	0.3%	FR adult	0.63	0.1%	Peaches	0.0%	Cherries (sweet)	0.0%	Apricots	0.1%	
	0.3%	NL general	0.61	0.1%	Peaches	0.0%	Cherries (sweet)	0.0%	Milk: Cattle	0.2%	
	0.3%	PL general	0.57	0.1%	Cherries (sweet)	0.1%	Peaches	0.0%	Plums	0.0%	
	0.3%	FI 3 years	0.53	0.1%	Peaches	0.0%	Apricots	0.0%	Potatoes	0.1%	
	0.2%	FI adult	0.42	0.1%	Coffee beans	0.0%	Peaches	0.0%	Potatoes	0.2%	
	0.2%	FI 6 years	0.40	0.1%	Peaches	0.0%	Potatoes	0.0%	Cherries (sweet)	0.1%	
	0.2%	FR infant	0.36	0.1%	Milk: Cattle	0.0%	Apricots	0.0%	Peaches	0.2%	
	0.2%	DK adult	0.33	0.1%	Peaches	0.0%	Milk: Cattle	0.0%	Plums	0.1%	
	0.2%	UK vegetarian	0.29	0.0%	Peaches	0.0%	Apricots	0.0%	Milk: Cattle	0.1%	
	0.1%	LT adult	0.25	0.0%	Cherries (sweet)	0.0%	Milk: Cattle	0.0%	Potatoes	0.1%	
	0.1%	UK adult	0.25	0.0%	Peaches	0.0%	Milk: Cattle	0.0%	Apricots	0.1%	
	0.1%	IE child	0.12	0.0%	Milk: Cattle	0.0%	Cherries (sweet)	0.0%	Peaches	0.0%	

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
27%	Peaches/canned	1/2	52	8%	Peaches/canned	2/2	16	20%	Peaches/canned	1/2	39	9%	Peaches/canned	2/2	16
17%	Peaches/juice	2/2	33	0.3%	Pumpkins/boiled	0.01/0.01	0.55	17%	Peaches/juice	2/2	33	0.2%	Sugar beets (root)/sugar	0.01/0.12	0.44
2%	Plums/juice	0.5/0.5	4.7	0.2%	Sugar beets (root)/sugar	0.01/0.12	0.44	2%	Plums/juice	0.5/0.5	4.7	0.2%	Pumpkins/boiled	0.01/0.01	0.40
0.6%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.2%	Cauliflowers/boiled	0.01/0.01	0.42	0.6%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.2%	Apples/juice	0.01/0.01	0.33
0.5%	Potatoes/fried	0.01/0.01	0.93	0.2%	Celeries/boiled	0.01/0.01	0.34	0.3%	Potatoes/dried (flakes)	0.01/0.05	0.59	0.1%	Cauliflowers/boiled	0.01/0.01	0.25
0.5%	Pumpkins/boiled	0.01/0.01	0.89	0.2%	Apples/juice	0.01/0.01	0.33	0.3%	Apples/juice	0.01/0.01	0.54	0.1%	Coffee beans/extraction	0.05/0.01	0.24
0.5%	Witloofs/boiled	0.01/0.01	0.87	0.1%	Broccoli/boiled	0.01/0.01	0.24	0.3%	Pumpkins/boiled	0.01/0.01	0.53	0.1%	Witloofs/boiled	0.01/0.01	0.22
0.4%	Broccoli/boiled	0.01/0.01	0.79	0.1%	Coffee beans/extraction	0.05/0.01	0.24	0.3%	Oranges/juice	0.01/0.01	0.53	0.1%	Wine grapes/juice	0.01/0.01	0.21
0.4%	Cauliflowers/boiled	0.01/0.01	0.70	0.1%	Courgettes/boiled	0.01/0.01	0.23	0.2%	Broccoli/boiled	0.01/0.01	0.47	0.1%	Celeries/boiled	0.01/0.01	0.20
0.3%	Escaroles/broad-leaved end	0.01/0.01	0.66	0.1%	Beetroots/boiled	0.01/0.01	0.22	0.2%	Witloofs/boiled	0.01/0.01	0.47	0.1%	Broccoli/boiled	0.01/0.01	0.20
0.3%	Potatoes/dried (flakes)	0.01/0.05	0.59	0.1%	Parsnips/boiled	0.01/0.01	0.21	0.2%	Potatoes/fried	0.01/0.01	0.44	0.1%	Rhubarbs/sauce/puree	0.01/0.01	0.19
0.3%	Leeks/boiled	0.01/0.01	0.57	0.1%	Kohlrabies/boiled	0.01/0.01	0.21	0.2%	Wine grapes/juice	0.01/0.01	0.44	0.09%	Beetroots/boiled	0.01/0.01	0.17
0.3%	Apples/juice	0.01/0.01	0.54	0.1%	Wine grapes/juice	0.01/0.01	0.21	0.2%	Cauliflowers/boiled	0.01/0.01	0.42	0.08%	Courgettes/boiled	0.01/0.01	0.16
0.3%	Oranges/juice	0.01/0.01	0.53	0.1%	Escaroles/broad-leaved	0.01/0.01	0.20	0.2%	Escaroles/broad-leaved	0.01/0.01	0.40	0.08%	Escaroles/broad-leaved endives/	0.01/0.01	0.16
0.3%	Turnips/boiled	0.01/0.01	0.51	0.1%	Florence fennels/boiled	0.01/0.01	0.19	0.2%	Carrots/juice	0.01/0.01	0.36	0.08%	Oranges/juice	0.01/0.01	0.15
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 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

Norflurazon (F)

LOQs (mg/kg) range from: 0.01 to: 0.02

Toxicological reference values

ADI (mg/kg bw per day):	0.005	ARfD (mg/kg bw):	0.3
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2018	Year of evaluation:	2018

Input values

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

Comments:

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)	14%	NL toddler	0.71	2%	Apples	2%	Milk: Cattle	1%	Maize/corn	12%	2%
	8%	NL child	0.42	2%	Sugar beet roots	1%	Apples	0.8%	Wheat	7%	0.9%
	8%	DE child	0.41	2%	Apples	0.8%	Wheat	0.8%	Oranges	8%	0.6%
	7%	GEMS/Food G06	0.35	1%	Wheat	0.7%	Tomatoes	0.4%	Potatoes	7%	0.2%
	6%	GEMS/Food G11	0.30	0.8%	Potatoes	0.7%	Soyabeans	0.7%	Wheat	6%	0.3%
	6%	GEMS/Food G07	0.29	0.8%	Wheat	0.8%	Potatoes	0.4%	Soyabeans	5%	0.6%
	6%	FR child 3–15 years	0.29	0.9%	Wheat	0.7%	Sugar beet roots	0.7%	Oranges	5%	0.8%
	6%	GEMS/Food G08	0.29	0.8%	Wheat	0.8%	Potatoes	0.4%	Soyabeans	5%	0.3%
	6%	IE adult	0.29	0.7%	Sweet potatoes	0.5%	Wheat	0.5%	Potatoes	5%	0.6%
	6%	GEMS/Food G15	0.28	0.9%	Wheat	0.7%	Potatoes	0.3%	Soyabeans	5%	0.5%
	6%	GEMS/Food G10	0.28	0.8%	Wheat	0.7%	Soyabeans	0.6%	Potatoes	5%	0.3%
	5%	DK child	0.26	1%	Rye	0.9%	Wheat	0.5%	Potatoes	5%	0.6%
	5%	UK infant	0.26	1%	Milk: Cattle	0.7%	Potatoes	0.5%	Wheat	4%	1%
	5%	FR toddler 2–3 years	0.26	0.8%	Milk: Cattle	0.6%	Apples	0.6%	Wheat	4%	1.0%
	5%	RO general	0.25	1%	Wheat	0.7%	Potatoes	0.4%	Tomatoes	5%	0.4%
	5%	UK toddler	0.25	0.8%	Wheat	0.7%	Potatoes	0.6%	Sugar beet roots	4%	0.7%
	4%	DE women 14–50 years	0.22	0.9%	Sugar beet roots	0.5%	Apples	0.4%	Wheat	4%	0.4%
	4%	SE general	0.22	0.8%	Potatoes	0.6%	Wheat	0.4%	Bananas	4%	0.4%
	4%	DE general	0.21	0.8%	Sugar beet roots	0.5%	Apples	0.4%	Wheat	4%	0.4%
	4%	PT general	0.21	1%	Potatoes	0.8%	Wheat	0.5%	Wine grapes	4%	
	4%	ES child	0.21	0.9%	Wheat	0.4%	Oranges	0.4%	Potatoes	4%	0.5%
	4%	NL general	0.19	0.6%	Sugar beet roots	0.5%	Potatoes	0.4%	Wheat	3%	0.3%
	3%	FI 3 years	0.17	0.9%	Potatoes	0.3%	Bananas	0.2%	Wheat	3%	
	3%	IT toddler	0.16	1%	Wheat	0.3%	Other cereals	0.3%	Tomatoes	3%	
	3%	FR adult	0.14	0.5%	Wine grapes	0.4%	Wheat	0.2%	Sugar beet roots	3%	0.3%
	3%	FR infant	0.14	0.5%	Milk: Cattle	0.4%	Potatoes	0.3%	Apples	2%	0.5%
	3%	ES adult	0.13	0.5%	Wheat	0.3%	Oranges	0.2%	Potatoes	2%	0.2%
	3%	FI 6 years	0.13	0.8%	Potatoes	0.2%	Wheat	0.2%	Bananas	3%	
	3%	FI adult	0.13	1%	Coffee beans	0.2%	Potatoes	0.1%	Rye	3%	
	2%	IT adult	0.12	0.8%	Wheat	0.2%	Tomatoes	0.2%	Apples	2%	
	2%	UK vegetarian	0.11	0.4%	Wheat	0.3%	Potatoes	0.2%	Oranges	2%	0.1%
	2%	LT adult	0.11	0.6%	Potatoes	0.4%	Apples	0.2%	Rye	2%	0.2%
	2%	DK adult	0.10	0.3%	Potatoes	0.2%	Wheat	0.2%	Apples	2%	0.3%
	2%	PL general	0.10	0.7%	Potatoes	0.4%	Apples	0.2%	Tomatoes	2%	
	2%	UK adult	0.10	0.3%	Wheat	0.3%	Potatoes	0.2%	Wine grapes	2%	0.1%
	0.8%	IE child	0.04	0.2%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle	0.7%	0.1%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
0.6%	Bovine: Liver	0.3/0.22	1.8
0.5%	Bovine: Edible offals (other	0.3/0.22	1.6
0.5%	Potatoes	0.01/0.01	1.5
0.5%	Melons	0.01/0.01	1.5
0.5%	Pears	0.01/0.01	1.4
0.4%	Oranges	0.01/0.01	1.3
0.4%	Watermelons	0.01/0.01	1.2
0.4%	Apples	0.01/0.01	1.1
0.3%	Pineapples	0.01/0.01	1.0
0.3%	Bananas	0.01/0.01	0.97
0.3%	Peaches	0.01/0.01	0.95
0.3%	Bovine: Kidney	0.3/0.22	0.83
0.3%	Mangoes	0.01/0.01	0.79
0.3%	Grapefruits	0.01/0.01	0.79
0.2%	Table grapes	0.01/0.01	0.73

