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SCIENTIFIC REPORT

Scientific support for preparing an EU position in the 57th session of the codex committee on pesticide residues (CCPR)

European Food Safety Authority (EFSA)

Correspondence: Ask a Question

The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The European Commission asked EFSA to provide support in the framework of Article 43 of Regulation (EC) No 396/2005 for the preparation of the EU position for 57th Session of the Codex Committee on Pesticide Residues (CCPR). In the current report, EFSA provided comments and recommendations on the proposed Codex maximum residue limits (CXLs) derived by the Joint Meeting on Pesticide Residues (JMPR) that will be discussed in the upcoming CCPR meeting. The current report should serve as the basis for deriving the EU position for the CCPR meeting.

KEYWORDS

57th CCPR meeting, consumer risk assessment, MRL setting, residue definitions, toxicological evaluation

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SUMMARY

For the preparation of the 57th session of the Codex Committee on Pesticide Residues (CCPR meeting), the European Commission asked European Food Safety Authority (EFSA) to provide comments on the individual active substances assessed in the 2025 Joint FAO/WHO Meeting on Pesticide Residues (JMPR), in particular on the recommended health-based guidance values (HBGVs) and the proposed maximum residue levels (MRLs) at step 3 and 6 of the Codex procedure.

In 2025, JMPR evaluated 38 active substances: four of them were assessed in the framework of the periodic review and seven active substances were assessed for the first time by JMPR; the remaining a.s. were assessed in view of setting new Codex maximum residue limits (CXLs) for new uses or other new information. For one additional active substance (acetamiprid), JMPR replied to specific concerns raised by the delegations, which were submitted by means of concern forms.

EFSA assessed the Codex MRL proposals as requested in the terms of reference and performed dietary risk assessments to support risk managers to derive a position for the upcoming CCPR meeting.

The report also contains information on Codex MRL proposals for active substance maintained at steps 4 or 7 of the Codex procedure.

In addition, EFSA commented on the topics presented in the JMPR report in the chapter 'General considerations' and provided comments on the follow-up assessments of JMPR on pesticides for which specific concerns on the toxicological or residue assessments were raised in the previous CCPR meetings.

It is highlighted that the EFSA comments were derived on the basis of the information provided in the JMPR report. Since EFSA does not have access to the original studies and more detailed information on the JMPR evaluation, the EFSA comments are restricted to the specific questions specified in the terms of reference and the concise information provided in the 2025 JMPR report. Hence, the comments on Codex MRL proposals reported in this report 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.

1 | INTRODUCTION

In accordance with Articles 5(3) and 13(e) of the European Union (EU) General Food Law (Regulation (EC) No 178/2002),[1] Codex maximum residue limits (CXLs) established by Codex Alimentarius Commission are international standards that have to be taken into consideration in the development of EU standards for pesticide residues in food to promote consistency between such international and EU technical standards while ensuring that the high level of protection adopted in the EU is maintained.

Codex MRL proposals are derived by the Joint Meeting on Pesticide Residues (JMPR), the scientific body responsible for the assessment of data provided by parties requesting the establishment of CXLs. The most recent JMPR evaluations for Codex MRL proposals are summarised in the 2025 JMPR Report. In total, JMPR assessed 38 active substances: four of them were assessed in the framework of the periodic review and seven active substances were assessed for the first time by JMPR; the remaining a.s. were assessed in view of setting new CXLs for new uses or other new information. For one additional active substance (acetamiprid), JMPR replied to specific concerns raised by the delegations, which were submitted by means of concern forms. The Codex MRL proposals and the other recommendations of JMPR will be presented in the next CCPR meeting for discussion and advancement in line with the Codex procedures.

1.1 | Background

On 18 March 2026, the European Commission requested EFSA to give advice and comments on the recommendations of the 2025 Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and on the proposed Codex MRLs in order to support the Commission in its preparation of the EU coordinated positions for the 57th session of the Codex Committee on Pesticide Residues (CCPR57) in 2026. This should cover the substances evaluated in the 2025 JMPR report and, where appropriate, other proposed Codex MRLs that were retained in the step procedure in previous years and may not have been covered by the 2025 JMPR Report but by (an) earlier JMPR report(s).

Additionally, the European Commission requested EFSA to give its comments to the general chapters of the 2025 JMPR report, where relevant for risk assessment, as well as comments on the other relevant documents for discussion in the CCPR57, e.g. as regards the JMPR priority list.

1.2 | Terms of Reference

The requested advice and comments on the recommendations of the 2025 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:

1. Background information on all active substances and metabolites 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).
2. A comparison of the proposed reference values with agreed EU reference values and an evaluation of the reasons for possible differences, in case new health-based guidance values are proposed by JMPR.
3. As regards the proposed draft Codex MRLs for discussion in CCPR57, EFSA should provide any relevant comment on the proposed MRLs and specifically address the following questions:

    a. Whether the residue definitions derived by JMPR are comparable with the existing EU residue definitions;
    b. Whether the proposed draft Codex MRLs are comparable with the existing EU MRLs;
    c. Whether the proposed draft Codex MRLs are sufficiently supported by data;
    d. Whether the proposed draft Codex MRLs are appropriate in terms of the data that have been used to establish them and in terms of the method used for their calculation;
    e. Whether the proposed draft Codex MRLs are safe for European consumers with regard to chronic and, where relevant, acute exposure.

The EFSA draft scientific report addressing point 1–3 of the ToR should be delivered within 4 weeks of the publication of the recommendations of the JMPR meeting, with the final EFSA report to be approved before the start of the CCPR meeting. If, due to late publication of the JMPR report, a complete assessment of all active substances is not feasible within 4 weeks, the report should cover the pesticides prioritised by Commission services.

The requested comments to the general chapters of the 2025 JMPR report, where relevant for risk assessment, as well as comments on the other relevant documents for discussion in CCPR57 can be provided as contributions to the EU-coordinated positions when these are discussed with the Member States and do not need to be covered by a scientific report.

[1]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

2 | ASSESSMENT

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

EFSA assigned a question number to the request (EFSA-Q-2026-00208) which covers the active substances covered by the mandate (2-phenylphenol and its sodium salts, acequinocyl, acynonapyr, azoxystrobin, beta-cyfluthrin, bifenthrin, boscalid, broflanilide, clothianidin, cyantraniliprole, cyfluthrin, cyprodinil, difenoconazole, dimethoate, dimpropyridaz, dinotefuran, etoxazole, flubendiamide, fludioxonil, fluopyram, guazatine, indoxacarb, ipflufenoquin, malathion, mefentrifluconazole, mepiquat-chloride, metaflumizone, metarylpicoxamid, metconazole, permethrin, proquinazid, pyraclostrobin, pyriofenone, pyriproxyfen, spidoxamat, spinetoram, thiamethoxam, tiafenacil and trifloxystrobin) and the request for comments on general considerations, as well as the a.s. for which Codex MRL proposals were retained at step 4 or 7.

The first draft of the individual chapters of the scientific report of EFSA covering the terms of reference (ToRs) 1–3 was shared with EU Member State experts and the European Commission for commenting on 8 July 2026. All the comments received during the Member State consultation were addressed as appropriate in the final EFSA scientific report.

A second draft report addressing the Member State comments was completed on 31 August 2026; this document was then further discussed in the second Council Working Party held on 1 September 2026.

The Member States consultation report (EFSA, 2026c) is a supporting document to this report, which is made publicly available. Furthermore, the exposure calculations for all crops reported in the framework of this review were performed using the EFSA Pesticide Residues Intake Model (PRIMo). A screenshot of the PRIMo calculations (report sheet of PRIMo 3.1) is presented in Appendix A for the individual substances assessed.

In Section 3 of the current report, EFSA provided comments on the discussion points presented in the JMPR report under 'General Considerations'.

In Section 4 of the report, EFSA assessed the responses provided by JMPR on specific concerns raised by the CCPR, requesting a re-evaluation by JMPR.

Chapter 5 of the current report presents the assessments in response to points 1–3 of the ToR for the Codex MRL proposals presented in the 2025 JMPR report. Chapter 6 deals with MRL proposals derived from previous JMPR meetings which were maintained at steps 4 or 7.

Background information on the active substances assessed by JMPR (point 1 of the ToR) was retrieved from the database on pesticides.[2] The EFSA data management system and in-house databases on previous EFSA assessments were used as sources of information to prepare the compilation on previous EFSA assessments.[3]

In order to address the second point of the ToRs on the health-based guidance values, EFSA compared 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[4] or in other relevant EU assessments (e.g. MRL applications). The following sources of information were used: EFSA conclusions available for the active substances under consideration, review reports prepared by the European Commission, draft assessment reports (DARs), renewal assessment reports (RARs) prepared by the Rapporteur Member States (RMSs), EFSA reasoned opinions and other sources of information if available.

For deriving the comments on the third point in the ToRs (comments on the Codex MRL proposals), EFSA used the following approach to address point 3 (a) to 3 (e):

Ad 3(a): EFSA compared the enforcement residue definition derived by JMPR with the residue definition established in the EU legislation (Regulation (EC) No 396/2005)[5] or the legislation under preparation. The EU residue definitions for risk assessment were retrieved from the EFSA conclusions, EFSA reasoned opinions on the MRL review under Article 12 of Regulation 396/2005 and the reports prepared by the European Commission in the framework of the peer review of active substances or Member State evaluations in draft assessment reports (DARs) or renewal assessment reports (RARs).

Ad 3(b): The comparison of the EU MRLs and the Codex MRL proposals is presented in tabular form. Codex MRL proposals that are higher than the existing EU MRLs are printed in bold. In line with the presentation of MRLs in the EU legislation, limit of quantification (LOQ) MRLs are labelled with an asterisk ('*') after the value. The comparison of Codex MRL proposals with existing EU MRLs is performed for commodities listed in Part A of the EU food classification (Annex I of Regulation (EC) No 396/2005), but not for products that are listed in Part B. An Excel table including the EU MRLs for the relevant commodities covered by the Codex MRL proposals is made publicly available as supporting documents to this scientific report.

Ad 3(c): For assessing whether the draft Codex MRL proposals for plant products are sufficiently supported by data, EFSA focused on the availability of residue trials and metabolism studies. If the data used to derive the Codex MRL proposal were in accordance with the number of trials specified in the FAO manual (FAO, 2016) and the agreed policy of JMPR, the Codex MRL proposals are considered to be sufficiently supported by data and the MRL proposals are flagged as 'the proposed Codex MRL is sufficiently supported by data'. Details on independence of residue trials, storage stability, analytical method validation and other details, which would be assessed in detail in the framework of EU MRL applications, are not reported in the JMPR reports. Hence, comments on these aspects of the dossier are not within the scope of the current assessment.

[2] https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en.

[3] Reference date for background information and other EU information (e.g. health-based guidance values, residue definitions, EU MRLs, etc.): 19 June 2026.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[5] 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.

For animal products, EFSA verified the plausibility of the Codex MRL proposals, based on the information provided in the JMPR reports on the results of dietary burden calculations and feeding studies. If the Codex MRL proposals for animal products passed the plausibility check, they are considered appropriate. A verification of the dietary burden calculation for all global regions (Europe, USA/Canada, Australia, Japan) cannot be performed in the framework of the current mandate, because comprehensive information on all authorised uses for feed commodities other than the commodities assessed by JMPR is not available to EFSA. In addition, the EU tool used for calculating the dietary burden does not comprise livestock diets from non-EU regions.

Ad 3(d): In order to assess the overall appropriateness of Codex MRL proposals as requested in the ToR, EFSA derived a conclusion on the availability of representative residue trials compliant with the residue definitions (considering also the extrapolation and scaling rules) and verified the MRL calculations (based on the OECD calculator; OECD, 2011). In addition, relevant points for risk management consideration were reported. The Codex MRL proposals are reported as acceptable/sufficiently supported by data if no obvious deficiencies were identified based on the information presented in the JMPR reports. If serious deficiencies are noted or if the Codex MRL proposals lead to chronic and/or acute public health concerns, the Codex MRL proposals are reported as not acceptable. In case relevant points not directly related to the scientific assessment were identified which require further risk management considerations, EFSA recommends further discussions to decide whether the Codex MRL proposals are acceptable.

Ad 3(e): For the assessment of the safety of the draft Codex MRL proposals, EFSA used the revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2018c, 2019n). For assessing the short-term (acute) consumer risk, EFSA applied the standard EU methodology, including the agreed EU variability factors. For the assessment of the long-term (chronic) 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. For active substances where the MRL review has not yet been completed, less refined calculations were performed: for commodities where the EU MRL is higher than the proposed Codex MRL, the EU MRL was used as input values for the risk assessment instead of the STMR value. The contribution of the individual crops under consideration in the CCPR meeting was calculated separately. Detailed explanations are provided if the standard approach had to be adjusted for the individual substances.

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 exposure assessments are usually compared with the EU health-based guidance values, unless it is specifically mentioned that the JMPR values were used. The used approaches are considered to be sufficiently conservative for a risk assessment screening.

It is highlighted that, due to the different data requirements, scientific and procedural guidelines and policies used at EU level and by JMPR, the assessment of residue data sets submitted in support of an EU MRL application and Codex MRL request may result in different recommendations at EU level and by JMPR.

EFSA comments were derived on the basis of the JMPR reports summarising the recommendations of the 2025 JMPR meeting, which were published on 29 May 2026. Due to the limited details reported in the JMPR report, the EFSA assessment might need to be revised, if more information on the data assessed by JMPR becomes available.

The comments presented in this report have been prepared considering the currently applicable guidance documents (guidance documents used by JMPR and accepted by the EU as well as EU 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.

The comments for the active substances under consideration reflect information available in JMPR reports, EFSA conclusions/reasoned opinions and other sources referenced approved until 19 June 2026. Due to the timelines agreed with the requestor, EFSA could not use the JMPR evaluations and other documents published at a later stage. Thus, the conclusions reached in this report should be considered as preliminary and might have to be reconsidered if more detailed information becomes available.

3 | COMMENTS ON CHAPTER 'GENERAL CONSIDERATIONS' OF JMPR REPORTS

3.1 | Updates on upcoming dietary risk assessment activities

In chapter 2.1 of the report, JMPR noted ongoing work on dietary risk assessment methodologies, including concerns and comments from CCPR56. An ad hoc expert meeting will be convened before the next JMPR to further develop suitable dietary exposure assessment approaches, supported by a background document covering current IEDI and GECDE methodologies, validation activities, responses to CCPR and JMPR questions and the terms of reference for the meeting.