Expand/collapse list

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

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%	Bovine: Liver	0.3/0.22	0.88
0.2%	Bovine: Edible offals (other	0.3/0.22	0.73
0.2%	Sheep: Liver	0.3/0.22	0.62
0.2%	Swine: Edible offals (other	0.3/0.22	0.57
0.2%	Swine: Kidney	0.3/0.22	0.48
0.2%	Bovine: Kidney	0.3/0.22	0.46
0.1%	Head cabbages	0.01/0.01	0.42
0.1%	Watermelons	0.01/0.01	0.41
0.1%	Melons	0.01/0.01	0.39
0.1%	Swedes/rutabagas	0.01/0.01	0.34
0.1%	Table grapes	0.01/0.01	0.34
0.1%	Swine: Liver	0.3/0.22	0.31
0.1%	Oranges	0.01/0.01	0.31
0.1%	Pears	0.01/0.01	0.31
0.10%	Potatoes	0.01/0.01	0.30

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Milk: Cattle	0.02/0.02	2.5
0.8%	Bovine: Liver	0.3/0.3	2.4
0.7%	Bovine: Edible offals (other	0.3/0.3	2.2
0.4%	Bovine: Kidney	0.3/0.3	1.1
0.3%	Melons	0.01/0.01	0.91
0.3%	Swine: Edible offals (other	0.3/0.3	0.90
0.2%	Watermelons	0.01/0.01	0.73
0.2%	Oranges	0.01/0.01	0.67
0.2%	Potatoes	0.01/0.01	0.66
0.2%	Apples	0.01/0.01	0.62
0.2%	Bananas	0.01/0.01	0.61
0.2%	Pineapples	0.01/0.01	0.61
0.2%	Pears	0.01/0.01	0.59
0.2%	Peaches	0.01/0.01	0.54
0.2%	Apricots	0.01/0.01	0.49

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Bovine: Liver	0.3/0.3	1.2
0.3%	Bovine: Edible offals (other than	0.3/0.3	1.00
0.3%	Sheep: Liver	0.3/0.3	0.84
0.3%	Swine: Edible offals (other than	0.3/0.3	0.78
0.3%	Milk: Cattle	0.02/0.02	0.77
0.2%	Swine: Kidney	0.3/0.3	0.66
0.2%	Bovine: Kidney	0.3/0.3	0.63
0.2%	Oranges	0.01/0.01	0.47
0.1%	Swine: Liver	0.3/0.3	0.42
0.1%	Plums	0.01/0.01	0.39
0.1%	Milk: Goat	0.02/0.02	0.37
0.1%	Pears	0.01/0.01	0.36
0.1%	Mandarins	0.01/0.01	0.33
0.1%	Potatoes	0.01/0.01	0.31
0.1%	Milk: Sheep	0.02/0.02	0.30