EFSA welcomes the proposed ad hoc expert meeting on JMPR dietary risk assessment methodologies and supports the inclusion of expertise in dietary exposure assessment, toxicology and pesticide residues. EFSA also agrees that participation of both JMPR and non-JMPR experts could provide valuable perspectives for the further development of the methodologies. Given the ongoing discussions regarding the IEDI and GECDE approaches, EFSA considers it important that the work includes comprehensive validation, transparency regarding methodological assumptions and variability drivers and clear criteria for the selection and application of dietary exposure methodologies. This would facilitate confidence in the resulting exposure assessments and support their use in regulatory decision-making.

3.2 | Integration of data from new approach methodologies (NAMs) into JMPR's pesticide safety assessments

In chapter 2.2 of the JMPR report, JMPR provided insights into the use of new approach methodologies (NAMs) in JMPR's hazard assessment of pesticide active substances and metabolites. JMPR indicated that NAMs may support decision-making or provide supplementary evidence within a weight-of-evidence approach, depending on their robustness, scientific validity and fitness for purpose. Although formal OECD validation is limited for many NAMs, JMPR intends to assess them case by case to ensure evaluations reflect the best available science.

JMPR also recognised the need to update EHC 240 to include guidance on the fit-for-purpose application, reporting and evaluation of NAMs, with input from JMPR and JECFA experts. JMPR further highlights the importance of building confidence among Member States and encouraging sponsors to submit NAM-derived data, supported by appropriate guidance and feedback.

EFSA welcomes JMPR's integration of NAMs data in the hazard assessment of pesticide active substances and metabolites and agrees with JMPR's considerations provided in the report. In EFSA's view, NAMs may provide relevant information for the hazard and risk assessment of pesticide active substances, provided that their reliability and regulatory relevance are demonstrated, aligned with the OECD *Guidance Document on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment* (OECD, 2005) and the *OECD Guidance Document on Good* In Vitro *Method Practices (GIVIMP)* (OECD, 2018). For regulatory use, NAM-derived information should be assessed with regard to biological plausibility, relevance of the test system and the method's applicability domain. NAMs data should be integrated with all available evidence within a structured weight-of-evidence assessment, for example, using integrated approaches to testing and assessment (IATA) frameworks.

EFSA has also committed to support the European Commission in its *Roadmap towards phasing out animal testing for chemical safety assessments*, adopted on 1 June 2026, which aims to accelerate the transition towards innovative non-animal approaches while maintaining a high level of protection of human health, animal health and the environment.

3.3 | Non-linear toxicokinetics guidance electronic working group

In chapter 2.3 of the JMPR report, JMPR informed that it recommends the electronic working group to continue its work with the aim of finalising the guidance for JMPR monographers and reviewers on non-linear toxicokinetics in 2026. As previously indicated (EFSA, 2024b, 2025g), EFSA did not have access to documents prepared by the JMPR on this topic. EFSA suggests asking JMPR to make more detailed information on the draft guidance available, and to launch a broader commenting. Experience from other bodies could help to further increase the quality of the document.

3.4 | Plasma and/or blood area under the concentration–time curve (AUC) ratio use for identification of major rat metabolites

In chapter 2.4 of the JMPR report, JMPR provided information on ADME aspects to consider when assessing whether a metabolite can be covered by studies of the parent compound, i.e. if the metabolite is a significant biotransformation product (higher than 10% of the administered/absorbed dose). It indicated that plasma (or blood) $AUC_{metabolite}$ to AUC_{parent} or $AUC_{total\ radioactivity}$ ratio should not be used as the sole determinant for the evaluation whether a metabolite is a significant biotransformation product, indicating that AUC is not a direct measure of systemic exposure on a mass balance basis. EFSA agrees with JMPR. If $AUC_{metabolite}$ of a metabolite compared to the $AUC_{total\ radioactivity}$ or AUC_{parent} > 10%, it only means that the metabolite is present at > 10% of the radioactivity in plasma, and not necessarily > 10% of the administered dose or absorbed dose.

3.5 | Update on the guidance document for WHO monographers and reviewers

In chapter 2.5 of the JMPR report, JMPR informed that the meeting discussed the draft Guidance Document for WHO monographers and reviewers, recommending the document to be revised as soon as possible for a final round of commenting. EFSA suggests asking JMPR to launch a broader commenting. Experience from other bodies could help to further increase the quality of the document.

3.6 | Transition of maximum residue recommendations for meat according to the new codex classification for food commodities

In chapter 2.6 of the JMPR report, JMPR summarised the request from the Codex Secretariat for advice on the transition of existing CXLs for fat-soluble pesticides in mammalian and poultry meat, usually identified by the suffix 'fat', to the new Codex commodity groups for mammalian muscle and avian muscle. JMPR recommended adding a footnote to clarify that,

for fat-soluble pesticides, the CXL applies to fat. The footnote would not be needed for CXLs derived by JMPR in 2024 or later.

EFSA recommends checking, once the database has been updated, whether the footnote has been included for all relevant CXLs. This clarification, together with the prioritisation of a full re-evaluation of residues in animal commodities under the new classification, would support a consistent implementation of CXLs for fat-soluble pesticides.

3.7 | Maximum residue level recommendations for fat-soluble pesticides for milk and milk fat under the new classification for animal commodities

CCPR 2025 requested JMPR to clarify the monitoring of fat-soluble pesticides in milk and milk fat. JMPR, therefore, agreed to add a footnote to all milk fat MRL recommendations stating that *'for monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk'*, whole milk should be analysed and the analytical result compared with the MRL established for whole milk, even where an MRL is also available for milk fat. This footnote was included in Annex 1 of the JMPR report for all milk fat recommendations (FM 0183). However, further clarification would be desirable regarding the practical implementation of MRLs established for the milk group under the revised Codex classification, in particular considering that group MRLs may be derived from data on a single milk-producing species and that milk fat content may differ substantially between species and dairy products.

3.8 | Publish the intake calculations for the metabolites assessed with the threshold of toxicological concern (TTC) approach in the report

In response to a CCPR56 request for greater transparency regarding TTC assessments, JMPR 2025 introduced summary tables containing the residue input values used in TTC calculations, accompanied by explanatory remarks where appropriate. The TTC calculation outputs were not included because of report size limitations and technical constraints. JMPR considered that publishing the input values, in combination with the established dietary intake models (IEDI and IESTI), provides sufficient transparency and allows the TTC assessments to be reproduced. EFSA acknowledges JMPR's effort to include such summary tables, which were provided in the relevant assessment sections for acynonapyr, fludioxonil, mepiquat chloride, metarylpicoxamid and tiafenacil. Similar tables were not provided for acequinocyl, dimpropyridaz, ipflufenoquin, malathion and proquinazid, although this is less clear for proquinazid, for which CXL proposals were made. EFSA therefore recommends, for transparency, that summary tables be presented consistently for all relevant substances for which the TTC approach is used.

3.9 | Dietary burden calculation for updates on maximum residue limits (MRLs) for animal commodities

Following reservations raised at CCPR56 on the advancement of proposed MRLs for animal commodities, in view of the need for updated dietary burden calculations and greater transparency on input values, the 2025 JMPR agreed to include comprehensive input tables for dietary burden calculations, also covering feed commodities evaluated in previous years. Updated calculations were performed for all compounds evaluated in 2025, using input values of raw agricultural commodities (RACs) where processed feed data were unavailable. JMPR considered that publishing these input tables, together with the OECD Feed Calculator, provides sufficient transparency and reproducibility. EFSA notes that the dietary burden calculations were transparently reported in the JMPR report for substances with CXL proposals in animal commodities.

3.10 | Revision of OECD TG 506: Stability of pesticide residues in stored commodities

In chapter 2.10 of the report, JMPR summarised the main updates introduced by the revision of OECD TG 506 on storage stability, including alignment with the current Codex Classification, reorganisation of commodities into four matrix groups (high water, high acid, high oil and dry commodities), and updated principles for selecting representative commodities and extrapolating storage stability data. These changes aim to harmonise storage stability assessments and improve consistency in residue evaluations. JMPR will apply the revised guideline from the beginning of 2026, while at EU level, it has been applicable since its publication in June 2025.

3.11 | Screening assessments following lowering of health-based guidance values (HBGVs)

EFSA appreciates the efforts made by JMPR to perform a screening for possible consumer health risks related to the CXLs of phosmet retained under the 4-year rule. The assessment demonstrates that the existing CXLs for apricots, grapes, citrus fruit, pome fruit, nectarines and peaches are not safe for consumers and should therefore not be kept under the 4-year rule.

For the existing CXLs for cotton seed, tree nuts, cattle meat (fat) and milks, JMPR was unable to conclude on the dietary risk.

As regards the existing CXL of 1 mg/kg for cattle meat (fat), EFSA noted that this CXL is labelled with the suffix 'V', indicating that it is resulting from a veterinary use. Considering that the database for veterinary MRLs does not contain an entry for phosmet, it seems not appropriate to keep the CXLs under the 4-year rule.

Although the existing CXL for milk (0.02 mg/kg) is not flagged with the suffix 'V', it is likely that it is also a veterinary MRL as in the JMPR evaluation of 1997, the CXL was reported in a similar way as the CXL for cattle meat, labelled with 'V' (see screenshot below) (Figure 1).

phosmet 729

Commodity		Recommendation			PHI,[1] days
		MRL mg/kg		STMR mg/kg	
CCN	Name	New	Previous		
AL 1021	Alfalfa forage green	w	40		
FP 0226	Apple	10	10	3.4	7
FS 0240	Apricot	10	5	2.9	7
FB 0020	Blueberries	w	10		
MM 0812	Cattle meat	w	1 (fat) V		
FC 0001	Citrus fruits	w	5		
SO 0691	Cotton seed	0.05		0	14
FI 0335	Feijoa	w	2		
FB 0269	Grapes	10	10	3.1	7-14
FI 0341	Kiwi	w	15		
AF 0645	Maize forage	w	10		
AS 0645	Maize fodder	w	10		
GC 0645	Maize	w	0.05		
ML 0106	Milks	w	0.02 V		
FS 0245	Nectarine	w	5		
AL 0072	Pea hay and fodder	w	10		
AL 0528	Pea vines green	w	10		
FS 0247	Peach	10	10	2.9	14
FP 0230	Pear	w	10	w	
VP 0063	Peas (pods and succulent seeds)	w	0.2		
VD 0063	Peas (dry)	w	0.02*		
VR 0589	Potato	0.05*	0.05	0.05	7
VO 0447	Sweet corn (corn-on-the-cobs)	w	0.05		
VR 0508	Sweet potato	w	10 (Po)		
TN 0085	Tree nuts	w	0.1		

[1]PHI on which the recommendations are based

FIGURE 1 JMPR recommendations for CXL on Phosmet.

Both CXLs (CXL for cattle meat and for milks) were recommended for withdrawal by JMPR in 1997. In 2005, in the JMPR report of 2005, JMPR recommended again to withdraw the CXLs for cattle meat and milks. Citation of JMPR report 2005:

> 'Although no detectable residues of phosmet or its oxon occurred in edible animal products in metabolism studies, the meeting was not able to estimate any maximum residue levels for animal feeds or animal products because of the high residues in animal feed items and the lack of animal transfer studies. Consequently, the meeting recommended the withdrawal of the existing CXLs for alfalfa fodder and forage, cattle meat and milks'.

With the exception of cotton seed (which was proposed to be maintained under the 4-year rule), no other CXLs for feed items are in place that would justify the need for setting CXLs for animal commodities.

Overall, EFSA recommends risk management discussion with Member States whether the 4-year rule can be applied to existing CXLs, if data are insufficient to conclude that they do not pose a consumer health risk. Furthermore, the available information does not provide evidence that the CXLs for animal products are still justified.

3.12 | Draft FAO/WHO JMPR standard operating procedures

In the last CCPR Meeting, the JMPR Secretariat reassured CCPR that FAO and WHO were working together to strengthen the governance of JMPR so that, in the future, differences could be addressed transparently while allowing JMPR's work to proceed without delay (para 34 of the CCPR report).

EFSA welcomes the efforts of JMPR to follow up on the topic and the intention to draft a FAO/WHO JMPR standard operating procedure, which should help to avoid delays in the publication of JMPR reports in case of divergent views of JMPR experts. JMPR is asked to provide further information whether the standard operating procedures will be made available to CCPR.

4 | RESPONSES TO SPECIFIC CONCERNS RAISED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR)

4.1 | Acetamiprid

In response to the EU concern form submitted to CCPR56 on acetamiprid, JMPR acknowledged the concerns regarding acute consumer risks related to potential developmental neurotoxicity and the EU request to prioritise the re-evaluation of toxicology and residues. JMPR noted that acetamiprid had been scheduled for follow-up evaluation in 2017, but no new toxicological assessment was performed because no toxicological information had been submitted. As the concern could not be fully addressed at the present meeting due to the short notice, JMPR recommended that CCPR prioritise acetamiprid for periodic re-evaluation. EFSA acknowledges and welcomes JMPR's response and the recommendation to prioritise acetamiprid for re-evaluation. However, considering the significance of the concerns raised and their potential implications for consumer safety, EFSA considers that concrete follow-up actions should be taken to ensure that the toxicological assessment of acetamiprid is reviewed as a matter of priority. EFSA therefore reiterates that the review of acetamiprid remains of high priority.

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 and WHO, 2026). 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 on whether the substance was assessed for toxicological properties (T) and/or for residues (R). The substances are sorted according to the codex number (Tables 1–209).

When references are made to previous JMPR reports/evaluations, the year of the JMPR assessment is reported (e.g. JMPR 2019). The respective reports can be retrieved on the JMPR website.[6]

5.1 | Dimethoate (27) T

5.1.1 | Background information – Dimethoate

TABLE 1 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	IT	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2019/1090[7]
EFSA conclusion available	Yes, see comments	EFSA (2018n)
MRL review performed	Yes, see comments	EFSA (2022c) (Statement; no MRL review required)
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	No, see comments	No classification CLP00[8] An evaluation by ECHA RAC is not available.
Endocrine effects of a.s.	No, see comment	No ED assessment according to the ECHA/EFSA guidance on the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 has been performed. EFSA (2018n): Dimethoate is proposed to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and toxic effects on the endocrine organs have been observed in the available database (effects on male reproductive organs);

[6] https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-residues-jmpr/reports/en/.

[7] Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance.) C/2019/4547. OJ L 173, 27.6.2019, pp. 39–41.

[8] Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

TABLE 1 (Continued)

	Comments, references
	therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine-disrupting properties may be met. Mechanistic data are available from the US EPA ToxCast programme indicating that dimethoate does not bind to oestrogen or androgen receptors, is negative in a steroidogenesis assay and is not an aromatase inhibitor. Considering that clear overt systemic toxicity was observed at doses producing the adverse effects on reproductive organs, the experts concluded that, on weight of evidence, dimethoate is unlikely to be an endocrine disruptor. It is noted that the dimethoate has not been classified for reproduction category 2.
Other relevant information	Dimethoate was authorised as a candidate for substitution. This substance is subject to PIC Regulation.[9] EFSA (2018n): There are positive in vitro gene mutation studies for dimethoate without adequate in vivo follow-up studies.

5.1.2 | Health-Based Guidance Values – Dimethoate

TABLE 2 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.001 mg/kg bw per day	JMPR, 2019	–	Reg. (EU) 2019/1090 and EFSA (2018) Considering that a genotoxic potential of the active substance cannot be excluded; reference values cannot be set.	No See comments on a.s.
ARfD	0.02 mg/kg bw	JMPR, 2019	–		No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2018n): Given that there are positive in vitro gene mutation studies for dimethoate without adequate in vivo follow-up studies, no threshold can be assumed, and therefore, no HBGVs were derived. JMPR 2019 (FAO and WHO, 2021): ADI based on NOAEL from a developmental toxicity study in rats designed to assess effects of dimethoate on AChE activity in pregnant rats, preweaning rats and young adult rats, applying a standard uncertainty factor of 100. ARfD based on NOAEL from an acute neurotoxicity study and a LOAEL from a special study in preweaning females and in young adult females, applying a standard uncertainty factor of 100. JMPR 2025 (WHO, 2025): A summary report on physiologically based pharmacokinetic (PBPK) modelling to support the use of chemical-specific adjustment factors for dimethoate was submitted by the sponsor for assessment by the JMPR, but the proposed chemical-specific adjustment factors were not accepted.				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Metabolites included in EU RD for RA: –				

5.1.3 | Residue definitions – Dimethoate

Not relevant, no Codex MRL proposals derived by JMPR.

5.1.4 | Codex MRL proposals – Dimethoate

No CXL proposals derived by JMPR.

5.1.5 | Consumer risk assessment – Dimethoate

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

[9]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

5.1.6 | Conclusions – Dimethoate

TABLE 3 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU.
Toxicological assessment	No HBGVs available.
Residue definitions	Not relevant, no Codex MRL proposals derived by JMPR.
Codex MRL proposals	Not relevant, no Codex MRL proposals derived by JMPR.
Dietary risk assessment	Not relevant, no Codex MRL proposals derived by JMPR.
Final conclusion	No Codex MRL proposals derived by JMPR.

5.2 | Malathion (49) R/T

5.2.1 | Background information – Malathion

TABLE 4 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	Periodic review	
RMS	CZ	
Approval status in the EU	Approved only for greenhouse, process of renewal of the approval ongoing	Commission Directive 2010/17/EU[10] Renewal Assessment Report (RAR) submitted, EFSA peer review has not started yet
EFSA conclusion available	Yes, see comments	EFSA (2009c) EFSA (2016j) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory information)
MRL review performed	No	–
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2014a) (various crops) EFSA (2011c) (camomile)
Classification of a.s. (cut-off criteria)	No, see comments	ATP01[11] ECHA RAC assessment not available
Endocrine effects of a.s.	Not assessed	
Other relevant information	Malathion is subject to PIC Regulation[12].	

5.2.2 | Health-Based Guidance Values – Malathion

TABLE 5 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	Comments	Value	Comments	HBGV comparable
ADI	0.3 mg/kg bw per day	JMPR, 2025	0.03 mg/kg bw per day	Reg. (EU) 2018/1495	No See comments on a.s.
ARfD	2 mg/kg bw	JMPR, 2025	0.3 mg/kg bw	Reg. (EU) 2018/1495	No See comments on a.s.

[10]Commission Directive 2010/17/EU of 9 March 2010 amending Council Directive 91/414/EEC to include malathion as active substance. OJ L 60, 10.3.2010, pp. 17–19.
[11]Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 235, 5.9.2009, p. 1–439.
[12]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012.

TABLE 5 (Continued)

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
Conclusion/comments on a.s.	EFSA (2009c): ADI based on NOAEL from 2-year rat study applying a standard uncertainty factor of 100 and an extra uncertainty factor of 10 for the case the specification would contain 0.2% of isomalathion (0.2% is the isomalathion content in the specification for Annex I; malathion with an isomalathion content of 0.03% was considered tested in the critical study). ARfD based on developmental NOAEL from developmental toxicity study in rabbits, applying a standard uncertainty factor of 100. JMPR 2016 and 2025 (FAO and WHO, 2017b, 2026): ADI based on NOAEL from 2-year rat study applying a standard uncertainty factor of 100. ARfD based on NOAEL from a human volunteer study (acetylcholine esterase inhibition) with the application of an uncertainty factor of 10. A summary report on physiologically based pharmacokinetic (PBPK) modelling to support the use of chemical-specific adjustment factors for malathion was submitted by the sponsor for assessment by the JMPR, but the proposed chemical-specific adjustment factors were not accepted. The reference points for ADI setting in the EU and JMPR assessment are the same. At EU level, an additional uncertainty factor of 10 was applied to cover the presence of isomalathion in the technical specification. Different studies were selected to set the ARfD. The human study used in the JMPR assessment to set the ARfD was also available for the EU assessment and the same NOAEL was derived from the study. The rabbit developmental toxicity study used in the EU assessment to set the ARfD was also available for the JMPR assessment, but a different developmental NOAEL was derived from the study.				
Comments on metabolites	JMPR 2016 and 2025 (FAO and WHO, 2017b, 2026): Malaoxon, desmethyl malathion (DMM), malathion mono- and dicarboxylic acid isomers (MMCA and MDCA), desmethyl malathion monocarboxylic acid (DM-MMCA) isomers and desmethyl malaoxon dicarboxylic acid (Mox-DCA) are covered by the HBGVs for malathion, applying potency factors of 30 for malaoxon, 0.36 for DMM, 0.53 for MMCA isomers, 0.22 for MDCA and 1 for DM-MMCA isomers and for Mox-DCA. For the potentially genotoxic metabolites monoethyl maleate, diethyl maleate and diethyl fumarate, JMPR applied the TTC for genotoxicity of 0.0025 µg/kg bw per day. For M18, tetraethyl dithiosuccinate and diethyl methylthiosuccinate, JMPR applied the TTC for Cramer class III compounds: 1.5 µg/kg bw per day for chronic exposure and 5 µg/kg bw for acute exposure. The TTC approach applied by JMPR is not acceptable at EU level. Metabolites included in EU RD for RA: • malaoxon • desmethyl-malathion (DMM) • monocarboxcylic acid-malathion (MMCA) • dicarboxylicacid-malathion (DMCA) EFSA (2009c): Regarding **DMM**, **MMCA** and **MDCA**, the metabolites should be considered as less toxic than malathion, but should be considered toxicologically relevant because of its acetylcholinesterase inhibition activity. Therefore, DMM, MMCA and MDCA are covered by the HBGVs of the parent. EFSA (2016j): Regarding **malaoxon**, a potency factor of 30 between malaoxon and malathion appears to be appropriate with regard to the acetylcholinesterase (AChE) inhibition after repeated dose exposure, which is relevant to the setting of the acceptable daily intake (ADI); nonetheless, uncertainty remains regarding acute exposure to consumers as the acute reference dose (ARfD) of malathion is based on increased incidence of resorptions observed in a developmental toxicity study in rabbits while this endpoint has not been investigated with malaoxon. Genotoxicity has not been investigated for malaoxon while evidence of leukaemia was found in males and females treated with malaoxon for 2 years at the high dose level of 114–141 mg/kg bw per day, that exhibited marked toxicity. While the RMS is of the opinion that an Ames test would be sufficient to address this endpoint, EFSA considers that genotoxicity investigations should cover not only bacterial gene mutation but also gene mutation and chromosome aberrations in mammalian cells and that this data gap does not allow to conclude on the toxicity profile of malaoxon. EFSA (2016j): Regarding metabolite **DM-MMCA**, the genotoxicity data package is insufficient to conclude on its genotoxic potential, which is a basic requirement to set reference values. Furthermore, the same uncertainty exists with regard to acute consumer exposure as identified for malaoxon, as developmental toxicity has not been investigated with DM-MMCA. As the genotoxic potential has not been addressed, no conclusion can be reached on the toxicity profile of the metabolite. EFSA (2016j): With regard to **MoxDCA**, the RMS considers that the metabolite would be covered by the toxicity profile of malaoxon based on an in silico toxicity assessments and SAR (structure–activity relationship) analysis showing that the metabolite would be more polar than malaoxon. In contrast, EFSA is of the opinion that no conclusion can be reached regarding the toxicity profile including the genotoxic potential of MoxDCA due to the lack of data and considering that more polar metabolites may possibly be more toxic than the less polar related compound.				

5.2.3 | Residue definitions – Malathion

TABLE 6 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Malathion	Reg. 396/2005: Malathion (sum of malathion and malaoxon expressed as malathion) Peer review (EFSA, 2009c): Malathion and malaoxon	No
	Animal products	Sum of malathion, butanedioic acid, 2-[(dimethoxyphosphinothioyl) thio]-, monoethyl ester (malathion monocarboxylic acid isomers) and butanedioic acid, [(dimethoxyphosphinothioyl) thio] (malathion dicarboxylic acid) (expressed as malathion) The residue is not fat soluble	Reg. 396/2005: Malathion (sum of malathion and malaoxon expressed as malathion) Peer review (EFSA, 2009c): Not required for the representative use assessed (strawberries, ornamentals) The residue is not fat soluble	No, see the comments
RD RA	Plant products	Not concluded	Peer review (EFSA, 2009c): Malathion, malaoxon, desmethyl-malathion, monocarboxcylic acid-malathion and dicarboxylicacid-malathion expressed as malathiontoxicological equivalents	Not applicable, JMPR not concluded
	Animal products	Not concluded	Peer review (EFSA, 2009c): Not required for the representative use assessed (strawberries, ornamentals)	Not applicable JMPR not concluded
Conclusion, comments	JMPR 2025 assessed malathion metabolism studies in alfalfa, cotton, lettuce, wheat (foliar and post-harvest), apples and rice. **In primary crops**, metabolism mainly proceeded through de-esterification to mono- and dicarboxylic acids, followed by incorporation into natural products. Parent malathion was the major residue component, whereas the more toxicologically potent malaoxon occurred at lower levels, with malaoxon-to-malathion ratios ranging from not detected in stored wheat grain to 23% TRR in apples. Minor metabolites included desmethyl-malathion and related carboxylic acids. **For rotational crops**, a confined study conducted at approximately 2N showed decreasing residues with increasing plant back intervals, with the lowest residues at 365 DAA. At 30 DAA, only parent malathion was identified in lettuce, turnip and wheat at low levels (0.02–0.03 mg/kg; 11%–20% TRR), while malaoxon was not detected. Residue transfer to rotational crops is not expected at GAP compliant use. **In livestock**, metabolism studies in goats and laying hens showed rapid metabolism of malathion. Parent malathion was not detected in tissues, milk or eggs; residues were mainly present as low-level polar metabolites and were not considered fat soluble. JMPR proposed malathion as the residue definition for enforcement in plant products. For dietary risk assessment, JMPR considered the sum of malathion and 30 × malaoxon appropriate, reflecting the higher toxicological potency of malaoxon. However, the residue definition for risk assessment was not finalised, mainly due to the lack of toxicological information for metabolites formed under sterilisation conditions, in particular monoethyl fumarate and mercaptosuccinate. For the metabolites tetraethyl dithiosuccinate, diethyl methylthiosuccinate and M18, limited toxicological information was available. JMPR, therefore, applied the TTC approach for Cramer class III compounds and did not include these metabolites in the residue definition for risk assessment. **For monoethyl maleate, diethyl maleate and diethyl fumarate, a genotoxic potential could not be excluded (see Table on HBGVs)**; JMPR, therefore, applied the TTC for genotoxicity and did not include these compounds in the residue definition for risk assessment. **At EU level, the enforcement residue definition for plant and animal products is the sum of malathion and malaoxon, expressed as malathion**. In the peer review, malathion and malaoxon were proposed for enforcement in plants, while no specific residue definition for animal products was required for the representative uses assessed. **For risk assessment in plants, the EU** residue definition includes malathion, malaoxon, desmethyl-malathion, malathion monocarboxylic acid and malathion dicarboxylic acid, expressed as malathion toxicological equivalents. Overall, the JMPR and EU residue definitions for enforcement are not comparable, JMPR proposed parent malathion only for plants and a different residue definition for animal products, whereas the EU definition includes malathion and malaoxon. For risk assessment, JMPR did not finalise the residue definition, while the EU definition includes additional toxicologically relevant metabolites.		

5.2.4 | Codex MRL proposals – Malathion

TABLE 7 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Apple	0.5 (W)	0.02*	JMPR 2025 could not conclude on residue definitions for risk assessment due to missing toxicological data to sufficiently characterised the relevant metabolites (see Table on residue definitions), Consequently, a consumer risk assessment could not be performed and JMPR proposed withdrawal of the CXLs.
Asparagus	1 (W)	0.02*	
Bean (dry)	2 (W)	0.02*	
Beans with pods (Phaseolus spp.) (immature pods and succulent seeds)	1 (W)	0.02*	
Blueberries	10 (W)	0.02*	
Citrus fruits (group)	7 (W)	2	
Cotton seed oil, crude	13 (W)	–	
Cotton seed oil, edible	13 (W)	–	
Cucumber	0.2 (W)	0.02*	
Grapes	5 (W)	0.02*	
Mustard greens	2 (W)	0.02*	
Onion, bulb	1 (W)	0.02*	
Peppers (subgroup)	0.1 (W)	0.02*	
Peppers, chili, Dried	1 (W)	–	
Spices, fruits and berries	1 (W)	0.02*	
Spices, roots and rhizomes	0.5 (W)	0.02*	
Spices, seeds	2 (W)	0.02*	
Spinach	3 (W)	0.02*	
Spring onion	5 (W)	0.02*	
Strawberry	1 (W)	0.02*	
Sweet corn (corn-on-the-cob)	0.02 (W)	0.02*	
Tomato	0.5 (W)	0.02*	
Tomato, juice	0.01 (W)	–	
Turnip greens	5 (W)	0.02*	
Turnip, garden	0.2 (W)	–	
Wheat bran, unprocessed	25 (W)	–	
Wheat, flour	0.2 (W)	–	
General comments			

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.2.5 | Consumer risk assessment – Malathion

Not performed, as JMPR did not finalise the residue definitions for risk assessment and therefore did not propose Codex MRLs.

5.2.6 | Conclusions – Malathion

TABLE 8 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (RAR submitted, EFSA peer review has not started yet).
Toxicological assessment	EU HBGV available.
Residue definitions	The enforcement residue definitions for plant and animal products differ between JMPR/Codex and the EU. For risk assessment, JMPR did not finalise the residue definitions.
Codex MRL proposals	No Codex MRL proposals are currently under discussion.
Dietary risk assessment	Not performed, as JMPR did not finalise the residue definitions for risk assessment.
Final conclusion	Not relevant, no Codex MRL proposals derived by JMPR.