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): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
0.4%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.2%	Pumpkins/boiled	0.01/0.01	0.55	0.4%	Sugar beets (root)/sugar	0.01/0.12	1.1	0.1%	Sugar beets (root)/sugar	0.01/0.12	0.44
0.3%	Potatoes/fried	0.01/0.01	0.93	0.1%	Sugar beets (root)/sugar	0.01/0.12	0.44	0.2%	Potatoes/dried (flakes)	0.01/0.05	0.59	0.1%	Pumpkins/boiled	0.01/0.01	0.40
0.3%	Pumpkins/boiled	0.01/0.01	0.89	0.1%	Cauliflowers/boiled	0.01/0.01	0.42	0.2%	Apples/juice	0.01/0.01	0.54	0.1%	Apples/juice	0.01/0.01	0.33
0.3%	Broccoli/boiled	0.01/0.01	0.79	0.1%	Celeries/boiled	0.01/0.01	0.34	0.2%	Pumpkins/boiled	0.01/0.01	0.53	0.08%	Cauliflowers/boiled	0.01/0.01	0.25
0.2%	Cauliflowers/boiled	0.01/0.01	0.70	0.1%	Apples/juice	0.01/0.01	0.33	0.2%	Oranges/juice	0.01/0.01	0.53	0.07%	Witloofs/boiled	0.01/0.01	0.22
0.2%	Leeks/boiled	0.01/0.01	0.69	0.08%	Broccoli/boiled	0.01/0.01	0.24	0.2%	Broccoli/boiled	0.01/0.01	0.47	0.07%	Wine grapes/juice	0.01/0.01	0.21
0.2%	Escaroles/broad-leaved end	0.01/0.01	0.66	0.08%	Courgettes/boiled	0.01/0.01	0.23	0.2%	Rhubarbs/sauce/puree	0.01/0.01	0.46	0.07%	Celeries/boiled	0.01/0.01	0.20
0.2%	Head cabbages/boiled	0.01/0.01	0.64	0.07%	Beetroots/boiled	0.01/0.01	0.22	0.1%	Potatoes/fried	0.01/0.01	0.44	0.07%	Broccoli/boiled	0.01/0.01	0.20
0.2%	Potatoes/dried (flakes)	0.01/0.05	0.59	0.07%	Kohlrabies/boiled	0.01/0.01	0.21	0.1%	Wine grapes/juice	0.01/0.01	0.44	0.06%	Rhubarbs/sauce/puree	0.01/0.01	0.19
0.2%	Apples/juice	0.01/0.01	0.54	0.07%	Wine grapes/juice	0.01/0.01	0.21	0.1%	Cauliflowers/boiled	0.01/0.01	0.42	0.06%	Beetroots/boiled	0.01/0.01	0.17
0.2%	Oranges/juice	0.01/0.01	0.53	0.07%	Escaroles/broad-leaved	0.01/0.01	0.20	0.1%	Escaroles/broad-leaved	0.01/0.01	0.40	0.05%	Courgettes/boiled	0.01/0.01	0.16
0.2%	Parsnips/boiled	0.01/0.01	0.51	0.06%	Florence fennels/boiled	0.01/0.01	0.19	0.1%	Head cabbages/boiled	0.01/0.01	0.38	0.05%	Escaroles/broad-leaved endives/	0.01/0.01	0.16
0.2%	Sweet potatoes/boiled	0.01/0.01	0.50	0.06%	Cassava roots/boiled	0.01/0.01	0.19	0.1%	Carrots/juice	0.01/0.01	0.36	0.05%	Oranges/juice	0.01/0.01	0.15
0.2%	Witloofs/boiled	0.01/0.01	0.49	0.06%	Witloofs/boiled	0.01/0.01	0.18	0.1%	Spinaches/frozen; boiled	0.01/0.01	0.33	0.05%	Leeks/boiled	0.01/0.01	0.14
0.2%	Florence fennels/boiled	0.01/0.01	0.45	0.06%	Celeriacs/boiled	0.01/0.01	0.18	0.1%	Pears/juice	0.01/0.01	0.33	0.04%	Currants (red, black and white)/	0.01/0.01	0.13
0.1%	Rhubarbs/sauce/puree	0.01/0.01	0.45	0.06%	Leeks/boiled	0.01/0.01	0.17	0.10%	Leeks/boiled	0.01/0.01	0.30	0.04%	Maize/oil	0.01/0.25	0.13
0.1%	Beetroots/boiled	0.01/0.01	0.44	0.05%	Sweet potatoes/boiled	0.01/0.01	0.15	0.10%	Currants (red, black and	0.01/0.01	0.29	0.04%	Florence fennels/boiled	0.01/0.01	0.12
0.1%	Wine grapes/juice	0.01/0.01	0.44	0.05%	Oranges/juice	0.01/0.01	0.15	0.09%	Sweet potatoes/boiled	0.01/0.01	0.28	0.04%	Sweet potatoes/boiled	0.01/0.01	0.12
0.1%	Carrots/juice	0.01/0.01	0.36	0.05%	Rhubarbs/sauce/puree	0.01/0.01	0.15	0.09%	Florence fennels/boiled	0.01/0.01	0.27	0.04%	Cassava roots/boiled	0.01/0.01	0.11
0.1%	Courgettes/boiled	0.01/0.01	0.35	0.04%	Peaches/canned	0.01/0.01	0.13	0.09%	Witloofs/boiled	0.01/0.01	0.26	0.04%	Celeriacs/boiled	0.01/0.01	0.11
0.1%	Spinaches/frozen; boiled	0.01/0.01	0.33	0.04%	Currants (red, black and	0.01/0.01	0.13	0.08%	Maize/oil	0.01/0.25	0.23	0.04%	Grapefruits/juice	0.01/0.01	0.11
0.1%	Pears/juice	0.01/0.01	0.33	0.04%	Maize/oil	0.01/0.25	0.13	0.07%	Salsifies/boiled	0.01/0.01	0.22	0.03%	Wine grapes/wine	0.01/0.01	0.09
0.1%	Chards/beet leaves/boiled	0.01/0.01	0.31	0.04%	Chards/beet leaves/boiled	0.01/0.01	0.13	0.07%	Parsnips/boiled	0.01/0.01	0.22	0.03%	Elderberries/juice	0.01/0.01	0.09
0.1%	Currants (red, black and wh	0.01/0.01	0.29	0.04%	Cardoons/boiled	0.01/0.01	0.12	0.07%	Jerusalem artichokes/	0.01/0.01	0.22	0.03%	Kohlrabies/boiled	0.01/0.01	0.09
0.1%	Kales/boiled	0.01/0.01	0.28	0.04%	Grapefruits/juice	0.01/0.01	0.11	0.07%	Courgettes/boiled	0.01/0.01	0.21	0.03%	Jerusalem artichokes/boiled	0.01/0.01	0.09
0.1%	Salsifies/boiled	0.01/0.01	0.26	0.03%	Wine grapes/wine	0.01/0.01	0.09	0.06%	Tomatoes/juice	0.01/0.01	0.19	0.03%	Jerusalem artichokes/boiled	0.01/0.01	0.09
0.1%	Jerusalem artichokes/boiled	0.01/0.01	0.26	0.03%	Onions/boiled	0.01/0.01	0.09	0.06%	Beetroots/boiled	0.01/0.01	0.19	0.03%	Salsifies/boiled	0.01/0.01	0.09
0.1%	Maize/oil	0.01/0.25	0.23	0.03%	Elderberries/juice	0.01/0.01	0.09	0.06%	Kiwi fruits/juice	0.01/0.01	0.18	0.03%	Pineapples/juice	0.01/0.01	0.09
0.1%	Gherkins/pickled	0.01/0.01	0.23	0.03%	Pineapples/juice	0.01/0.01	0.09	0.06%	Peaches/juice	0.01/0.01	0.17	0.03%	Chards/beet leaves/boiled	0.01/0.01	0.09
0.1%	Peaches/canned	0.01/0.01	0.21	0.03%	Spinaches/frozen; boiled	0.01/0.01	0.08	0.06%	Kales/boiled	0.01/0.01	0.17	0.03%	Spinaches/frozen; boiled	0.01/0.01	0.08
0.1%	Tomatoes/juice	0.01/0.01	0.19	0.03%	Salsifies/boiled	0.01/0.01	0.08	0.05%	Elderberries/juice	0.01/0.01	0.16	0.03%	Carrots/canned	0.01/0.01	0.08
0.1%	Kiwi fruits/juice	0.01/0.01	0.18	0.03%	Carrots/canned	0.01/0.01	0.08	0.05%	Pineapples/juice	0.01/0.01	0.14	0.03%	Pineapples/canned	0.01/0.01	0.08
0.1%	Peaches/juice	0.01/0.01	0.17	0.03%	Jerusalem artichokes/	0.01/0.01	0.08	0.05%	Celeriacs/juice	0.01/0.01	0.14	0.02%	Barley/beer	0.01/0	0.07
0.1%	Shallots/boiled	0.01/0.01	0.16	0.02%	Barley/beer	0.01/0	0.07	0.04%	Chards/beet leaves/boiled	0.01/0.01	0.13	0.02%	Onions/boiled	0.01/0.01	0.07
0.1%	Elderberries/juice	0.01/0.01	0.16	0.02%	Beans/canned	0.01/0.01	0.07	0.04%	Beans (with pods)/boiled	0.01/0.01	0.13	0.02%	Beans/canned	0.01/0.01	0.07
0.1%	Pineapples/canned	0.01/0.01	0.16	0.02%	Shallots/boiled	0.01/0.01	0.06	0.04%	Wheat/milling (flour)	0.01/0.01	0.12	0.02%	Shallots/boiled	0.01/0.01	0.07
0.0%	Pineapples/juice	0.01/0.01	0.14	0.02%	Potatoes/dried (flakes)	0.01/0.05	0.06	0.04%	Raspberries/juice	0.01/0.01	0.12	0.02%	Peaches/canned	0.01/0.01	0.06
0.0%	Celeriacs/juice	0.01/0.01	0.14	0.02%	Head cabbages/canned	0.01/0.01	0.05	0.03%	Brussels sprouts/boiled	0.01/0.01	0.10	0.02%	Potatoes/dried (flakes)	0.01/0.05	0.06
0.0%	Beans (with pods)/boiled	0.01/0.01	0.13	0.02%	Beans (without pods)/	0.01/0.01	0.05	0.03%	Gherkins/pickled	0.01/0.01	0.10	0.02%	Head cabbages/canned	0.01/0.01	0.05
0.0%	Wheat/milling (flour)	0.01/0.01	0.12	0.02%	Coffee beans/extraction	0.01/0	0.05	0.03%	Plums/juice	0.01/0.01	0.09	0.02%	Beans (without pods)/boiled	0.01/0.01	0.05
0.0%	Raspberries/juice	0.01/0.01	0.12	0.01%	Wheat/bread/pizza	0.01/0.01	0.04	0.03%	Pineapples/canned	0.01/0.01	0.09	0.02%	Palm hearts/canned	0.01/0.01	0.05
0.0%	Brussels sprouts/boiled	0.01/0.01	0.10	0.01%	Purslanes/boiled	0.01/0.01	0.04	0.03%	Sugar canes/sugar	0.01/0.01	0.09	0.02%	Coffee beans/extraction	0.01/0	0.05
0.0%	Plums/juice	0.01/0.01	0.09	0.01%	Rice/milling (polishing)	0.01/0	0.04	0.03%	Peaches/canned	0.01/0.01	0.09	0.01%	Wheat/bread/pizza	0.01/0.01	0.04
0.0%	Sugar canes/sugar	0.01/0.01	0.09	0.01%	Wheat/pasta	0.01/0.01	0.04	0.03%	Coconuts/milk	0.01/0.01	0.09	0.01%	Purslanes/boiled	0.01/0.01	0.04
0.0%	Coconuts/milk	0.01/0.01	0.09	0.01%	Coconuts/milk	0.01/0.01	0.04	0.03%	Lentils/boiled	0.01/0.01	0.08	0.01%	Rice/milling (polishing)	0.01/0	0.04
0.0%	Lentils/boiled	0.01/0.01	0.08	0.01%	Peas (with pods)/boiled	0.01/0.01	0.03	0.03%	Peas (without pods)/	0.01/0.01	0.08	0.01%	Wheat/pasta	0.01/0.01	0.04
0.0%	Peas (without pods)/canned	0.01/0.01	0.08	0.01%	Tomatoes/sauce/puree	0.01/0.01	0.03	0.03%	Passion fruits/juice	0.01/0.01	0.08	0.01%	Coconuts/milk	0.01/0.01	0.04
0.0%	Passion fruits/juice	0.01/0.01	0.08	0.01%	Peas (without pods)/boiled	0.01/0.01	0.03	0.02%	Peas/canned	0.01/0	0.07	0.01%	Peas (with pods)/boiled	0.01/0.01	0.03
0.0%	Peas/canned	0.01/0	0.07	0.01%	Turnips/boiled	0.01/0.01	0.03	0.02%	Shallots/boiled	0.01/0.01	0.07	0.01%	Tomatoes/sauce/puree	0.01/0.01	0.03
0.0%	Rice/milling (polishing)	0.01/0	0.06	0.01%	Peas/canned	0.01/0	0.03	0.02%	Rice/milling (polishing)	0.01/0	0.06	0.01%	Peas (without pods)/boiled	0.01/0.01	0.03
0.0%	Cranberries/juice	0.01/0.01	0.06	0.01%	Pineapples/canned	0.01/0.01	0.03	0.02%	Cranberries/juice	0.01/0.01	0.06	0.01%	Turnips/boiled	0.01/0.01	0.03
0.0%	Azarole (mediteranean med	0.01/0.01	0.06	0.01%	Potatoes/chips	0.01/0.01	0.03	0.02%	Azarole (mediteranean	0.01/0.01	0.06	0.01%	Peas/canned	0.01/0	0.03
0.0%	Wheat/milling (wholemeal)-l	0.01/0.01	0.06	0.01%	Table grapes/raisins	0.01/0.05	0.02	0.02%	Wheat/milling	0.01/0.01	0.06	0.01%	Potatoes/chips	0.01/0.01	0.03
0.0%	Millet/boiled	0.01/0	0.05	0.01%	Lemons/juice	0.01/0.01	0.02	0.02%	Millet/boiled	0.01/0	0.05	0.01%	Table grapes/raisins	0.01/0.05	0.02
0.0%	Buckwheat/bulgur and grits	0.01/0.01	0.05	0.01%	Wheat/bread (wholemeal)	0.01/0.01	0.02	0.02%	Buckwheat/bulgur and	0.01/0.01	0.05	0.01%	Lemons/juice	0.01/0.01	0.02
0.0%	Cultivated fungi/fried	0.01/0.01	0.05	0.01%	Litchis/canned	0.01/0.01	0.02	0.02%	Cultivated fungi/fried	0.01/0.01	0.05	0.01%	Wheat/bread (wholemeal)	0.01/0.01	0.02
0.0%	Soyabeans/soy milk	0.01/0.01	0.04	0.01%	Litchis/canned	0.01/0.01	0.02	0.01%	Soyabeans/soy milk	0.01/0.01	0.04	0.01%	Litchis/canned	0.01/0.01	0.02
0.0%	Litchis/canned	0.01/0.01	0.04	0.01%	Okra, lady's fingers/boiled	0.01/0.01	0.02	0.01%	Litchis/canned	0.01/0.01	0.04	0.01%	Okra, lady's fingers/boiled	0.01/0.01	0.02
0.0%	Rye/boiled	0.01/0.01	0.04	0.00%	Quinces/jam	0.01/0.01	0.01	0.01%	Rye/boiled	0.01/0.01	0.04	0.00%	Quinces/jam	0.01/0.01	0.01
0.0%	Oat/boiled	0.01/0.01	0.04	0.00%	Quinces/jam	0.01/0.01	0.01	0.01%	Oat/boiled	0.01/0.01	0.04	0.00%	Quinces/jam	0.01/0.01	0.01
0.0%	Buckwheat/boiled	0.01/0.01	0.04	0.00%	Quinces/jam	0.01/0.01	0.01	0.01%	Buckwheat/boiled	0.01/0.01	0.04	0.00%	Quinces/jam	0.01/0.01	0.01
0.0%	Barley/cooked	0.01/0.01	0.04	0.00%	Grape leaves/canned	0.01/0.01	0.01	0.01%	Barley/cooked	0.01/0.01	0.04	0.00%	Grape leaves/canned	0.01/0.01	0.01
0.0%	Peanuts/peanut butter	0.01/0.01	0.04	0.00%	Sugar canes/sugar	0.01/0.01	0.01	0.01%	Peanuts/peanut butter	0.01/0.01	0.04	0.00%	Sugar canes/sugar	0.01/0.01	0.01
0.0%	Rye/milling (wholemeal)-bal	0.01/0.01	0.04	0.00%	Carob (st johns bread)/	0.01/0.01	0.01	0.01%	Rye/milling (wholemeal)-	0.01/0.01	0.04	0.00%	Carob (st johns bread)/flour	0.01/0.01	0.01
0.0%	Lemons/jam	0.01/0.01	0.03	0.00%	Cranberries/dried	0.01/0.01	0.01	0.01%	Lemons/jam	0.01/0.01	0.03	0.00%	Cranberries/dried	0.01/0.01	0.01
0.0%	Lemons/jam	0.01/0.01	0.03	0.00%	Cocoa (fermented beans)/	0.01/0	0.01	0.01%	Lemons/jam	0.01/0.01	0.03	0.00%	Cocoa (fermented beans)/	0.01/0	0.01
0.0%	Lemons/jam	0.01/0.01	0.03	0.00%	Chicory roots/processed	0.01/0.01	0.00	0.01%	Lemons/jam	0.01/0.01	0.03	0.00%	Chicory roots/processed (not	0.01/0.01	0.00
0.0%	Lemons/jam	0.01/0.01	0.03	0.00%	Arrowroots/starch	0.01/0.01	0.00	0.01%	Lemons/jam	0.01/0.01	0.03	0.00%	Arrowroots/starch	0.01/0.01	0.00
0.0%	Oat/milling (flakes)	0.01/0.01	0.03	0.00%	Tea (dried leaves of	0.01/0	0.00	0.01%	Oat/milling (flakes)	0.01/0.01	0.03	0.00%	Tea (dried leaves of Camellia	0.01/0	0.00
0.0%	Figs/jam	0.01/0.01	0.03	0.00%	Hops/beer	0.01/0	0.00	0.01%	Figs/jam	0.01/0.01	0.03	0.00%	Hops/beer	0.01/0	0.00
0.0%	Pomegranates/juice	0.01/0.01	0.03	0.00%	Soursop/juice	0.01/0.01	0.00	0.01%	Pomegranates/juice	0.01/0.01	0.03	0.00%	Soursop/juice	0.01/0.01	0.00
0.0%	Sunflower seeds/oils	0.01/0.02	0.02	0.00%	Cumin seed/processed	0.01/0.01	0.00	0.01%	Sunflower seeds/oils	0.01/0.02	0.02	0.00%	Cumin seed/processed (not	0.01/0.01	0.00
0.0%	Wild fungi/canned	0.01/0.01	0.02	0.00%	Rooibos leaves/infusion	0.01/0	0.00	0.01%	Wild fungi/canned	0.01/0.01	0.02	0.00%	Rooibos leaves/infusion	0.01/0	0.00
0.0%	Coffee beans/extraction	0.01/0	0.02	0.00%	Camomille flowers/infusion	0.01/0	0.00	0.01%	Coffee beans/extraction	0.01/0	0.02	0.00%	Camomille flowers/infusion	0.01/0	0.00
0.0%	Olives for oil production/oils	0.01/0.02	0.02	0.00%	Turmeric (Curcuma)/boiled	0.01/0.01	0.00	0.01%	Olives for oil production/	0.01/0.02	0.02	0.00%	Turmeric (Curcuma)/boiled	0.01/0.01	0.00
0.0%	Barley/milling (flour)	0.01/0.01	0.02	0.00%	Cinnamon/processed (not	0.01/0.01	0.00	0.01%	Barley/milling (flour)	0.01/0.01	0.02	0.00%	Cinnamon/processed (not	0.01/0.01	0.00
0.0%	Guavas/juice	0.01/0.01	0.02	0.00%	Hybiscus flowers/infusion	0.01/0	0.00	0.01%	Guavas/juice	0.01/0.01	0.02	0.00%	Hybiscus flowers/infusion	0.01/0	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 Norflurazon (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; 2018/11/18