5.3 | 2-Phenylphenol and its sodium salts (56) R/T

5.3.1 | Background information – 2-Phenylphenol and its sodium salts

TABLE 9 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	Periodic review	
RMS	ES	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Expiration of approval 15/11/2027 Commission Directive 2009/160/EU[13] EFSA peer review ongoing
EFSA conclusion available	Yes, see comments	EFSA (2009a) EFSA peer review ongoing
MRL review performed	Yes, see comments	EFSA (2017b)
EU MRL applications or other EU assessments	No	–
Classification of a.s. (cut-off criteria)	No, see comments	No classification No harmonised classification, but assessment available from ECHA RAC (ECHA, 2022a). No classification for cut-off criteria.
Endocrine effects of a.s.	Assessment ongoing	During the expert consultation (TC 92)[14], it was concluded that insufficient information is available to conclude the ED assessment, and further data were requested. The peer review process has not been concluded yet.
Other relevant information	–	

5.3.2 | Health-Based Guidance Values – 2-Phenylphenol and its sodium salts

TABLE 10 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	–	Evaluation could not be finalised due to lack of relevant toxicological data	0.4 mg/kg bw per day	EFSA, 2009	Not applicable See comments on a.s.
ARfD	–		Not necessary	EFSA, 2009	Not applicable See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2009a): ADI based on NOAEL from 2-year rat study, applying a standard uncertainty factor of 100. ARfD not allocated. During the latest EFSA expert consultation within the peer review (TC 92)[14], the ADI was lowered to 0.25 mg/kg bw per day and the ARfD was set at the same level. These are both based on a developmental NOAEL from the rabbit developmental toxicity study, applying a standard uncertainty factor of 100. It is noted that the peer review process has not been concluded yet. In 2025, JMPR did not finalise the toxicological assessment due to increased liver carcinomas in mice, transitional cell bladder carcinomas in rats and indications of in vivo genotoxicity. The evaluation was postponed pending an MoA analysis for these tumours under the IPCS framework. In its previous assessment (JMPR 1999; FAO and WHO, 1999), JMPR established an ADI of 0.4 mg/kg bw per day based on a NOAEL from a 2-year rat study and a standard uncertainty factor of 100. No ARfD was allocated. In the latest EFSA expert consultation within the peer review TC 92[14], 2-phenylphenol and sodium 2-phenylphenol were concluded unlikely to be genotoxic. A NOAEL for carcinogenicity of 39 mg/kg bw per day based on neoplasms in the urinary bladder in males at 200 mg/kg bw per day was set. The bladder carcinogenicity is relevant to humans and classification as Carc. 2 (H351) was concluded by ECHA RAC (ECHA, 2022a).			
Comments on metabolites	Metabolites included in JMPR RD for RA: – Metabolites included in EU RD for RA: • 2-phenylhydroquinone and their conjugates In the latest EFSA expert consultation within the peer review (TC 92)[14], it was not concluded neither on genotoxicity potential nor on the general toxicity for this metabolite.				

[13]Commission Directive 2009/160/EU of 17 December 2009 amending Council Directive 91/414/EEC to include 2-phenylphenol as active substance. OJ L 338, 19.12.2009, pp. 83–86.
[14]https://www.efsa.europa.eu/sites/default/files/2023-12/minutes-ppr-mammalian-toxicity.pdf.

5.3.3 | Residue definitions – 2-Phenylphenol and its sodium salts

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Sum of 2-phenylphenol and its salts and conjugates, expressed as 2-phenylphenol	Reg. 396/2005: 2-phenylphenol (sum of 2-phenylphenol and its conjugates, expressed as 2-phenylphenol)	Yes
	Animal products	Not concluded Fat solubility not specified	Reg. 396/2005: 2-phenylphenol MRL review (EFSA, 2017b): 2-phenylphenol The residue is fat soluble	Not applicable, see the comments
RD RA	Plant products	Not concluded	MRL review (EFSA, 2017b): Sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates (tentative) Peer review (EFSA, 2009a): Provisional, for fruit crops only: Sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates expressed as 2-phenylphenol	Not applicable, see the comments
	Animal products	Not concluded	MRL review (EFSA, 2017b): 2-phenylphenol Peer review (EFSA, 2009a): Proposal not possible as no metabolites could be identified/ not required for notified use in citrus fruit	Not applicable, see the comments
Conclusion, comments	JMPR 2025 assessed plant metabolism in oranges and pears following post-harvest dip treatments. In both crops, residues were mainly represented by parent 2-phenylphenol, present as free and conjugated forms and accounting for more than 80% of the TRR. Only minor metabolites, namely PHQ (2-phenylhydroquinone) and 2-MBP (2-methoxybiphenyl), were identified at low levels, mainly in orange peel. Based on these data, JMPR derived the residue definition for enforcement in plant commodities as the **sum of 2-phenylphenol, its salts and conjugates, expressed as 2-phenylphenol**. However, JMPR was unable to conclude on residue definitions for risk assessment in plant and animal commodities due to the unfinalised toxicological evaluation (see table above on HBGV) and lack of validated analytical methods, in particular for conjugated residues in livestock. At EU level, during the peer review process currently ongoing (TC 96),[15] the same fruit metabolism studies were available. Similar residue definition was proposed for enforcement, confirming the existing one. For risk assessment, the proposed residue definition was the **sum of 2-phenylphenol, its salts and conjugates, expressed as 2-phenylphenol**, whereas the **existing** residue definition also **includes** 2-phenylhydroquinone. Although this metabolite was not included in the proposed risk assessment residue definition in the latest EFSA peer review, a data gap was identified to address its genotoxicity. It is noted that the available metabolism studies only cover post-harvest uses; therefore, the residue definition is limited to this use pattern. Any extension to other uses would need to be supported by appropriate metabolism studies covering those uses.			

5.3.4 | Codex MRL proposals – 2-Phenylphenol and its sodium salts

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Pear	20 Po (W)	20 (Po)	JMPR 2025 proposed withdrawal of the CXL for pear, as no residue trials were submitted and the residue definition for risk assessment could not be finalised. The existing EU MRL for pear (Po) is based on this CXL.
General comments	JMPR 2025 estimated a CXL of 6 mg/kg for citrus, based on residue data from foam applications to oranges, lemons and grapefruits. However, no CXL was proposed because the residue definition for risk assessment could not be finalised. The existing CXL of 10 mg/kg, based on post-harvest use, is currently implemented in the EU MRL database. EFSA therefore considers that withdrawal of the existing CXL for citrus fruits should also be proposed.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended; Po, the recommendation accommodates post-harvest treatment of the commodity.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[15] https://www.efsa.europa.eu/sites/default/files/2021-10/pesticides-residues-minutes.pdf.

5.3.5 | Consumer risk assessment – 2-Phenylphenol and its sodium salts

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

5.3.6 | Conclusions – 2-Phenylphenol and its sodium salts

TABLE 11 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (currently ongoing).
Toxicological assessment	EU HBGV available.
Residue definitions	The EU and Codex residue definitions for enforcement in plants are identical. JMPR did not finalise the residue definitions for risk assessment in plants or for enforcement and risk assessment in livestock. In the EU peer review currently ongoing, the proposed residue definition for risk assessment in plants is similar with the enforcement residue definition.
Codex MRL proposals	No new Codex MRL proposals under discussion.
Dietary risk assessment	No dietary risk assessment performed.
Final conclusion	Risk managers should discuss and decide the final EU position on whether the EU MRL for pears should be maintained. For citrus fruits, withdrawal of the CXL should also be proposed, as the residue definition for risk assessment in plants could not be finalised.

5.4 | Guazatine (114) R/T

5.4.1 | Background information – Guazatine

TABLE 12 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	Periodic review	
RMS	No RMS assigned	
Approval status in the EU	Not approved	Commission Decision 2008/934/EC[16]
EFSA conclusion available	Yes, see comments	EFSA (2010b)
MRL review performed	Yes, see comments	EFSA (2013h)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2014g) (citrus fruits)
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Guazatine is subject to PIC Regulation.[17]	

5.4.2 | Health-Based Guidance Values – Guazatine

TABLE 13 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.008 mg/kg bw per day	JMPR, 2025	–	Not applicable	Not applicable
ARfD	Unnecessary	JMPR, 2025	–	Not applicable	Not applicable
Conclusion/ comments on a.s.	The JMPR established the ADI based on a NOAEL of 0.8 mg/kg bw per day from a 52-week study in dogs and using a safety factor of 100.				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Metabolites included in EU RD for RA: –				

[16]Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive. 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p. 11–14.

[17]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

5.4.3 | Residue definitions – Guazatine

TABLE 14 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Fruit commodities: sum of guazatine acetates (guazatine)	Reg. 396/2005: Guazatine (guazatine acetate, sum of components) MRL review (EFSA, 2013h) and Peer review (EFSA, 2010b): Guazatine acetates	Yes
	Animal products	Not concluded Fat solubility not specified	MRL review (EFSA, 2013h) and Peer review (EFSA, 2010b): Not applicable The residue is not fat soluble	Not applicable, see comments
RD RA	Plant products	Fruit commodities: Sum of guazatine acetates (guazatine)	MRL review (EFSA, 2013h) and Peer review (EFSA, 2010b): Guazatine acetates	Yes
	Animal products	Not concluded	MRL review (EFSA, 2013h) and Peer review (EFSA, 2010b): Not applicable	Not applicable, see comments
Conclusion, comments	The residue definitions for enforcement and RA for plants are the same in the EU and JMPR. For livestock, in the EU peer-review since no animal metabolism study, livestock feeding study were provided no RDs were derived. The JMPR also did not conclude on the livestock RDs because the metabolism study on lactating cows could not identify quantified radioactive residues in milk and tissues; in addition, there are no suitable analytical methods for animal matrices.			

5.4.4 | Codex MRL proposals – Guazatine

No CXL proposals derived by JMPR due to the lack of appropriate storage stability studies.

5.4.5 | Consumer risk assessment – Guazatine

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

5.4.6 | Conclusions – Guazatine

TABLE 15 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU (a decision not to include guazatine in Annex I to Directive 91/414/EEC entered into force on 31 December 2008).
Toxicological assessment	No EU HBGV available.
Residue definitions	Not relevant, no Codex MRL proposals derived by JMPR.
Codex MRL proposals	Not relevant, no Codex MRL proposals derived by JMPR.
Dietary risk assessment	Not relevant, no Codex MRL proposals derived by JMPR.
Final conclusion	Not relevant, no Codex MRL proposals derived by JMPR.

5.5 | Permethrin (120) T

5.5.1 | Background information – Permethrin

TABLE 16 Background information.

	Comments, references
JMPR assessment	JMPR meeting 2025
Type of JMPR evaluation	Periodic review
RMS	No RMS assigned

(Continues)

TABLE 16 (Continued)

		Comments, references
Approval status in the EU	Not approved	Commission Decision 2000/817/EC[18]
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	Yes, see comments	(EFSA, 2016i) (Art.43 assessment – setting of MRLs in certain products of animal origin)
Classification of a.s. (cut-off criteria)	No, see comments	No classification CLP00[19]
Endocrine effects of a.s.	Not assessed	
Other relevant information	Permethrin is authorised for use in veterinary medicine, as biocide and is also subject to PIC Regulation.[20]	

5.5.2 | Health-Based Guidance Values – Permethrin

TABLE 17 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.05 mg/kg bw per day	JMPR, 2025	–	Not applicable	Not applicable
ARfD	0.05 mg/kg bw	JMPR, 2025	–	Not applicable	Not applicable
Conclusion/ comments on a.s.	The 2025 JMPR report confirmed the ADI of 0.05 mg/kg bw established by the JMPR 2002, based on a NOAEL of 5 mg/kg bw per day in a 2-year study in rats and 90-day and 1-year studies in dog and applying a safety factor of 100. The 2025 JMPR report set an ARfD of 0.05 mg/kg bw based on a NOAEL of 5 mg/kg bw per day in the 90-day dog study where clinical signs including tremors were observed after single dosing, using a safety factor of 100. The previous ARfD of 1.5 mg/kg bw was withdrawn.				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Metabolites included in EU RD for RA: –				

5.5.3 | Residue definitions – Permethrin

Not relevant, no Codex MRL proposals derived by JMPR.

5.5.4 | Codex MRL proposals – Permethrin

No CXL proposals derived by JMPR.

5.5.5 | Consumer risk assessment – Permethrin

Not relevant, no Codex MRL proposals were derived by JMPR

5.5.6 | Conclusions – Permethrin

TABLE 18 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU (a decision not to include permethrin in Annex I to Directive 91/414/EEC entered into force on 28 December 2000).
Toxicological assessment	No EU HBGV available.

[18]2000/817/EC: Commission Decision of 27 December 2000 concerning the non-inclusion of permethrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substanc.OJ L 332, 28.12.2000, pp. 114–115.

[19]Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008.

[20]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

TABLE 18 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Residue definitions	Not relevant, no Codex MRL proposals were derived by JMPR.
Codex MRL proposals	Not relevant, no Codex MRL proposals were derived by JMPR.
Dietary risk assessment	Not relevant, no Codex MRL proposals were derived by JMPR.
Final conclusion	Not relevant, no Codex MRL proposals were derived by JMPR.

5.6 | Cyfluthrin (157) R – Beta-Cyfluthrin (228) R

5.6.1 | Background information – Cyfluthrin and Beta-Cyfluthrin

TABLE 19 Background information.

		Comments, references
Cyfluthrin		
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	DE	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2022/801[21] No application to renew the approval was submitted
EFSA conclusion available	No	
MRL review performed	Yes, see comments	EFSA (2021g)
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP18[22] ECHA (2020a)
Endocrine effects of a.s.	Not assessed	No ED assessment performed for cyfluthrin in EU
Other relevant information	Cyfluthrin is authorised for use in veterinary medicine and is used as biocide.	
Beta-Cyfluthrin		
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	DE	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2020/892[23]
EFSA conclusion available	Yes, see comments	EFSA (2020e) EFSA (2018k)
MRL review performed	Yes, see comments	EFSA (2021g)
EU MRL applications or other EU assessments	No, see comments	Art.12 confirmatory data (ongoing)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP18[22] ECHA (2020b)
Endocrine effects of a.s.	No, see comment	EFSA (2018k, 2020e): The conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. It was concluded that beta-cyfluthrin is unlikely to have endocrine disrupting properties.
Other relevant information	Beta-cyfluthrin is authorised for use in veterinary medicine and is subject to PIC Regulation.[24]	

[21]Commission Implementing Regulation (EU) 2022/801 of 20 May 2022 amending Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council. C/2022/3216. OJ L 143, 23.5.2022, pp. 7–10.

[22]Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 129, 3.5.2022, p. 1–17.

[23]Commission Implementing Regulation (EU) 2020/892 of 29 June 2020 concerning the non-renewal of the approval of the active substance beta-cyfluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2020/4221. OJ L 206, 30.6.2020, pp. 5–7.

[24]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

5.6.2 | Health-Based Guidance Values – Cyfluthrin and Beta-Cyfluthrin

TABLE 20 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
Cyfluthrin					
ADI	0.04 mg/kg bw per day	JMPR, 2006	0.01 mg/kg bw per day	EFSA, 2018, 2020	No See comments on a.s.
ARfD	0.04 mg/kg bw	JMPR, 2006	0.01 mg/kg bw	EFSA, 2018, 2020	No See comments on a.s.
Beta-Cyfluthrin					
ADI	0.04 mg/kg bw per day	JMPR, 2006	0.01 mg/kg bw per day	EFSA, 2018, 2020	No See comments on a.s.
ARfD	0.04 mg/kg bw	JMPR, 2006	0.01 mg/kg bw	EFSA, 2018, 2020	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2018k, 2020e): For beta-cyfluthrin, the ADI and ARfD are based on a NOAEL from a 4-week rat study, applying a standard uncertainty factor of 100. Considering the acceptable read-across between cyfluthrin and beta-cyfluthrin (e.g. for long-term and reproductive toxicity), and the similar toxicological profile of both compounds in short-term and developmental studies, it can be considered that the critical study (4-week rat, used for the derivation of the ADI and ARfD) identified for beta-cyfluthrin will also cover the toxicological profile of cyfluthrin. JMPR 2006 (FAO and WHO, 2006a): A group ARfD for cyfluthrin and beta-cyfluthrin was based on a NOAEL of from a 4-week study with beta-cyfluthrin using an uncertainty factor of 25. The JMPR considered establishing a group ADI of 0.06 mg/kg bw per day based on an overall NOAEL from a 2-year dietary study with cyfluthrin in rats, applying a standard uncertainty factor of 100. Noting that the proposed ADI was higher than the ARfD, the JMPR established the ADI at 0.04 mg/kg bw per day (the same value as the ARfD). It is noted that the reference point for HBGV setting in the EU and JMPR assessment are the same. In the EU assessment, an uncertainty factor of 100 was applied, whereas in the JMPR assessment, the uncertainty factor applied was 25.				
Comments on metabolites	Metabolites included in JMPR RD for RA: not relevant Metabolites included in EU RD for RA: not relevant				

5.6.3 | Residue definitions – Cyfluthrin and Beta-Cyfluthrin

TABLE 21 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyfluthrin (sum of isomers)	Reg. 396/2005 (implementing MRL review): Cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers)	Yes
	Animal products	Cyfluthrin (sum of isomers) The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Cyfluthrin (sum of isomers)	MRL review (EFSA, 2021g) and Peer review (EFSA, 2020e): Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)	Yes
	Animal products	Cyfluthrin (sum of isomers)	MRL review (EFSA, 2021g) and Peer review (EFSA, 2020e): Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)	Yes
Conclusion, comments	The EU residue definition for MRL enforcement and risk assessment in plants and livestock is equivalent to the JMPR residue definitions.			

5.6.4 | Codex MRL proposals – Cyfluthrin and Beta-Cyfluthrin

TABLE 22 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.02 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of eggs.
Grapes	**0.4**	0.01*	cGAP: USA, Foliar, 4 × 28 g a.s./ha, 14-day RTI, 3-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is not acceptable for the table grapes as it leads to an acute risk for the EU consumer (see consumer risk assessment section) Follow-up action: None.
Grape, raisin	1.5	–	JMPR derived a processing factor of 3.7. Currently, no EU MRLs are established for processed products.
Grape, juice	–	–	JMPR derived a processing factor of 0.097. Currently, no EU MRLs are established for processed products.
Grape, must	–	–	JMPR derived a processing factor of 1.3. Currently, no EU MRLs are established for processed products.
Grape pomace, wet	15	–	JMPR derived a processing factor of 5.2. Currently, no EU MRLs are established for processed products.
Grape, wine	–	–	JMPR derived a processing factor of 0.021. Currently, no EU MRLs are established for processed products.
Group of avians, edible offal of	0.01*	0.01*	Max. dietary burden (EU laying poultry): 0.393 ppm. The highest maximum and the mean dietary burdens for poultry are 0.40 ppm and 0.23 ppm, respectively. No residues above the LOQ of the analytical method (0.01 mg/kg) used were observed in the feeding study for laying hens at the lowest dose level equivalent to 2 ppm in the diet (approximately five times higher than the maximum burden in poultry). Therefore, the JMPR proposed MRLs for eggs and poultry tissues at the level of the LOQ of 0.01 mg/kg. Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian fats	0.01*	0.01*	See group of avians, edible offal.
Group of avian muscle	0.01*	0.01*	See group of avians, edible offal.
Group of edible offal (mammalian)	0.02	Liver and kidney from swine, ruminants, equine and others: 0.02 edible offals from swine, ruminants, equine and others: 0.2	Max. dietary burden (AUS beef cattle): 2.88 ppm. Max. residues in kidney: 0.013 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of eggs	0.01*	0.01*	See group of avians, edible offal.
Group of mammalian fats (except milk fats)	0.2	0.2	Max. dietary burden (AUS beef cattle): 2.88 ppm. Max. residues in fat: 0.19 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milk fats[c]	0.3	–	In the EU, specific MRLs are not set for milk fats.
Group of muscle (from mammals other than marine mammals)	0.01*	0.01	Max. dietary burden (AUS beef cattle): 2.88 ppm. Max. residues in muscle: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

(Continues)

TABLE 22 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Mammalian meat (from mammals other than marine mammals)	0.2 (fat) (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Group of milks	0.01	0.02 (cattle, sheep and goat) 0.01 (horse)	Max. dietary burden (AUS dairy cattle): 2.297 ppm. Max. residues in milk: 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Milks	0.01 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milks.
Poultry edible offal	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian, edible offal.
Poultry meat	0.01* (fat) (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian muscle.
Wheat	**0.05**	0.04	cGAP: USA, Foliar, 2 × 21 g a.s./ha, 3-day RTI, 30-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: The JMPR extrapolated the MRL to Triticale. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None.
Wheat, bran	–	–	JMPR derived a processing factor of 1.11. Currently, no EU MRLs are established for processed products.
Wheat, flour	–	–	JMPR derived a processing factor of 0.35. Currently, no EU MRLs are established for processed products.
Wheat, germ	–	–	JMPR derived a processing factor of 0.77. Currently, no EU MRLs are established for processed products.
Wheat, gluten	0.08		JMPR derived a processing factor of 1.61. Currently, no EU MRLs are established for processed products.
Wheat, starch	–	–	JMPR derived a processing factor of 0.205. Currently, no EU MRLs are established for processed products.
Wheat, wholemeal bread	–	–	JMPR derived a processing factor of 0.695. Currently, no EU MRLs are established for processed products.
Wheat, wholemeal flour	–	–	JMPR derived a processing factor of 0.0106. Currently, no EU MRLs are established for processed products.
Triticale	**0.05**	0.04	See wheat.
General comments			

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.6.5 | Consumer risk assessment – Cyfluthrin and Beta-Cyfluthrin

TABLE 23 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. grapes and wheat).	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2021g) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. grapes and wheat).	**Specific comments:** –

TABLE 23 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: **The calculated short-term exposure exceeded the ARfD for table grapes.** **Table grapes: 163% of ARfD** **Wine grapes 21% of ArfD** **Wheat: 7% of ARfD**	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 24% of the ADI. Among the crops under consideration, wheat was identified as the main contributor, accounting for up to 2% of the ADI.	**Results:** Long-term exposure: Max 3% of the JMPR ADI. Short-term exposure: Highest result for grapes: 40% of ARfD GECDE mean: Max. 4% (infants and toddler) GECDE max: Max. 10% (infants and toddler)

5.6.6 | Conclusions – Cyfluthrin and Beta-Cyfluthrin

TABLE 24 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU (no request for renewal was submitted).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs are identical.
Codex MRL proposals	The proposed Codex MRL is not acceptable for table grapes as it leads to acute risk for EU consumer.
Dietary risk assessment	Acute intake concern identified for table grapes.
Final conclusion	The final EU position should be discussed/decided by risk managers.

5.7 | Bifenthrin (178) R/T

5.7.1 | Background information – Bifenthrin

TABLE 25 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status in the EU	Not approved	Approval expired on 31 July 2019; The application for renewal was withdrawn by the applicant
EFSA conclusion available	Yes, see comments	EFSA (2009b) EFSA (2011b) EFSA (2015f) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data) EFSA (2016k) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2015d)
EU MRL applications or other EU assessments	Yes, see comments	Art.43 assessment for an updated MRL risk assessment (ongoing) EFSA (2024i) (Art.43 assessment – outcome of the stakeholder consultation) EFSA (2023a) (Art.43 assessment) EFSA (2020m) (Art. 12 confirmatory data and import tolerance in maize grain and sweet corn)
Classification of a.s. (cut-off criteria)	No, see comments	(ECHA, 2011b; ATP5[25])
Endocrine effects of a.s.	Not assessed	
Other relevant information	Bifenthrin was approved as a candidate for substitution and as biocide for wood preservation (product type PT08). This substance is subject to PIC Regulation[26] and belongs to the class of PFAS chemicals.	

[25]Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 261, 3.10.2013, p. 5–22.

[26]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

5.7.2 | Health-Based Guidance Values – Bifenthrin

TABLE 26 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.01 mg/kg bw per day	JMPR, 2009	0.015 mg/kg bw per day	Reg. (EU) 2018/291	No See comments on a.s.
ARfD	0.01 mg/kg bw	JMPR, 2009	0.03 mg/kg bw	Reg. (EU) 2018/291	No See comments on a.s.
Conclusion/ comments on a.s.	In the framework of a recent assessment by EFSA (EFSA, 2023a), it was concluded that, due to the deficiencies listed below, the derivation of toxicological reference values according to current scientific standards is not possible, and therefore, the experts recommended to withdraw the previous EU HBGVs (previous ADI derived in 2011: 0.015 mg/kg bw per day, previous ARfD derived in 2011: 0.03 mg/kg bw). • According to current standards, the genotoxic potential of bifenthrin was found to be inconclusive. • The assessment of the validity of the toxicological studies and reliability of their results is limited by the lack of details on the toxicological studies reported in the DAR (France, 2005) (e.g. that do not allow to verify the compliance of these studies with the current version of the test guidelines), and the unknown validity of the analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicity studies. These limitations imply, for instance, that it is not possible to understand the difference in NOAELs derived by the EU and the JMPR assessments, as is the case of the maternal and developmental toxicity NOAELs of a developmental toxicity study in rats (critical to the risk assessment). • A search for published literature has not been conducted; the JMPR identified a published study (Wolansky et al., 2006) not available to the EU peer review, that was used as the basis to derive an ARfD. • The endocrine disruptive potential of bifenthrin was not assessed according to the current ECHA/EFSA Guidance (ECHA and EFSA, 2018). It is expected that additional toxicological information would be needed to perform such an assessment. • An interspecies comparative in vitro metabolism study performed on animal species used in pivotal studies and on human material is not available to determine the relevance of the toxicological animal data to humans and whether additional testing of potential unique human metabolites would be required. EFSA (2024i): Additional data were submitted following a call for data ran from 8 May 2024 to 8 July 2024 that might have an impact on the conclusions of the previous assessment (EFSA, 2023a). The provided data set was considered potentially relevant to address the data gaps identified in the targeted review of bifentrhin (EFSA, 2023a) and to support the evaluation of the TRVs. In 2009, JMPR derived an ADI based on a maternal and developmental NOAEL in a developmental toxicity study in rats, applying a standard uncertainty factor of 100 and an ARfD based on a threshold dose from an acute toxicity in rats, applying a standard uncertainty factor of 100 (FAO and WHO, 2011a). New studies were available and evaluated by the JMPR 2025 meeting and it was concluded that they would not affect the current ADI and ARfD. These studies will be reviewed as part of a periodic re-evaluation in the future. A toxicological monograph addendum was not prepared.				
Comments on metabolites	Metabolites included in JMPR RD for RA: not relevant Metabolites proposed for inclusion in EU RD for RA EFSA (2011b): • BP-acid • hydroxyl-methyl bifenthrin and its fatty acid conjugates Both metabolites are covered by the HBGVs of the parent EFSA (2011b)				

5.7.3 | Residue definitions – Bifenthrin

TABLE 27 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	**JMPR evaluation**	**EU evaluation**	**RDs comparable**
RD enf	Plant products	Bifenthrin (sum of isomers)	Reg. 396/2005 (implementing MRL review): Bifenthrin (sum of isomers)	Yes
	Animal products	Bifenthrin (sum of isomers) The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Bifenthrin (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Bifenthrin (sum of isomers)	MRL review (EFSA, 2015d) and Peer review (EFSA, 2011b): Bifenthrin (sum of isomers)	Yes
	Animal products	Bifenthrin (sum of isomers)	MRL review (EFSA, 2015d): Bifenthrin (sum of isomers) Peer review (EFSA, 2011b): Ruminant liver and kidney: Sum of bifenthrin (sum of isomers) and BP-acid, expressed as bifenthrin Eggs, poultry liver: Sum bifenthrin (sum of isomers) and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin Milk and all other animal products: Bifenthrin (sum of isomers)	Yes (compared with the RD derived in the MRL Art 12 review)
Conclusion, comments	RD for enforcement for plants and livestock in the EU and JMPR are the same. For animal products, the EU RD-RA proposed in the Art. 12 MRL review is the same.			