Pydiflumetofen (F)

LOQs (mg/kg) range from:	0.01	to:	0.07
Toxicological reference values			
ADI (mg/kg bw per day):	0.09	ARfD (mg/kg bw):	0.3
Source of ADI:	Peer review	Source of ARfD:	Peer review (not
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 : ---

	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)	0.9%	PT general	0.80	0.8%	Wine grapes	0.1%	Table grapes				0.9%
	0.8%	FR adult	0.71	0.7%	Wine grapes	0.0%	Table grapes				0.8%
	0.6%	RO general	0.54	0.5%	Wine grapes	0.1%	Table grapes				0.6%
	0.6%	GEMS/Food G07	0.53	0.5%	Wine grapes	0.1%	Table grapes				0.6%
	0.5%	NL toddler	0.45	0.5%	Table grapes		FRUIT AND TREE NUTS				0.5%
	0.5%	IE adult	0.44	0.4%	Wine grapes	0.1%	Table grapes				0.5%
	0.5%	GEMS/Food G11	0.42	0.3%	Wine grapes	0.1%	Table grapes				0.5%
	0.4%	DE child	0.40	0.4%	Table grapes	0.0%	Wine grapes				0.4%
	0.4%	GEMS/Food G08	0.40	0.3%	Wine grapes	0.1%	Table grapes				0.4%
	0.4%	GEMS/Food G15	0.39	0.3%	Wine grapes	0.1%	Table grapes				0.4%
	0.4%	DE women 14–50 years	0.33	0.3%	Wine grapes	0.1%	Table grapes				0.4%
	0.4%	UK adult	0.33	0.3%	Wine grapes	0.0%	Table grapes				0.4%
	0.4%	DK adult	0.33	0.3%	Wine grapes	0.1%	Table grapes				0.4%
	0.4%	GEMS/Food G06	0.32	0.3%	Table grapes	0.0%	Wine grapes				0.4%
	0.4%	DE general	0.32	0.3%	Wine grapes	0.1%	Table grapes				0.4%
	0.3%	NL child	0.30	0.3%	Table grapes	0.0%	Wine grapes				0.3%
	0.3%	UK vegetarian	0.26	0.3%	Wine grapes	0.0%	Table grapes				0.3%
	0.3%	NL general	0.24	0.2%	Wine grapes	0.1%	Table grapes				0.3%
	0.2%	GEMS/Food G10	0.21	0.1%	Wine grapes	0.1%	Table grapes				0.2%
	0.2%	FR child 3–15 years	0.21	0.1%	Wine grapes	0.1%	Table grapes				0.2%
	0.1%	ES adult	0.13	0.1%	Wine grapes	0.0%	Table grapes				0.1%
	0.1%	FI adult	0.11	0.1%	Wine grapes	0.0%	Table grapes				0.1%
	0.1%	PL general	0.09	0.1%	Table grapes		FRUIT AND TREE NUTS				0.1%
	0.1%	UK toddler	0.08	0.1%	Table grapes	0.0%	Wine grapes				0.1%
	0.1%	FR toddler 2–3 years	0.07	0.1%	Wine grapes	0.0%	Table grapes				0.1%
	0.1%	FI 3 years	0.07	0.1%	Table grapes	0.0%	Wine grapes				0.1%
	0.1%	DK child	0.05	0.1%	Table grapes		FRUIT AND TREE NUTS				0.1%
	0.1%	FI 6 years	0.05	0.1%	Table grapes	0.0%	Wine grapes				0.1%
	0.0%	IT adult	0.04	0.0%	Table grapes		FRUIT AND TREE NUTS				0.0%
	0.0%	IT toddler	0.03	0.0%	Table grapes		FRUIT AND TREE NUTS				0.0%
	0.0%	IE child	0.02	0.0%	Table grapes		FRUIT AND TREE NUTS				0.0%
	0.0%	ES child	0.01	0.0%	Table grapes	0.0%	Wine grapes				0.0%
	0.0%	UK infant	0.01	0.0%	Table grapes	0.0%	Wine grapes				0.0%
	0.0%	FR infant	0.01	0.0%	Wine grapes	0.0%	Table grapes				0.0%
	0.0%	LT adult	0.00	0.0%	Table grapes		FRUIT AND TREE NUTS				0.0%
		Column7			FRUIT AND TREE NUTS		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 Pydiflumetofen (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Table grapes	1.5/0.85	62
3%	Wine grapes	1.5/0.85	7.9

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Table grapes	1.5/0.85	29
7%	Wine grapes	1.5/0.85	20

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
22%	Table grapes	1.5/1.5	66
5%	Wine grapes	1.5/1.5	14

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Wine grapes	1.5/1.5	36
10%	Table grapes	1.5/1.5	31

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Wine grapes/juice	1.5/0.02	0.76

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Table grapes/raisins	1.5/2.08	2.6
0.8%	Wine grapes/wine	1.5/0.27	2.5
0.1%	Wine grapes/juice	1.5/0.02	0.36

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Wine grapes/juice	1.5/0.02	0.76

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Table grapes/raisins	1.5/2.08	2.6
0.8%	Wine grapes/wine	1.5/0.27	2.5
0.1%	Wine grapes/juice	1.5/0.02	0.36

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Pydiflumetofen (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; 2018/11/18

Pyriofenone

LOQs (mg/kg) range from:	0.01	to:	1.5
Toxicological reference values			
ADI (mg/kg bw per day):	0.07	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA 2013	Source of ARfD:	EFSA 2013
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)
	2%	NL toddler	1.71	0.9%	Milk: Cattle	0.2%	Table grapes	0.2%	Currants (red, black and white)	2%	
	1%	DE child	1.02	0.3%	Milk: Cattle	0.2%	Table grapes	0.2%	Apples	0.8%	
	1%	NL child	1.01	0.3%	Milk: Cattle	0.1%	Table grapes	0.1%	Currants (red, black and white)	0.8%	
	1%	GEMS/Food G06	0.92	0.3%	Watermelons	0.2%	Table grapes	0.1%	Cucumbers	0.4%	
	1%	RO general	0.89	0.6%	Wine grapes	0.2%	Milk: Cattle	0.1%	Watermelons	0.4%	
	1%	IE adult	0.86	0.4%	Wine grapes	0.2%	Melons	0.1%	Milk: Cattle	0.4%	
	1%	GEMS/Food G07	0.82	0.5%	Wine grapes	0.1%	Milk: Cattle	0.1%	Wheat	0.4%	
	1%	GEMS/Food G15	0.81	0.3%	Wine grapes	0.1%	Watermelons	0.1%	Milk: Cattle	0.4%	
	1%	PT general	0.81	0.8%	Wine grapes	0.1%	Potatoes	0.1%	Wheat	0.2%	
	1%	FR child 3–15 years	0.79	0.3%	Milk: Cattle	0.1%	Wine grapes	0.1%	Melons	0.7%	
	1%	GEMS/Food G08	0.79	0.3%	Wine grapes	0.1%	Milk: Cattle	0.1%	Wheat	0.4%	
	1%	FR adult	0.79	0.8%	Wine grapes	0.1%	Milk: Cattle	0.0%	Melons	0.2%	
	1%	DK child	0.77	0.4%	Cucumbers	0.2%	Milk: Cattle	0.1%	Rye	0.4%	
	1%	GEMS/Food G11	0.72	0.3%	Wine grapes	0.1%	Milk: Cattle	0.1%	Table grapes	0.5%	
	1.0%	UK infant	0.68	0.6%	Milk: Cattle	0.1%	Strawberries	0.0%	Potatoes	0.8%	
	1.0%	DE women 14–50 years	0.67	0.3%	Wine grapes	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.4%	
	1.0%	FR toddler 2–3 years	0.67	0.4%	Milk: Cattle	0.1%	Wine grapes	0.0%	Apples	0.7%	
	0.9%	GEMS/Food G10	0.65	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Cucumbers	0.4%	
	0.9%	DE general	0.64	0.3%	Wine grapes	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.4%	
	0.9%	UK toddler	0.61	0.3%	Milk: Cattle	0.1%	Currants (red, black and white)	0.1%	Wheat	0.6%	
	0.8%	SE general	0.55	0.2%	Milk: Cattle	0.1%	Cucumbers	0.1%	Bovine: Muscle/meat	0.5%	
	0.8%	FI 3 years	0.54	0.2%	Cucumbers	0.1%	Strawberries	0.1%	Raspberries (red and yellow)	0.2%	
	0.7%	NL general	0.51	0.2%	Wine grapes	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.4%	
	0.7%	DK adult	0.47	0.3%	Wine grapes	0.1%	Milk: Cattle	0.1%	Cucumbers	0.2%	
	0.6%	ES child	0.44	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Watermelons	0.4%	
	0.6%	FR infant	0.43	0.2%	Milk: Cattle	0.1%	Courgettes	0.0%	Strawberries	0.4%	
	0.6%	UK adult	0.41	0.4%	Wine grapes	0.0%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.6%	FI 6 years	0.40	0.2%	Cucumbers	0.1%	Strawberries	0.1%	Watermelons	0.1%	
	0.6%	UK vegetarian	0.39	0.3%	Wine grapes	0.0%	Milk: Cattle	0.0%	Wheat	0.2%	
	0.5%	ES adult	0.36	0.1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Melons	0.2%	
	0.4%	FI adult	0.31	0.1%	Wine grapes	0.1%	Cucumbers	0.1%	Coffee beans	0.1%	
	0.4%	IT toddler	0.25	0.1%	Wheat	0.0%	Courgettes	0.0%	Strawberries	0.1%	
	0.4%	LT adult	0.25	0.1%	Cucumbers	0.1%	Milk: Cattle	0.0%	Potatoes	0.2%	
	0.3%	IT adult	0.22	0.1%	Wheat	0.0%	Courgettes	0.0%	Melons	0.1%	
	0.2%	PL general	0.17	0.0%	Potatoes	0.0%	Table grapes	0.0%	Apples	0.1%	
	0.1%	IE child	0.10	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Currants (red, black and white)	0.1%	

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	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	IESTI new	IESTI new
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)	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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	**IESTI new**	**IESTI new**
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)	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; 2018/11/18

Tioxazafen

LOQs (mg/kg) range from: 0.01 to: 4.0

Toxicological reference values

ADI (mg/kg bw per day):	0.05	ARfD (mg/kg bw):	0.5
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 : ---

	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)	4%	NL toddler	1.88	2%	Milk: Cattle	0.2%	Apples	0.1%	Maize/corn	1%	0.1%
	3%	FR toddler 2–3 years	1.57	1%	Milk: Goat	1%	Milk: Cattle	0.1%	Apples	0.4%	0.1%
	2%	FR child 3–15 years	1.01	0.9%	Milk: Cattle	0.4%	Milk: Goat	0.1%	Wheat	0.5%	0.1%
	2%	UK infant	1.01	2%	Milk: Cattle	0.1%	Potatoes	0.1%	Eggs: Chicken	0.4%	0.0%
	2%	NL child	0.98	1.0%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Milk: Goat	0.8%	0.1%
	2%	DE child	0.87	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Wheat	0.8%	0.0%
	2%	GEMS/Food G06	0.84	0.5%	Milk: Goat	0.4%	Milk: Sheep	0.1%	Wheat	0.6%	0.1%
	1%	DE women 14–50 years	0.73	0.5%	Milk: Cattle	0.3%	Milk: Sheep	0.2%	Milk: Goat	0.4%	0.0%
	1%	GEMS/Food G15	0.71	0.5%	Milk: Sheep	0.3%	Milk: Cattle	0.1%	Wheat	0.5%	0.1%
	1%	UK toddler	0.66	0.8%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.5%	0.0%
	1%	DE general	0.65	0.5%	Milk: Cattle	0.2%	Milk: Sheep	0.2%	Milk: Goat	0.4%	0.0%
	1%	DK child	0.54	0.5%	Milk: Cattle	0.1%	Rye	0.1%	Wheat	0.5%	0.1%
	1%	ES child	0.53	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Milk: Goat	0.4%	0.1%
	1%	GEMS/Food G07	0.51	0.3%	Milk: Cattle	0.1%	Milk: Goat	0.1%	Wheat	0.5%	0.1%
	1%	SE general	0.51	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Potatoes	0.4%	0.1%
	1.0%	RO general	0.50	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.5%	0.0%
	1.0%	GEMS/Food G11	0.48	0.3%	Milk: Cattle	0.1%	Soyabeans	0.1%	Potatoes	0.5%	0.2%
	1.0%	GEMS/Food G08	0.48	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Milk: Goat	0.5%	0.1%
	1.0%	GEMS/Food G10	0.48	0.2%	Milk: Cattle	0.1%	Milk: Goat	0.1%	Soyabeans	0.5%	0.2%
	1.0%	FR infant	0.48	0.7%	Milk: Cattle	0.0%	Potatoes	0.0%	Milk: Goat	0.2%	0.0%
	0.9%	FR adult	0.45	0.4%	Milk: Goat	0.2%	Milk: Cattle	0.0%	Wine grapes	0.3%	0.0%
	0.8%	NL general	0.38	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Potatoes	0.4%	0.0%
	0.7%	IE adult	0.37	0.2%	Milk: Cattle	0.1%	Sweet potatoes	0.0%	Wheat	0.5%	0.0%
	0.5%	ES adult	0.27	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Milk: Goat	0.3%	0.0%
	0.4%	DK adult	0.22	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.2%	0.0%
	0.4%	PT general	0.21	0.1%	Potatoes	0.1%	Wheat	0.0%	Wine grapes	0.4%	0.0%
	0.4%	LT adult	0.20	0.2%	Milk: Cattle	0.1%	Potatoes	0.0%	Apples	0.2%	0.0%
	0.4%	UK vegetarian	0.18	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.0%
	0.3%	UK adult	0.17	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.0%
	0.3%	FI 3 years	0.17	0.1%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.3%	0.0%
	0.3%	IT toddler	0.16	0.1%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.3%	0.0%
	0.3%	FI 6 years	0.13	0.1%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.3%	0.0%
	0.3%	FI adult	0.13	0.1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.3%	0.0%
	0.2%	IT adult	0.12	0.1%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.2%	0.0%
	0.2%	IE child	0.12	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.0%
	0.2%	PL general	0.10	0.1%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.2%	0.0%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
0.07%	Poultry: Muscle/meat	0.01/0.02	0.34
0.05%	Swine: Muscle/meat	0.01/0.02	0.24
0.04%	Bovine: Liver	0.03/0.03	0.20
0.04%	Bovine: Edible offals (other	0.03/0.03	0.18
0.03%	Bovine: Muscle/meat	0.01/0.02	0.14
0.03%	Other farmed animals:	0.01/0.02	0.14
0.02%	Equine: Muscle/meat	0.01/0.02	0.12
0.02%	Sheep: Muscle/meat	0.01/0.02	0.11
0.02%	Bovine: Kidney	0.03/0.03	0.09
0.02%	Soyabeans	0.04/0.04	0.09
0.02%	Swine: Edible offals (other	0.03/0.03	0.08
0.01%	Bovine: Fat tissue	0.03/0.03	0.05
0.01%	Swine: Fat tissue	0.03/0.03	0.04
0.01%	Swine: Kidney	0.03/0.03	0.03
0.01%	Swine: Liver	0.03/0.03	0.03