5.7.4 | Codex MRL proposals – Bifenthrin

TABLE 28 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Citrus fruits	0.05 (W)	–	The existing CXL is being replaced with the new proposals for the group of oranges, sweet, sour, the subgroup of lemons and limes and subgroup of mandarins.
Citrus pulp, dry	0.5	–	JMPR derived a processing factor of 2.45. Currently, no EU MRLs are established for processed products.
Citrus oil, edible	20	–	JMPR derived a processing factor of 78. Currently, no EU MRLs are established for processed products.
Cranberry	**1.5**	0.01*	cGAP: USA, foliar, 3 × 112 g a.s./ha, RTI 7 days, PHI 30 days Number of trials: 5 Sufficiently supported by data: Yes Specific comments: The CXL is supported by data. The consumer risk assessment was performed with EU HBGVs recommended for withdrawal, and an EU assessment of the HBGVs, residue definition and MRL review of bifenthrin is ongoing (see general comments). **Conclusion:** It is recommended to discuss with Member States whether the CXLs are acceptable in view of the ongoing EU assessment of the HBGVs. Follow-up action: None
Edible offal (mammalian)	0.2 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Group of edible offal (mammalian)	0.2	Liver and kidney from swine, ruminants, equine and others: 0.2 Edible offals from swine, ruminants, equine and others: 3	The JMPR included the only feed item (citrus pulp, dried) in an updated dietary burden calculation. This did not result in a significant change of the dietary burdens of farm animals conducted by the 2022 JMPR. Therefore, the JMPR did not recalculate and confirmed the previous MRL recommendations for animal commodities.
Group of mammalian fats (except milk fats)	3	3	See group of edible offal (mammalian).
Group of milk fats[c]	3	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	0.2	0.2	See group of edible offal (mammalian).
Group of muscle (from mammals other than marine mammals)	**0.3**	0.2	See group of edible offal (mammalian). Specific comments: There is a discrepancy in the JMPR report for the CXL value estimated for the group of mammalian muscle: 0.2 mg/kg (page 115) or 0.3 mg/kg according to table 5.5.2 (page 114). The consumer risk assessment was performed with EU HBGVs recommended for withdrawal, and an EU assessment of the HBGVs, residue definition and MRL review of bifenthrin is ongoing (see general comment). **Conclusion:** It is recommended to discuss with Member States whether the CXLs are acceptable in view of the ongoing EU assessment of the HBGVs. Follow-up action: None
Meat (from mammals other than marine mammals)	3 (fat) (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milk fats[c]	3 (W)	–	The existing CXL is being replaced with the new proposal for the group of milk fats.
Milks	0.2 (W)	–	The existing CXL is being replaced with the new proposal for the group of milks.
Orange juice	–	–	JMPR derived a processing factor of 0.03. Currently, no EU MRLs are established for processed products.
Orange marmalade	–	–	JMPR derived a processing factor of 0.34. Currently, no EU MRLs are established for processed products.
Subgroup of lemons and limes	**0.05**	0.05 (lemons and limes) 0.01* (kumquat)	cGAP: USA, Soil application to bare soil beneath citrus trees at 560 g a.s./ha, 1-day PHI. Number of trials: 36 Sufficiently supported by data: Yes

(Continues)

TABLE 28 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
			Specific comments: The JMPR proposed the MRL based on trials on lemons, oranges, and grapefruits from a cGAP from the United States, already assessed by JMPR 2010, where all residues were below the LOQ except for a single value of 0.05 mg/kg. The consumer risk assessment was performed with EU HBGVs recommended for withdrawal, and an EU assessment of the HBGVs, residue definition and MRL review of bifenthrin is ongoing (see general comment). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable due to the ongoing EU toxicological assessment. Follow-up action: None
Subgroup of mandarins	0.05	0.05	See subgroup of lemons and limes.
Subgroup of oranges, sweet, sour	**0.2**	0.05	cGAP: Brazil, Foliar, 2 × 58.5 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: Four trials were conducted with 2 foliar applications at 31 g a.s./ha, and four trials with 2 applications at 58.5 g a.s./ha. Underdosed trials were upscaled using the proportionality approach. **Conclusion:** The CXL is supported by data. However, the risk assessment used EU HBGVs recommended for withdrawal, and an EU assessment of the HBGVs, residue definition and MRL review of bifenthrin is ongoing (see general comment) Follow-up action: None
Subgroup of pummelos and grapefruits	0.05	0.05	See subgroup of lemons and limes.
General comments	In the targeted review of the MRLs for bifenthrin (EFSA, 2023a), EFSA noted that the consumer risk assessment for bifenthrin could not be finalised due to the lack of robust HBGVs. Following a subsequent call for data to address the data gaps identified in the targeted review, EFSA concluded that the additional data submitted could be potentially used to support the evaluation of the HBGVs for bifenthrin (EFSA, 2024i). At request of the European Commission, EFSA received a mandate (EFSA-Q-2025-00684) to conclude on the toxicological properties of bifenthrin, to set HBGVs and residue definition for bifenthrin, and, pending the set of HBGVs and RD, to perform a review of the existing MRLs.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.7.5 | Consumer risk assessment – Bifenthrin

TABLE 29 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 (PRIMo rev. 3.1) was performed for all commodities, for which the Codex MRLs proposed were higher than the current EU MRLs (i.e. cranberry, kumquat, oranges). The risk assessment was performed with the EU ARfD which was recommended to be withdrawn, as the ARfD does not comply with the current scientific standards (see section on toxicological reference values). The calculations are indicative, because the EU HBGVs are not confirmed. A risk management decision is required to endorse the withdrawal of the HBGVs. The calculations are therefore affected by additional, non-standard uncertainties.	**RA assumptions:** An indicative long-term dietary risk assessment was performed using PRIMo rev. 3.1. The most recent long-term risk assessment (EU Scenario 1a) (EFSA, 2023a) was updated, including the STMR values derived by JMPR for the crops for which Codex MRLs proposed were higher than the current EU MRLs (i.e. cranberry, kumquat, oranges). The calculations are indicative, because the EU HBGVs are not confirmed. The risk assessment was performed with the EU ADI which was recommended to be withdrawn, as the ADI does not comply with the current scientific standards (see section on toxicological reference values). The calculations are indicative, because the EU HBGVs are not confirmed. A risk management decision is required to endorse the withdrawal of the HBGVs. The calculations are therefore affected by additional, non-standard uncertainties.	**Specific comments:**

TABLE 29 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for the crops under assessment. Oranges: 49% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 39% of the ADI. Among the crops under consideration, oranges were identified as the main contributors, accounting for up to 1% of the ADI.	**Results:** Long-term exposure: Max 40% of the JMPR ADI. Short-term exposure: Highest result for milk: 70% of ARfD

5.7.6 | Conclusions – Bifenthrin

TABLE 30 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU.
Toxicological assessment	EU HBGVs recommended for withdrawal; an EU assessment of the HBGVs, residue definition and MRL review of bifenthrin is ongoing.
Residue definitions	EU and Codex RDs are identical.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data, but EFSA highlighted the need for further risk management discussions.
Dietary risk assessment	No acute and no chronic intake concern identified.

5.8 | Pyriproxyfen (200) R

5.8.1 | Background information – Pyriproxyfen

TABLE 31 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	NL	
Approval status in the EU	Approved	Commission Implementing Regulation (EU) 2020/968[27]
EFSA conclusion available	Yes, see comments	EFSA (2019e)
MRL review performed	Yes, see comments	EFSA (2022g)
EU MRL applications or other EU assessments	Yes, see comments	The MRL application assessed before the MRL review are not listed.
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP01[28] ECHA (2024)
Endocrine effects of a.s.	No, see comment	EFSA (2019e): pyriproxyfen was concluded as unlikely to meet the scientific criteria for the determination of the ED properties as laid down in Commission Regulation (EC) No 2018/605 and according to the ECHA/EFSA guidance (ECHA and EFSA, 2018).
Other relevant information		Pyriproxyfen is authorised as biocide.

[27]Commission Implementing Regulation (EU) 2020/968 of 3 July 2020 renewing the approval of the active substance pyriproxyfen in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2020/4359. OJ L 213, 6.7.2020, pp. 7–11.

[28]Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 235, 5.9.2009, p. 1–439.

5.8.2 | Health-Based Guidance Values – Pyriproxyfen

TABLE 32 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.1 mg/kg bw per day	JMPR, 1999	0.05 mg/kg bw per day	EFSA, 2019	No See comments on a.s.
ARfD	Unnecessary	JMPR, 1999	1 mg/kg bw	EFSA, 2019	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2019e): ADI based on LOAEL from long-term mouse study, applying a standard uncertainty factor of 100 and an additional uncertainty factor of 3, given that the reference point is a LOAEL and not a NOAEL. ARfD based on a developmental NOAEL in the developmental toxicity study in rabbits, applying a standard uncertainty factor of 100. JMPR 1999 (FAO and WHO, 1999): ADI based on NOAEL from 1-year dog study, applying a standard uncertainty factor of 100. ARfD not allocated due to low acute toxicity. The long-term toxicity study in mouse used by EU to set the ADI has also been reported by JMPR 1999 (FAO and WHO, 1999), but the LOAEL identified in the EU assessment was considered the NOAEL in the JMPR assessment. The rabbit developmental toxicity study used by EU to set the ARfD has also been reported in JMPR 1999 (FAO and WHO, 1999), but no developmental toxicity was reported and the NOAEL was set at the highest dose tested.				
Comments on metabolites	Metabolites included in EU RD for RA: • 4′-OH-pyriproxyfen EFSA (2019e): No experimental data available for toxicological assessment. The metabolite was not identified as a major rat metabolite and was therefore not considered covered by the toxicological studies performed with pyriproxyfen.				

5.8.3 | Residue definitions – Pyriproxyfen

TABLE 33 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	Reg. 396/2005: Pyriproxyfen MRL review (EFSA, 2022g): Fruits, pulses/oilseeds, root and tuber (vegetables seedbeds: BBCH 00 – early post-emergence), following foliar treatment: Pyriproxyfen Leafy crops, except tea: data gap Peer review (EFSA, 2019e): Pyriproxyfen (applicable to fruit and pulses/oilseeds crops – Foliar treatment)	Yes
	Animal products	Pyriproxyfen The residue is fat soluble	Reg. 396/2005: Pyriproxyfen MRL review (EFSA, 2022g) and Peer review (EFSA, 2019e): Pyriproxyfen The residue is fat soluble	Yes
RD RA	Plant products	Pyriproxyfen	MRL review (EFSA, 2022g): Fruits, pulses/oilseeds, root and tuber (vegetables seedbeds: BBCH 00 – early post-emergence), following foliar treatment: Pyriproxyfen Leafy crops, except tea: data gap Tea – foliar treatment: Sum of pyriproxyfen and 4′-OH-pyriproxyfen, expressed as pyriproxyfen Peer review (EFSA, (2019e): Pyriproxyfen (applicable to fruit and pulses/oilseeds crops – Foliar treatment)	No, for tea and for leafy crops is still open
	Animal products	Pyriproxyfen	MRL review (EFSA, 2022g): Pyriproxyfen Peer review (EFSA, 2019e): Pyriproxyfen	Yes
Conclusion, comments	JMPR assessed plant metabolism studies in fruit crops (apples and tomatoes) and pulses/oilseeds (cotton seed) in 2000, based on which a residue definition for plants was proposed as pyriproxyfen. However, the metabolism data available for these two crop groups are not considered sufficient to support extrapolation of the residue definition for risk assessment to leafy crops. Regarding livestock, a residue definition for risk assessment was not considered necessary during the EU peer review, based on the representative uses assessed. In the MRL review, however, pyriproxyfen was authorised for feed items that might be fed to livestock and the residue definition proposed for animal commodities was pyriproxyfen. JMPR assessed commodities of animal origin in 1999 and derived a residue definition for animal products covering also the parent compound only.			

5.8.4 | Codex MRL proposals – Pyriproxyfen

TABLE 34 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Cabbage, head	**0.6**	0.01*	cGAP: USA, 2 × 0.075 kg a.s./ha, 14-day RTI, 7-day PHI Number of trials: 6 Sufficiently supported by data: No Specific comments: No metabolism studies are available for leafy crops; therefore, the assessment remains incomplete (see also the section on residue definitions). **Conclusion:** The proposed Codex MRL is not acceptable because in the EU the residue definition does not cover leafy crops group. Follow-up action: –
Cattle, edible offal of	0.01* (W)	–	The existing CXL is replaced with the new proposal for the group of edible offal.
Cattle meat	0.01* (fat) (W)	–	The existing CXL is replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Cauliflower	**0.3**	0.01*	cGAP: USA, 2 × 0.075 kg a.s./ha, 14-day RTI, 7-day PHI Number of trials:7 Sufficiently supported by data: No Specific comments and conclusion: see the comments on head cabbage
Eggplant	0.6 (W)	–	The existing CXL is replaced with the new proposal for the subgroup of eggplant.
Goat, edible offal of	0.01* (W)	–	See cattle edible offal.
Goat meat	0.01* (fat) (W)	–	See cattle meat.
Grapes	**3**	0.01*	cGAP: USA, 3 × 0.12 kg a.s./ha, 14-day RTI, 21-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Grape, dried	4	–	JMPR derived a processing factor of 1.3. Currently, no EU MRLs are established for processed products.
Grapes, juice	–	–	JMPR derived a processing factor of < 0.04. Currently no EU MRLs are established for processed products.
Group of avian, edible offal of	0.01*	0.01*	Max. dietary burden poultry layer: Europe, 0.11 ppm. Max. residues in liver: < 0.01 mg/kg Sufficiently supported by data: see the specific comments Specific comments: Despite the CXL proposal is at the level of LOQ, JMPR updated the livestock dietary burden using the maximum residues for mustard greens and head cabbage which is not acceptable until the metabolic pattern will be addressed
Group of avian fats	**0.15**	0.01*	Max. dietary burden poultry layer: Europe, 0.11 ppm. Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: No Specific comments: Although the dietary burden for poultry is very low and residues in poultry tissues are not expected, residues from leafy brassica should not be included in the dietary burden calculation. In addition, the proposed CXL for avian fat appears overestimated: at a dietary burden of 90 ppm, the maximum residue in fat was 0.92 mg/kg, while at the calculated dietary burden of 0.11 ppm, residues in fat are expected to be well below 0.01 mg/kg. Therefore, a CXL at the LOQ of 0.01 mg/kg would be sufficient. **Conclusion:** The proposed Codex MRL is not acceptable. See the specific comments. Follow-up action: None
Group of avian muscle	0.01*	0.01*	See group of avian edible offal.
Group of edible offal (mammalian)	0.01*	0.01*	Max. dietary burden (dairy cattle): Australia, 4.55 ppm. Mean/max. residues in liver: < 0.01 mg/kg Despite the CXL proposal is at the level of LOQ, JMPR updated the livestock dietary burden using the maximum residues for mustard greens and head cabbage which is not acceptable until the metabolic pattern will be addressed.