Expand/collapse list

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

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)
0.05%	Poultry: Muscle	0.01/0.02	0.23
0.04%	Soyabeans	0.04/0.04	0.22
0.02%	Bovine: Muscle	0.01/0.02	0.11
0.02%	Other farmed animals:	0.01/0.02	0.11
0.02%	Bovine: Liver	0.03/0.03	0.10
0.02%	Swine: Muscle/meat	0.01/0.02	0.10
0.02%	Equine: Muscle/meat	0.01/0.02	0.10
0.02%	Sheep: Muscle/meat	0.01/0.02	0.09
0.02%	Poultry: Liver	0.01/0.02	0.09
0.02%	Bovine: Edible offals (other	0.03/0.03	0.08
0.01%	Sheep: Liver	0.03/0.03	0.07
0.01%	Swine: Edible offals (other	0.03/0.03	0.07
0.01%	Swine: Kidney	0.03/0.03	0.06
0.01%	Bovine: Kidney	0.03/0.03	0.05
0.01%	Swine: Fat tissue	0.03/0.03	0.05

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.05%	Bovine: Liver	0.03/0.03	0.24
0.04%	Bovine: Edible offals (other	0.03/0.03	0.22
0.03%	Poultry: Muscle/meat	0.01/0.01	0.17
0.02%	Swine: Muscle/meat	0.01/0.01	0.12
0.02%	Bovine: Kidney	0.03/0.03	0.11
0.02%	Soyabeans	0.04/0.04	0.09
0.02%	Swine: Edible offals (other	0.03/0.03	0.09
0.01%	Bovine: Muscle/meat	0.01/0.01	0.07
0.01%	Other farmed animals:	0.01/0.01	0.07
0.01%	Bovine: Fat tissue	0.03/0.03	0.06
0.01%	Equine: Muscle/meat	0.01/0.01	0.06
0.01%	Sheep: Muscle/meat	0.01/0.01	0.05
0.01%	Swine: Fat tissue	0.03/0.03	0.05
0.01%	Swine: Kidney	0.03/0.03	0.04
0.01%	Swine: Liver	0.03/0.03	0.04

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Soyabeans	0.04/0.04	0.22
0.02%	Bovine: Liver	0.03/0.03	0.12
0.02%	Poultry: Muscle	0.01/0.01	0.12
0.02%	Bovine: Edible offals (other than	0.03/0.03	0.10
0.02%	Sheep: Liver	0.03/0.03	0.08
0.02%	Swine: Edible offals (other than	0.03/0.03	0.08
0.01%	Swine: Kidney	0.03/0.03	0.07
0.01%	Bovine: Kidney	0.03/0.03	0.06
0.01%	Swine: Fat tissue	0.03/0.03	0.06
0.01%	Bovine: Muscle	0.01/0.01	0.06
0.01%	Other farmed animals:	0.01/0.01	0.06
0.01%	Swine: Muscle/meat	0.01/0.01	0.05
0.01%	Equine: Muscle/meat	0.01/0.01	0.05
0.01%	Sheep: Muscle/meat	0.01/0.01	0.05
0.01%	Poultry: Liver	0.01/0.01	0.05

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/soy milk	0.04/0.01	0.05
0.0%	Soyabeans/boiled	0.04/0.01	0.02

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)

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Soyabeans/soy milk	0.04/0.01	0.05
0.00%	Soyabeans/boiled	0.04/0.01	0.02

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

IESTI new

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 Tioxazafen 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

Imazalil

LOQs (mg/kg) range from:	0.01	to:	0.02
Toxicological reference values			
ADI (mg/kg bw per day):	0.025	ARfD (mg/kg bw):	0.05
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)
	61%	NL toddler	15.32	44%	Potatoes	10%	Milk: Cattle	3%	Strawberries		51%
	57%	PT general	14.20	55%	Potatoes	0.3%	Strawberries	0.3%	Oranges		57%
	56%	FI 3 years	13.92	49%	Potatoes	3%	Strawberries	2%	Cucumbers		56%
	50%	SE general	12.52	43%	Potatoes	2%	Milk: Cattle	1%	Strawberries		47%
	46%	NL child	11.51	36%	Potatoes	4%	Milk: Cattle	3%	Strawberries		42%
	45%	FI 6 years	11.34	40%	Potatoes	2%	Strawberries	1%	Cucumbers		45%
	45%	GEMS/Food G11	11.17	41%	Potatoes	1%	Milk: Cattle	0.8%	Strawberries		43%
	45%	GEMS/Food G08	11.15	41%	Potatoes	0.9%	Milk: Cattle	0.8%	Strawberries		43%
	44%	UK toddler	11.02	36%	Potatoes	3%	Milk: Cattle	2%	Strawberries		40%
	44%	UK infant	10.94	34%	Potatoes	6%	Milk: Cattle	2%	Strawberries		37%
	43%	GEMS/Food G07	10.82	39%	Potatoes	1%	Milk: Cattle	0.7%	Oranges		42%
	43%	RO general	10.74	39%	Potatoes	2%	Milk: Cattle	0.6%	Tomatoes		41%
	41%	GEMS/Food G15	10.23	37%	Potatoes	1%	Milk: Cattle	0.4%	Strawberries		39%
	39%	DE child	9.86	27%	Potatoes	4%	Strawberries	3%	Milk: Cattle		36%
	36%	PL general	9.12	36%	Potatoes	0.3%	Tomatoes	0.2%	Strawberries		36%
	35%	LT adult	8.82	33%	Potatoes	0.8%	Cucumbers	0.6%	Milk: Cattle		34%
	35%	GEMS/Food G10	8.81	31%	Potatoes	0.9%	Strawberries	0.9%	Milk: Cattle		34%
	33%	DK child	8.30	25%	Potatoes	3%	Cucumbers	2%	Milk: Cattle		31%
	29%	IE adult	7.30	24%	Potatoes	1%	Strawberries	0.7%	Milk: Cattle		28%
	29%	NL general	7.23	25%	Potatoes	1%	Milk: Cattle	0.7%	Strawberries		27%
	28%	FR toddler 2–3 years	6.96	19%	Potatoes	5%	Milk: Cattle	1%	Strawberries		23%
	26%	GEMS/Food G06	6.48	21%	Potatoes	1%	Cucumbers	1%	Tomatoes		25%
	25%	FR child 3–15 years	6.14	16%	Potatoes	4%	Milk: Cattle	2%	Strawberries		20%
	25%	FR infant	6.13	20%	Potatoes	3%	Milk: Cattle	1%	Strawberries		22%
	24%	ES child	6.06	19%	Potatoes	2%	Milk: Cattle	1%	Oranges		22%
	18%	DE general	4.44	13%	Potatoes	2%	Milk: Cattle	0.9%	Strawberries		16%
	17%	DE women 14–50 years	4.20	11%	Potatoes	2%	Milk: Cattle	1.0%	Strawberries		15%
	17%	UK vegetarian	4.15	14%	Potatoes	0.6%	Strawberries	0.5%	Milk: Cattle		16%
	16%	UK adult	4.10	15%	Potatoes	0.5%	Milk: Cattle	0.4%	Strawberries		16%
	16%	DK adult	3.95	13%	Potatoes	0.8%	Milk: Cattle	0.6%	Strawberries		15%
	15%	FI adult	3.73	12%	Potatoes	1%	Strawberries	0.7%	Cucumbers		15%
	13%	ES adult	3.14	10%	Potatoes	0.8%	Milk: Cattle	0.6%	Oranges		11%
	12%	IT toddler	2.90	9%	Potatoes	1.0%	Strawberries	0.5%	Tomatoes		12%
	10%	FR adult	2.59	8%	Potatoes	1.0%	Strawberries	0.7%	Milk: Cattle		9%
	8%	IT adult	1.91	6%	Potatoes	0.4%	Strawberries	0.4%	Tomatoes		8%
	7%	IE child	1.84	6%	Potatoes	0.6%	Milk: Cattle	0.2%	Strawberries		7%

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

Acute risk assessment/children	Acute risk assessment/adults/general population	Acute risk assessment/children	Acute risk assessment/adults/general population
Details–acute risk assessment/children	Details–acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children	Results for adults	IESTI new Results for children	IESTI new Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1	No. of commodities for which ARfD/ADI is exceeded (IESTI): 1	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 7	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 6

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1415%	Potatoes	9/4.6	707
72%	Oranges	10/0.27	36
66%	Cucumbers	0.5/0.5	33
65%	Strawberries	2/2	33
42%	Grapefruits	10/0.27	21
42%	Mandarins	15/0.36	21
25%	Lemons	15/0.36	12
20%	Blackberries	2/0.94	10
19%	Bananas	3/0.1	9.7
19%	Tomatoes	0.3/0.16	9.3
17%	Raspberries (red and	2/0.94	8.7
14%	Limes	15/0.36	7.2
10%	Milk: Cattle	0.02/0.04	5.0
9%	Bovine: Liver	0.3/0.53	4.3
8%	Bovine: Edible offals (other	0.3/0.53	3.9

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
275%	Potatoes	9/4.6	137
37%	Strawberries	2/2	19
28%	Cucumbers	0.5/0.5	14
17%	Oranges	10/0.27	8.3
15%	Blackberries	2/0.94	7.7
13%	Mandarins	15/0.36	6.5
10%	Raspberries (red and	2/0.94	5.1
10%	Grapefruits	10/0.27	4.8
6%	Lemons	15/0.36	3.2
6%	Gherkins	0.5/0.5	3.0
5%	Tomatoes	0.3/0.16	2.5
5%	Limes	15/0.36	2.5
4%	Bovine: Liver	0.3/0.53	2.1
4%	Bananas	3/0.1	2.1
4%	Bovine: Edible offals (other	0.3/0.53	1.8

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1337%	Oranges	10/10	668
1186%	Potatoes	9/9	593
1021%	Mandarins	15/15	510
942%	Grapefruits	10/10	471
699%	Lemons	15/15	350
368%	Bananas	3/3	184
259%	Limes	15/15	129
65%	Strawberries	2/2	33
43%	Blackberries	2/2	21
39%	Cucumbers	0.5/0.5	20
37%	Raspberries (red and	2/2	18
26%	Sweet peppers/bell	0.5/0.5	13
18%	Tomatoes	0.3/0.3	9.1
5%	Milk: Cattle	0.02/0.02	2.5
5%	Bovine: Liver	0.3/0.3	2.4

IESTI new

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
989%	Mandarins	15/15	495
937%	Oranges	10/10	469
562%	Potatoes	9/9	281
420%	Grapefruits	10/10	210
167%	Bananas	3/3	84
115%	Lemons	15/15	58
91%	Limes	15/15	45
37%	Strawberries	2/2	19
33%	Blackberries	2/2	16
22%	Raspberries (red and yellow)	2/2	11
17%	Cucumbers	0.5/0.5	8.3
12%	Tomatoes	0.3/0.3	5.8
8%	Gherkins	0.5/0.5	4.0
7%	Sweet peppers/bell peppers	0.5/0.5	3.5
2%	Bovine: Liver	0.3/0.3	1.2

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1	Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) 7

Processed commodities

Results for children	Results for adults	IESTI new Results for children	IESTI new Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2	No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 2	No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
860%	Potatoes/fried	9/4.6	430
309%	Potatoes/dried (flakes)	9/11.96	154
23%	Gherkins/pickled	0.5/0.5	11
22%	Raspberries/juice	2/0.94	11
13%	Oranges/juice	10/0.12	6.3
4%	Courgettes/boiled	0.1/0.05	1.8
3%	Tomatoes/juice	0.3/0.08	1.5
1%	Lemons/jam	15/0.19	0.58
0.2%	Wheat/milling (flour)	0.01/0.01	0.12
0.1%	Wheat/milling (wholemeal)	0.01/0.01	0.06
0.1%	Rye/boiled	0.01/0.01	0.04
0.1%	Oat/boiled	0.01/0.01	0.04
0.1%	Barley/cooked	0.01/0.01	0.04
0.1%	Rye/milling (wholemeal)	0.01/0.01	0.04
0.1%	Oat/milling (flakes)	0.01/0.01	0.03
0.0%	Barley/milling (flour)	0.01/0.01	0.02
0.0%	Limes/juice	15/0.19	0.02

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Potatoes/dried (flakes)	9/11.96	15
14%	Potatoes/chips	9/2.6	6.8
4%	Oranges/juice	10/0.12	1.8
3%	Grapefruits/juice	10/0.12	1.3
2%	Courgettes/boiled	0.1/0.05	1.1
0.7%	Lemons/juice	15/0.19	0.36
0.5%	Tomatoes/sauce/puree	0.3/0.08	0.27
0.1%	Barley/beer	0.01/0	0.07
0.09%	Wheat/bread/pizza	0.01/0.01	0.04
0.08%	Wheat/pasta	0.01/0.01	0.04
0.03%	Wheat/bread (wholemeal)	0.01/0.01	0.02

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
402%	Potatoes/fried	9/4.6	201
309%	Potatoes/dried (flakes)	9/11.96	154
22%	Raspberries/juice	2/0.94	11
13%	Oranges/juice	10/0.12	6.3
10%	Gherkins/pickled	0.5/0.5	4.9
3%	Tomatoes/juice	0.3/0.08	1.5
2%	Courgettes/boiled	0.1/0.05	1.1
1%	Lemons/jam	15/0.19	0.58
0.2%	Wheat/milling (flour)	0.01/0.01	0.12
0.1%	Wheat/milling	0.01/0.01	0.06
0.07%	Rye/boiled	0.01/0.01	0.04
0.07%	Oat/boiled	0.01/0.01	0.04
0.07%	Barley/cooked	0.01/0.01	0.04
0.07%	Rye/milling (wholemeal)-	0.01/0.01	0.04
0.06%	Oat/milling (flakes)	0.01/0.01	0.03
0.04%	Barley/milling (flour)	0.01/0.01	0.02
0.04%	Limes/juice	15/0.19	0.02

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Potatoes/dried (flakes)	9/11.96	15
14%	Potatoes/chips	9/2.6	6.8
4%	Oranges/juice	10/0.12	1.8
3%	Grapefruits/juice	10/0.12	1.3
2%	Courgettes/boiled	0.1/0.05	0.80
0.7%	Lemons/juice	15/0.19	0.36
0.5%	Tomatoes/sauce/puree	0.3/0.08	0.27
0.1%	Barley/beer	0.01/0	0.07
0.09%	Wheat/bread/pizza	0.01/0.01	0.04
0.08%	Wheat/pasta	0.01/0.01	0.04
0.03%	Wheat/bread (wholemeal)	0.01/0.01	0.02

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

For processed commodities, the toxicological reference value was exceeded in one or several cases.

Appendix B – Comments on draft Codex MRL proposals maintained at step 4 or 7

In the following table, EFSA provides some background information on MRL proposals presented in previous CCPR meetings that were not advanced due to concerns raised by the governmental delegations or other procedural reasons.

Table B.1: Detailed information on the MRL proposals maintained at step 4 or 7

Active substance	Commodity	Step	CXL proposal/ existing CXL	Discussions in previous CCPR meetings	EU MRL	Recent EU assessments
Diquat (31)	Beans (dry)	4	0.05/0.2	In 2014, Canada asked to maintain the existing CXLs for bean (dry) (0.2 mg/kg); and lentil (dry) (0.2 mg/kg) under the 4 year rule awaiting data from Canada. In 2014, the CCPR also decided to maintain the proposed draft MRLs for edible offal (mammalian), eggs, meat (from mammals other than marine mammals), poultry (edible offal), poultry meat (all 0.01*) and milks (0.001*) at step 4 (CCPR 46, REP14/PR,-para 40) CCPR 2015: The proposed draft MRL for beans dry and livestock commodities were retained at step 4 waiting data from Canada and Australia CCPR 2016: No discussion CCPR 2017: No discussion CCPR 2018: No discussion CCPR 2019: New MRL proposals have been derived by JMPR for the commodities under discussion, except edible offal mammalian, eggs, milk and poultry edible offal. In the 2018, JMPR report the withdrawal of the existing CXLs was recommended	0.2	See EFSA report. Section 5.1 **Conclusion:** In the light of the new residue definitions derived in the EU, the proposed MRLs would not be compatible with the EU residue definitions derived in the peer review Following the 4-year rule, a decision should be taken in 2019 CCPR meeting to withdraw the CXLs and the Codex MRL proposals at step 4
	Edible offal (Mammalian)	4	0.01*/0.05*		0.05*	
	Eggs	4	0.01*/0.05*		0.05	
	Meat (from mammals other than marine mammals)	4	0.01*/0.05*		0.05*	
	Milks	4	0.001*/0.01*		0.01*	
	Poultry meat	4	0.01*0.05*		0.05*	
	Poultry, edible offal of	4	0.01*/0.05*		0.05*	
Oxamyl (126)	Peppers chili, dried	4	0.01*	The Codex MRL proposals were kept at step 4 awaiting a re-evaluation of the issue related to the setting of MRLs for the subgroup of peppers (in 2017 JMPR proposed to exclude martynia, okra and roselle)	0.01*	The EU position of 2018 is still valid where the EU supported the advancement of the proposed MRLs for the two commodities It is noted that for dried chili peppers, usually the EU would not express its support, since it is a processed commodity for which no EU MRLs are established
	Peppers subgroup of (includes all commodities in this subgroup, except martynia, okra and roselle)	4	0.01*		0.01*	