(Continues)

TABLE 34 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of mammalian fats (except milk fats)	**0.015**	0.01*	Max. dietary burden (dairy cattle): Australia, 4.55 ppm. Max. residues in fat: 0.014 mg/kg Sufficiently supported by data: No Specific comments: JMPR updated the livestock dietary burden using the maximum residues for mustard greens and head cabbage. However, these commodities belong to the leafy crop group, for which the metabolic pattern has not yet been elucidated. **Conclusion:** The proposed CXLs is not acceptable, as it is based on an increased dietary burden resulting from uses on brassicas (head cabbage and mustard green), which are not covered by the available plant metabolism studies. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	0.01*	0.01*	See group of edible offal (mammalian).
Mustard greens	**4**	0.01*	cGAP: USA, 2 × 0.075 kg a.s./ha, 14-day RTI, 7-day PHI Number of trials: 4 Sufficiently supported by data: No Specific comments: No metabolism studies are available for leafy crops; therefore, the assessment remains incomplete (see also the section on residue definitions). **Conclusion:** The proposed Codex MRL is not acceptable because in the EU the residue definition doesn't cover leafy crops group (see above the residue Follow-up action: –
Prune, dried	0.5	–	JMPR derived a processing factor of 2.9. Currently no EU MRLs are established for processed products.
Strawberry	**0.7**	0.05	cGAP: USA, 2 × 0.15 kg a.s./ha, 30-day RTI, 2-day PHI Number of trials: 8 Sufficiently supported by data: see the specific comments Specific comments: JMPR considered four trials conducted at 0.5× cGAP insufficient and therefore included additional berry trials performed at 0.5× cGAP and harvested at 3 DALA instead of 2 DALA. Based on the Mann–Whitney *U*-test, JMPR concluded that the different harvest interval did not significantly affect residues and applied a scaling factor of 2 to all trials. **Conclusion:** The proposed Codex MRL is not acceptable, as the second data set deviates from the reference GAP in two parameters, which is not consistent with the conditions for applying the proportionality approach as outlined in the FAO Manual 2016. Follow-up action: –
Subgroup of beans with pods	**0.1**	0.01*	cGAP: USA, 2 × 0.075 kg/ha, 14-day RTI, 7-day PHI Number of trials: 6 Sufficiently supported by data: Yes, according with Codex rules Specific comments: In EU, at least 8 trials would be needed for a major crop. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Subgroup of bush berries	**1.5**	0.01*	cGAP: USA, 2 × 0.12 kg a.s./ha, 14-day RTI, 7-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Subgroup of cherries	1.5	1.5	cGAP: USA, 3 × 0.12 kg a.s./ha, 14-day RTI, 14-day PHI Number of trials: 7 Sufficiently supported by data: Yes Specific comments: The existing EU MRLs is based on the same data set. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –

TABLE 34 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Subgroup of eggplants	0.6	0.6	cGAP: Italy, 2 × 0.113 kg/ha, 14-day RTI, 3-day PHI Number of trials: – Sufficiently supported by data: see specific comments Specific comments: JMPR 2024 did not support extrapolation from peppers to the subgroup of eggplants due to insufficient label coverage (only tomato and aubergine were registered) for all subgroup commodities. In 2025, however, JMPR accepted the extrapolation based on its interpretation of the French label and the limited number of commodities in the subgroup; the US GAPs were not retained, as the scaling factor exceeded 4. The current EU MRL is based on the CXL. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: –
Subgroup of peaches	**0.5**	0.4 (apricots) 0.5 (peaches)	cGAP: USA, 3 × 0.12 kg a.s./ha, 14-day RTI, 14-day PHI Number of trials: 7 Sufficiently supported by data: Yes Specific comments: the existing EU MRL for peaches is based on the same data set. The EU MRL for apricot is derived from an EU GAP. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Subgroup of plums	0.15	0.3	cGAP: USA, 3 × 0.12 kg a.s./ha, 14-day RTI, 14-day PHI Number of trials: 9 Sufficiently supported by data: Yes Specific comments: A similar GAP was assessed by EFSA in 2013; however, the data set appears to differ. At EU level, the highest residue was 0.2 mg/kg, whereas in JMPR data set the highest residue was 0.045 mg/kg from a comparable GAP. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: To check details in JMPR evaluation whether the HR is 0.2mg/kg.
General comments			

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.8.5 | Consumer risk assessment – Pyriproxyfen

TABLE 35 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (apricot, grapes, blueberries, currants (red, black and white), gooseberries (green, red and yellow), rose hips, strawberries, beans with pods, cauliflower, Chinese cabbage, head cabbage, mammalian and poultry fats). The calculations are indicative, as the proposals for leafy crops are not supported by the available metabolism studies and it remains unclear whether the residue definition for risk assessment should be extended. The calculations are therefore affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2022g) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (apricot, grapes, blueberries, currants (red, black and white), gooseberries (green, red and yellow), rose hips strawberries, beans with pods, cauliflower, Chinese cabbage, head cabbage, mammalian and poultry fats). The calculations are indicative, as the proposals for leafy crops are not supported by the available metabolism studies and it remains unclear whether the residue definition for risk assessment should be extended. The calculations are therefore affected by additional, non-standard uncertainties. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –

(Continues)

TABLE 35 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for the crops under assessment. Max IESTI was found for table grapes: 14% of ARfD	**Results:** **No long-term consumer health risk was identified**. The overall chronic exposure accounted for 12% of the ADI. Among the crops under consideration, table grapes were identified as the main contributor, accounting for up to 0.5% of the ADI.	**Results:** Long-term exposure: Max 1% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 2% (e.g. infants and toddler) GECDE max: Max. 10% (e.g. adults female)

5.8.6 | Conclusions – Pyriproxyfen

TABLE 36 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU.
Toxicological assessment	EU HBGV available. JMPR considered an ARfD not necessary.
Residue definitions	The EU and Codex residue definitions are comparable, except for tea leaves. However, the available plant metabolism studies do not support uses on leafy crops, for which the residue definition remains open.
Codex MRL proposals	The proposed Codex MRLs are not sufficiently supported by data for cabbage, cauliflower, mustard green, strawberries, avian and mammalian fats.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers whether the extrapolation of the CXL to the subgroup of eggplants is acceptable.

5.9 | Cyprodinil (207) R/T

5.9.1 | Background information – Cyprodinil

TABLE 37 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 2006/64/CE[29] EFSA conclusion published in February 2025. Discussion at risk management level ongoing
EFSA conclusion available	Yes, see comments	EFSA (2025b)
MRL review performed	Yes, see comments	EFSA (2013m)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2021c) (blueberries, cranberries, currants and gooseberries) EFSA (2019h) (rhubarbs) EFSA (2019b) (Florence fennel) EFSA (2015b) (celery)
Classification of a.s. (cut-off criteria)	No, See comments	Toxic for reproduction cat. 1B or 2 No assessment has been performed by ECHA RAC. The EU peer review concluded that criteria for classification according to Regulation (EC) No 1272/2008 may be met either in category 2 or in category 1B (EFSA, 2025b).
Endocrine effects of a.s.	Yes, see comments	Cyprodinil meets the endocrine disruptor (ED) criteria for humans and non-target organisms (EFSA, 2025b)
Other relevant information	Cyprodinil is approved in Europe as candidate for substitution.	

[29]Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, pp. 107–111.

5.9.2 | Health-Based Guidance Values – Cyprodinil

TABLE 38 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.03 mg/kg bw per day	JMPR, 2003/2019	0.03 mg/kg bw per day	EFSA, 2025	Yes See comments on a.s.
ARfD	Unnecessary	JMPR, 2003/2019	2 mg/kg bw	EFSA, 2025	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2025b): ADI based on NOAEL from 2-year rat study, applying a standard uncertainty factor of 100. ARfD based on NOAEL from acute neurotoxicity study in rat, applying a standard uncertainty factor of 100. JMPR 2003 (FAO and WHO, 2004): ADI based on NOAEL from 2-year rat study, applying a standard uncertainty factor of 100. ARfD not allocated.				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Although not included in the JMPR residue definition for risk assessment, the metabolites CGA321185, CGA232449 and NOA422054 were toxicologically assessed. They were concluded unlikely to be genotoxic based on the available in vitro data. JMPR concluded that, where relevant, the TTC approach for Cramer class III compounds may be applied in the risk assessment. Metabolites included in EU RD for RA: • (2-anilino- 6- cyclopropylpyrimidin- 4-yl)methanol (CGA232449) (free and conjugated) • 4-[(4- cyclopropyl- 6-methylpyrimidin-2-yl)amino]phenol (CGA304075) (free form and glucuronide) • (2-amino- 6- cyclopropylpyrimidin- 4-yl)methanol) (NOA422054) (free and conjugated) EFSA (2025b): HBGVs of parent are applicable to CGA304075. The toxicological profile of CGA232449 and NOA422054 cannot be concluded since the genotoxicity assessments are inconclusive and repeat dose toxicity has not been investigated.				

5.9.3 | Residue definitions – Cyprodinil

TABLE 39 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Cyprodinil	Reg. 396/2005: Cyprodinil Peer review (EFSA, 2025b): Fruit crops: Cyprodinil Cereal/grass crops: Cyprodinil by default (provisional, pending submission of new metabolism study on cereals) Rotational crops: NOA 422054 (free and conjugated) (provisional, pending confirmation of most suitable marker once data to finalise the residue definition for risk assessment in rotational crops are available – see below) MRL review (EFSA, 2013m): Cyprodinil	Yes,
	Animal products	Cyprodinil The residue is fat soluble	Reg. 396/2005: Animal commodities except milk: Cyprodinil (sum of cyprodinil and CGA304075 (free), expressed as cyprodinil) Milk: Cyprodinil (Sum of cyprodinil and CGA304075 (free and conjugated), expressed as cyprodinil) Peer review (EFSA, 2025b): Sum of cyprodinil and CGA304075 (free form and glucuronide) expressed as cyprodinil MRL review (EFSA, 2013m): Animal commodities except milk: Sum of cyprodinil and CGA304075 (free), expressed as cyprodinil Milk: Cyprodinil (Sum of cyprodinil and CGA304075 (free and conjugated), expressed as cyprodinil) The residue is fat soluble	No
RD RA	Plant products	Cyprodinil	Peer review (EFSA, 2025b): Fruit crops: Cyprodinil and CGA232449 (free and conjugated) (provisional) Cereal/grass crops: Cyprodinil by default (provisional) Rotational crops: NOA 422054 (free and conjugated) (provisional) MRL review (EFSA, 2013m): Cyprodinil	Yes
	Animal products	Cyprodinil	Peer review (EFSA, 2025b): Sum of cyprodinil and CGA304075 (free form and glucuronide) expressed as cyprodinil MRL review (EFSA, 2013m): Animal commodities except milk: Sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil Milk: Cyprodinil (Sum of cyprodinil and CGA304075 (free and conjugated), expressed as cyprodinil)	No

(Continues)

TABLE 39 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	**Plant products**: The residue definitions for enforcement and risk assessment derived by JMPR and at EU levels are identical. In the framework of the renewal of the approval for cyprodinil, a new provisional residue definition for risk assessment for fruit crops was proposed: cyprodinil and CGA232449 (free and conjugated), pending submission of toxicity data on CGA232449. In addition, a residue definition for rotational crops was proposed provisionally proposed: NOA422054 (free and conjugate), pending submission of toxicity data on NOA422054 and on documentation of the maximum storage duration and conditions of the residue samples of the available rotational crop field trials, and additional rotational crop trials measuring levels of NOA422054 and CGA321915, including conjugated residues, and covering the PEC accumulation in 20 cm of soil for cyprodinil, CGA249287 and CGA321915). Mango is an evergreen tree and papaya a short-lived perennial; thus, these crops would generally not be considered rotational crops according to the EFSA guidance on rotational crops (EFSA, 2023g). **Animal products**: In contrast to the JMPR, the EU residue definitions for enforcement and risk assessment include metabolite CGA304075 in either free (animal tissues) or in free and conjugated form (milk). However, the Codex MRLs are proposed at the LOQ for commodities of animal origin; therefore, the differences in residue definitions are of low importance for the consumer exposure assessment.			

5.9.4 | Codex MRL proposals – Cyprodinil

TABLE 40 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of eggs.
Group of avian, edible offal of	0.01*	0.02*	Max. dietary burden (EU, poultry layer): 2.107 ppm. In the laying hen metabolism study, cyprodinil was not detected in poultry tissues, except in kidney at 0.001 mg/kg, and was present in eggs at 0.002–0.011 mg/kg at feeding levels of 215 and 226 ppm. Since these levels are about 100-fold higher than the estimated poultry DB, JMPR 2025 maintained the existing CXL and STMR values for poultry commodities at the LOQ of 0.01 mg/kg. Max residues in eggs and poultry tissues: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian fats	0.01*	0.02*	See group of avian edible offal.
Group of avian muscle	0.01*	0.02*	See group of avian edible offal.
Group of edible offal (mammalian)	0.02	Liver from – swine: 0.02* – ruminants, equine and others: 0.05 Kidney from – swine: 0.02* – ruminants, equine and others: 0.05 Edible offals from Swine, ruminants, equine and others: 0.02*	Max. dietary burden (AUS dairy cattle): 32.43 ppm. Max residues in liver: 0.013 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of eggs	0.01*	0.02*	See group of avian edible offal
Group of mammalian fats (except milk fats)	0.01*	0.02*	Max. dietary burden (AUS dairy cattle): 32.43 ppm. In the cattle feeding study, no residues of cyprodinil were quantified in muscle, fat and milk above the LOQ (0.01 mg/kg) at feeding levels up to 50 ppm. Max residues in liver: value mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of milk fats[c]	0.01*	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	0.02*	0.02*	See group of mammalian fats (except milk fats)

TABLE 40 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of muscle (from mammals other than marine mammals)	0.01*	0.02*	See group of mammalian fats (except milk fats)
Mango	**0.6**	0.02*	cGAP: Brazil, foliar, 4 × 563 g a.s./ha, 14-day RTI, 7-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs because information on the toxicity of CGA232449 and residue levels is not available. Follow-up action: None.
Meat (from mammals other than marine mammals)	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milk	0.0004* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milks.
Papaya	**0.5**	0.02*	cGAP: Brazil, foliar, 4 × 563 g a.s./ha, 14-day RTI, 7-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs because information on the toxicity of CGA232449 and residue levels is not available. Follow-up action: None.
Poultry edible offal	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian, edible offal.
Poultry meat	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian fats.
General comments	Papaya and mango are not livestock feed commodities; however, the JMPR recalculated residues for cattle and poultry commodities. For poultry, the CXLs were maintained based on metabolism data showing residues below 0.01 mg/kg, except in eggs, at dose levels approximately 100-fold higher than the estimated dietary burden. For ruminants, the CXL proposals were maintained based on a cattle feeding study at 50 ppm, while the dietary burden was 0.01 mg/kg, with quantifiable residues observed only in liver, up to 0.013 mg/kg.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.9.5 | Consumer risk assessment – Cyprodinil

TABLE 41 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. mango, papaya, swine liver, swine kidney, edible offal from swine, ruminants, equine and others). The calculations are indicative, because the residue definition for risk assessment in the EU includes additional metabolites. Therefore, the calculations are affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2021c) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. mango, papaya, swine liver, swine kidney, edible offal from swine, ruminants, equine and others). The calculations are indicative, because the proposed residue definition for risk assessment in the EU includes CGA232449, pending submission of additional toxicological data for this metabolite. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –

(Continues)

TABLE 41 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for the crops under assessment. Mango: 2% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 56% of the ADI. Among the crops under consideration, mango was identified as the main contributor, accounting for up to 0.1% of the ADI.	**Results:** Long-term exposure: Max 80% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 190% (e.g. infants and toddler) GECDE max: Max. 790% (e.g. infants and toddler)

5.9.6 | Conclusions – Cyprodinil

TABLE 42 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (peer review finalised by EFSA, discussions ongoing at risk management level).
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex RDs for enforcement are identical; for RA, Codex RDs are less comprehensive.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers, since renewal process is ongoing.