Active substance	Commodity	Step	CXL proposal/ existing CXL	Discussions in previous CCPR meetings	EU MRL	Recent EU assessments
				In 2018, JMPR confirmed the previous MRL proposals since the GAPs under consideration do not cover the minor crops listed in the subgroup of peppers		
Propamocarb 148	Cabbages, Head	4	1	In 2015, CCPR agreed to hold the proposed draft MRLs for cabbages and kale at step 4, awaiting new data (livestock feeding study) from the manufacturer and re-evaluation by JMPR in 2018 No new information was provided for the 2018 JMPR meeting	0.7	In 2015 CCPR, EU made a reservation regarding the advancement of the proposed MRLs for the two crops because a different policy on establishing MRLs for animal feed commodities when livestock dietary burdens exceed the dose levels used in animal feeding studies The renewal process of the approval of propamocarb is currently ongoing; EFSA expert meeting is planned for April 2019 **Conclusion:** In 2019, no discussion is expected for this substance Overall, the advancement of the proposed MRLs is not supported as long as the expected residues in food of animal origin were not assessed, taking into account the residues in cabbage and kale
	Kale	4	20		20	
Propiconazole 160	Cherries, subgroup of (including all commodities in this subgroup)	4	3Po	In 2018, the EU proposed that the MRLs should be derived using a different calculation method (using the mean residue + 4SD). CCPR agreed to keep all the proposed draft MRLs at step 4 awaiting JMPR re-evaluation in 2018 In 2018 JMPR, revised MRL proposals were derived by JMPR	0.01*	**Conclusions:** See comments in EFSA report Section 5.5
	Lemons and Limes (including citron) Subgroup of (including all commodities in this subgroup)	4	10Po		5	
	Mandarins (including mandarin-like hybrids) Subgroup of (including all commodities in this subgroup)	4	10Po		5	

Active substance	Commodity	Step	CXL proposal/ existing CXL	Discussions in previous CCPR meetings	EU MRL	Recent EU assessments
	Orange oil	4	2800		–	
	Oranges, sweet, sour (including orange-like hybrids) subgroup of (including all commodities in this subgroup)	4	15Po		9	
	Peach	4	0.7Po		5	
	Pineapple	4	4Po		0.02*	
	Plums, subgroup of (includes all commodities in this subgroup)	4	0.5Po		0.01*	
	Pumelo and grapefruit (including Shaddock-like hybrids) subgroup of (including all commodities in this subgroup)	4	6Po		5	
Bifenthrin (178)	Okra	7	0.2	For the proposed Codex MRLs for strawberries, celery and lettuce JMPR identified acute intake concerns; the proposals was retained at step 4 awaiting data from the manufacturer for an alternative GAP to be assessed by 2017 JMPR In 2017, CCPR decided to retain the draft MRL proposals for okra at step 7, awaiting information on authorised GAP to be submitted by India before 2019 Bifenthrin is now scheduled for 2019 JMPR (BARLEY, BARLEY (STRAW FODDER) – 4-year rule granted in 2014/STRAWBERRY, LETTUCE HEAD, CELERY (alternative GAP)/okra – India) If data will not be submitted by 2019, a decision on withdrawal of the MRL proposal will be taken	0.2	In 2012 the EU proposed to withdraw the MRL for strawberries, due to acute intake concerns identified by JMPR. For the remaining MRL proposals no EU reservation was made In the MRL review under Article 12 (Reg. (EU) 2017/170, the MRL derived for okra was identical with the proposed CXLs. For celery and lettuce the MRL is set at the LOQ in the EU **Conclusion:** No discussion is expected in 2019, since the data are expected to be assessed by 2019 JMPR
	Strawberry	4	3/1		0.1	
	Celery	4	3		0.01*	
	Lettuce head	4	4		0.01*	

Active substance	Commodity	Step	CXL proposal/ existing CXL	Discussions in previous CCPR meetings	EU MRL	Recent EU assessments
Fenpyroximate (193)	Apricot	4	0.4	In 2018, the EU opposed the advancement of the proposed MRLs for cherries, peaches, plums subgroup, watermelons and tomatoes because of acute intake concerns identified by JMPR In 2018, CCPR agreed to keep the proposed draft MRLs for apricot; cherries (subgroup); cherry tomato; peach; plums (subgroup); watermelon; and tomato at step 4, awaiting evaluation of the additional toxicological data by the 2020 JMPR		**Conclusion:** No discussion expected for 2019 CCPR
	Cherries, subgroup of (includes all commodities in this subgroup)	4	2			
	Cherry tomato	4	0.3			
	Peach	4	0.8			
	Plums, subgroup of (including fresh prunes) (includes all commodities in this subgroup)	4	0.8			
	Tomato	4	0.8			
	Watermelon	4	0.05			
Cyprodinil 207	Pomegranate	4	10	In 2018, the EU proposed that the MRL should be derived using a different calculation method (using the mean residue + 4SD). CCPR agreed to keep the proposed draft MRL at step 4 awaiting JMPR re-evaluation in 2018 In 2018, JMPR revised MRL proposals were derived by JMPR	0.02*	**Conclusion:** See comments in EFSA report 2019, Section 5.12
Sulfoxaflor (252)	Tree nuts	4	0.015	In 2015, CCPR decided to retain the MRL proposal at step 4 awaiting JMPR evaluation in 2016. (the proposed MRL at step 4 was not advanced since the GAP authorised in US differed from the GAP that was reported to JMPR) In 2016, JMPR reported that data on tree nuts have been provided, but since the label was submitted too late, no assessment was performed CCPR 2016: no discussion In 2016, JMPR assessed sulfoxaflor for new uses. However, since no information on the authorised GAPs was provided, no new MRL proposal was derived	0.02*	**Conclusion:** See comments in EFSA report 2019, Section 5.17 If the new MRL proposal for tree nuts is advanced in 2019 CCPR, the previous proposal should be withdrawn

Active substance	Commodity	Step	CXL proposal/ existing CXL	Discussions in previous CCPR meetings	EU MRL	Recent EU assessments
				CCPR 2017: It was decided to assess tree nuts together with the new uses on other crops that were scheduled for the 2018 JMPR In 2018, JMPR derived a MRL proposal of 0.03 mg/kg for tree nuts		
Cyclaniliprole (296)	Cherries, subgroup of (includes all commodities in this subgroup)	4	0.9	In 2017, JMPR used a model to estimate MRLs for the crops listed since the submitted residue trials did not match with the GAP. The EU and other Codex Members noted that the model needed validation to ensure that the derived MRL proposals were appropriate. In 2018, CCPR agreed to keep all the proposed draft MRLs at step 4 pending the evaluation of new data and revised GAP information by the 2019 JMPR. CCPR also invited JMPR to engage with national regulators to continue validation of the model	0.01*	**Conclusion:** No discussions are expected for 2019 CCPR
	Cherry tomato	4	0.1		0.01*	
	Edible offal (mammalian)	4	0.01 (*)		0.01*	
	Eggplants, subgroup of (includes all commodities in this subgroup)	4	0.1		0.01*	
	Flowerhead brassicas, subgroup of (includes all commodities in this subgroup)	4	1		0.01*	
	Fruiting vegetables, cucurbits- cucumbers and summer squashes, subgroup of (includes all commodities in this subgroup)	4	0.06		0.01*	
	Fruiting vegetables, cucurbits – melons, pumpkins and winter squashes (subgroup of) (includes all commodities in this subgroup)	4	0.15		0.01*	
	Grapes	4	0.8		0.01*	
	Head brassicas, subgroup of (includes all commodities in this subgroup)	4	0.7		0.01*	

Active substance	Commodity	Step	CXL proposal/ existing CXL	Discussions in previous CCPR meetings	EU MRL	Recent EU assessments
	Leaves of Brassicaceae, subgroup of, (includes all commodities in this subgroup)	4	15		0.01*	
	Mammalian fats (except milk fats	4	0.01 (*)		0.01*	
	Meat (from mammals other than marine mammals)	4	0.01 (*) (fat)		0.01* (muscle)	
	Milk fats	4	0.01 (*)		–	
	Milks	4	0.01 (*)		0.01*	
	Peaches, subgroup of (including apricots and nectarine) (includes all commodities in this subgroup)	4	0.3		0.01*	
	Peppers chili, dried	4	2		–	
	Peppers, subgroup of (includes all (except martynia, okra and roselle) commodities in this subgroup)	4	0.2		0.01*	
	Plums, subgroup of (including fresh Prunes) (includes all commodities in this subgroup)	4	0.2		0.01*	
	Pome fruits, group of (includes all commodities in this group)	4	0.3		0.01*	
	Prunes, dried	4	0.8		–	
	Straw and fodder (dry) of cereal grains	4	0.45 (dw)		–	
	Tomato	4	0.1		0.01*	
	Tomato, dried	4	0.4		–	