5.10 | Pyraclostrobin (210) R

5.10.1 | Background information – Pyraclostrobin

TABLE 43 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	DE	DE volunteered to act as RMS for this a.s.
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 2004/30/EC[30] EFSA conclusion published in March 2025. Discussion at risk management level ongoing
EFSA conclusion available	Yes, see comments	EFSA (2025c)
MRL review performed	Yes, see comments	EFSA (2011f)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2025c) (Art.10 in sweet corn and products of animal origin assessed under the peer review) EFSA (2023c) (import tolerance in papayas) EFSA (2019) (sweet corn) EFSA (2018o) (soya bean) EFSA (2018r) (Art.10 and import tolerance in various crops) EFSA (2018q) (import tolerance in rice) EFSA (2018p) (Art. 12 confirmatory data) EFSA (2017a) (various crops) EFSA (2016h) (beet leaves (chards)) EFSA (2014h) (swedes and turnips) EFSA (2014c) (chicory roots) EFSA (2013b) (cucumbers and Jerusalem artichokes) EFSA (2012a) (leafy brassica and various cereals)

[30]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, pp. 50–53.

TABLE 43 (Continued)

		Comments, references
Classification of a.s. (cut-off criteria)	No, see comments	No classification ECHA (2022b) ATP[31]
Endocrine effects of a.s.	No, see comment	Does not meet the endocrine disruptor criteria (EFSA, 2025c)
Other relevant information	–	

5.10.2 | Health-Based Guidance Values – Pyraclostrobin

TABLE 44 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		HBGV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.03 mg/kg bw per day	JMPR, 2003/2018	0.03 mg/kg bw per day	Directive 2004/30/EC	Yes
ARfD	0.7 mg/kg bw	JMPR, 2003/2018	0.03 mg/kg bw	Directive 2004/30/EC and EFSA (2025)	No
Conclusion/ comments on a.s.	EFSA (2025c): ADI based on NOAELs from 2-year rat studies and maternal NOAEL from developmental toxicity study in rabbit, applying a standard UF of 100. ARfD based on maternal NOAEL in the developmental toxicity study in rabbit, applying a standard UF of 100. JMPR 2018 (FAO and WHO, 2019): ADI based on NOAELs from 2-year rat studies applying a standard UF of 100. ARfD based on the overall NOAEL of 5.8 mg/kg bw per day in 90-day and 1-year dog feeding studies, applying an UF of 8 (2.5 for interspecies toxicodynamic differences, 3.2 for inter-individual toxicodynamic differences). Vomiting and diarrhoea were identified as the critical effects in the dog studies. JMPR considered these effects secondary to a direct local effect of pyraclostrobin on the gastrointestinal tract, related to local concentration and independent of absorption and metabolism. Therefore, JMPR deviated from the default 100-fold safety factor by excluding the interspecies and interindividual toxicokinetic factors of 4 and 3.2, respectively. JMPR did not use the rabbit developmental toxicity study for setting the ARfD, noting that the observed effects in this study, i.e. decreased body weight gain and reduced feed consumption, were likely due to local gastrointestinal effects associated with high concentrations of pyraclostrobin or to taste disturbance resulting from regurgitation or leakage of the gavage solution.				
Comments on metabolites	Metabolites included in EU RD for RA: • methyl [2-({[1-(4- chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)phenyl]carbamate (500M07) ○ No data available for genotoxicity and general toxicity • metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety • metabolites containing the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety • 1-(4-chlorophenyl)-1H-pyrazol-3-ol (500M04) ○ Unlikely to be genotoxic. ○ ADI of 0.1 mg/kg bw per day based on NOAEL from 90-day rat study, using a standard UF of 100 and an additional factor of 10. ○ ARfD: not required • 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol (500M85) ○ No data available for genotoxicity and general toxicity				

5.10.3 | Residue definitions – Pyraclostrobin

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	Pyraclostrobin	Reg. 396/2005 (implementing MRL review): Pyraclostrobin Peer review (EFSA, 2025c): Pyraclostrobin	Yes
	Animal products	Pyraclostrobin The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Pyraclostrobin Peer review (EFSA, 2025c): Pyraclostrobin The residue is fat soluble	Yes

(Continues)

[31]Commission Delegated Regulation (EU) 2024/2564 of 19 June 2024 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the harmonised classification and labelling of certain substances. C/2024/3992. OJ L, 2024/2564, 30.9.2024.

TABLE 45 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Pyraclostrobin	Peer review (EFSA, 2025c): Pyraclostrobin and 500M07 **(provisional)** MRL review (EFSA, 2011f): Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin	No
	Animal products	Pyraclostrobin	Peer review (EFSA, 2025c): Poultry and ruminants: Pyraclostrobin and its metabolites analysed as 500M04 and 500M85, sum expressed as pyraclostrobin Or Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4- chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin Fish: Pyraclostrobin MRL review (EFSA, 2011f): Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin	No
Conclusion, comments	JMPR and EU residue definitions for enforcement are comparable for both plant and animal commodities. For risk assessment **in plant commodities**, the EU peer review included metabolite **500M07 together with parent. The expression is provisional pending on the toxicity profile for metabolite 500M07. However, residue data for representative uses of the EU peer review** (EFSA, 2025c) **were expressed provisionally as pyraclostrobin**. **For animal commodities**, the EU residue definition is broader than the JMPR residue definition, as it **covers pyraclostrobin and its metabolites analysed as 500M04 and 500M85**. During the EU peer review, two analytical options were retained for the residue definition: determination of the individual metabolites 500M04 and 500M85, **or** application of a common-moiety approach covering metabolites containing the specified pyrazole moieties, expressed as pyraclostrobin.'			

5.10.4 | Codex MRL proposals – Pyraclostrobin

TABLE 46 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Eggs	0.05* (W)	–	The existing CXL is replaced with the new proposal for the group of eggs.
Eggplant	0.3 (W)	–	The existing CXL is replaced with the new proposal for subgroup of eggplants.
Edible offal (mammalian)	0.05 (W)	–	The existing CXL is replaced with the new proposal for the group of edible offal (mammalian).
Group of avian fats	0.05*	0.05*	Max. dietary burden (poultry layer): EU: 6.67 ppm. Specific comments: In 2025, JMPR updated the dietary burden calculation to reflect the latest OECD feed tables, resulting in a lower dietary burden (0.65×) compared with JMPR 2018. No feeding study was available; the MRL proposals were derived from metabolism studies. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian muscle	0.05*	0.05*	See group of avian fats.
Group of avian, edible offal	0.05*	0.05*	See group of avian fats.
Group of edible offal (mammalian)	0.05	0.05*	Max. dietary burden beef cattle: Australia 26 ppm. Specific comments: In 2025, JMPR updated the dietary burden calculation to reflect the latest OECD feed tables, resulting in a lower dietary burden (0.89×) compared with JMPR 2018. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of eggs	0.05*	0.05*	See group of avian fats.

TABLE 46 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of mammalian fats (except milk fats)	**0.5**	0.05*	Max. dietary burden (beef cattle): Australia, 26 ppm. Specific comments: In 2025, JMPR updated the dietary burden calculation to reflect the latest OECD feed tables, resulting in a lower dietary burden (0.89×) compared with JMPR 2018. JMPR has not consider the feeding study for the MRL proposals but metabolism studies. **Conclusion:** The proposed Codex MRL is not acceptable since based on the results of the feeding studies, an MRL of 0.05 mg/kg would be sufficient. Follow-up action: None
Group of milks	**0.03**	0.01*	Max. dietary burden (dairy cattle): Australia, 26 ppm. Specific comments: In 2025, JMPR updated the dietary burden calculation to reflect the latest OECD feed tables, resulting in a lower dietary burden (0.89×) compared with JMPR 2018. JMPR has not consider the feeding study for the MRL proposals but metabolism studies. **Conclusion:** The proposed Codex MRL is not acceptable since based on the results of the feeding studies, an MRL of 0.01 mg/kg would be sufficient. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	**0.06**	0.05*	See group of mammalian fats
Mammalian fats (except milk fats)	0.5 (W)	–	The existing CXL is replaced with the new proposal for the group of mammalian fats. See group of mammalian fats.
Meat (from mammals other than marine mammals)	0.5 (fat) (W)	–	The existing CXL, derived from metabolism studies and based on residue levels in fat, is replaced by the new proposal for the group of mammalian muscle. See group of mammalian fats.
Milks	0.03 (W)	–	The existing CXL is replaced with the new proposal for the group of milks. See group of milks.
Poultry fats	0.05* (W)	–	The existing CXL is replaced with the new proposal for the group of avian fats. See group of avian fats.
Poultry meat	0.05* (W)	–	The existing CXL is replaced with the new proposal for the group of avian muscle. See group of avian fats.
Poultry, edible offal of	0.05* (W)	–	The existing CXL is replaced with the new proposal for the group of avian edible offal. See group of avian fats.
Subgroup of eggplants	0.3	0.3	cGAP: USA, 6×0.224 kg/ha, 7-day RTI, 0-day PHI Number of trials: 24 Sufficiently supported by data: Yes Specific comments: The data set consists of 21 trials on tomatoes conducted in the USA under outdoor and greenhouse conditions and 3 trials conducted in Brazil. It is noted that, according to EU rules, outdoor and indoor trials cannot be combined. **Conclusion:** The proposed Codex MRL is supported by data; however, a higher CXL of 0.4 mg/kg would result from the data set. Follow-up action: –
Subgroup of spices, seeds	**0.8**	0.1*	cGAP: No GAP information or residue trials for the use of pyraclostrobin on cumin seed were provided Number of trials: JMPR received monitoring data from India and of the 1319 samples analysed, 68 samples contained residues above 0.1 mg/kg. Sufficiently supported by data: At least 120 samples should have residues above 0.1 mg/kg to estimate upper 95% one-tailed confidence limit of the 95th percentile Specific comments: According to the current Codex procedure (FAO, 2016), more than 120 samples with quantifiable residues are needed to estimate the upper 95% one-tailed confidence limit of the 95th percentile. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –

(Continues)

TABLE 46 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
General comments	–		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.
*Indicates that the input value is proposed at the limit of quantification.
[a]Commodity description according to Codex food classification.
[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.10.5 | Consumer risk assessment – Pyraclostrobin

TABLE 47 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (spices, seeds and animal commodities). The calculations are indicative. Therefore, the calculations are affected by additional, non-standard uncertainties For animal commodities the conversion factor of 2 derived under peer review was used to accommodate for the additional metabolites included in the EU residue definition for risk assessment	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2025c) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. spices seeds and animal commodities). For animal commodities the conversion factor of 2 derived under peer review was used to accommodate for the additional metabolites included in the EU residue definition for risk assessment	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Cattle milk: 8% of ARfD For the remaining commodities, the IESTI accounted less than 10% of the ARfD.	**Results:** **No long-term consumer health risk was identified**. The overall chronic exposure accounted for 22% of the ADI. Among the crops under consideration, cattle milk was identified as the main contributor, accounting for up to 3.8% of the ADI.	**Results:** Long-term exposure: Max. 7% of the JMPR ADI. Short-term exposure: Highest result for eggplants:1% of ARfD GECDE mean: Max. 20% (e.g. infants and toddler) GECDE max: Max. 60% (e.g. infants and toddler)

5.10.6 | Conclusions – Pyraclostrobin

TABLE 48 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (peer review finalised by EFSA, discussions ongoing at risk management level).
Toxicological assessment	EU HBGV available for pyraclostrobin and 500M04. For metabolites, 500M07 500M85 HBGVs are still needed.
Residue definitions	EU and Codex RDs for enforcement in plant and animal are identical. For the risk assessment, the EU residue definitions are wider.
Codex MRL proposals	The proposed Codex MRLs are not sufficiently supported for animal commodities (ruminants).
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be decided by risk managers regarding the CXL proposals in animal commodities.

5.11 | Fludioxonil (211) R/T

5.11.1 | Background information – Fludioxonil

TABLE 49 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 2007/76/EC[32] EFSA conclusion published in September 2024. Discussion at risk management level ongoing
EFSA conclusion available	Yes, see comments	EFSA (2024f) EFSA (2007)
MRL review performed	Yes, see comments	EFSA (2011d)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2021h) (import tolerance in sugar beet roots and bananas) EFSA (2021b) (small fruits and berries) EFSA (2020i) (elderberries) EFSA (2020c) (oilseeds) EFSA (2019g) (Art. 12 confirmatory data) EFSA (2019i) (rhubarbs) EFSA (2019c) (Florence fennels) EFSA (2016e) (various crops) EFSA (2016b) (import tolerance in pineapples) EFSA (2013c) (cucurbits inedible peel and radishes) EFSA (2012e) (celery, celery leaves and radishes) EFSA (2011h) (leafy crops)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP14[33] ECHA (2017)
Endocrine effects of a.s.	Yes, see comments	The substance meets the ED criteria for the EAS modality (EFSA, 2024f)
Other relevant information	Fludioxonil is approved in Europe as candidate for substitution and is used as biocide.	

5.11.2 | Health-Based Guidance Values – Fludioxonil

TABLE 50 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.4 mg/kg bw per day	JMPR, 2004/2022	0.37 mg/kg bw per day	EFSA, 2024	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2004/2022	1 mg/kg bw	EFSA, 2024	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2024f): ADI based on NOAEL from 2-year rat study, supported by the NOAEL from the 1-year dog study, applying a standard uncertainty factor of 100. ARfD based on maternal NOAELs from developmental toxicity studies in rats and rabbits, applying a standard uncertainty factor of 100. JMPR 2004 (FAO and WHO, 2006b): ADI based on NOAEL from 2-year rat study, applying a standard uncertainty factor of 100. ARfD not allocated. The reference point for ADI setting was the same in the JMPR and EU evaluations, but different rounding approaches resulted in slightly different ADI values. The developmental toxicity studies used for ARfD setting in the EU are also reported in the JMPR evaluation but were not used by JMPR for ARfD setting.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid (CGA192155) EFSA (2024f): HBGVs of parent apply to CGA192155 Metabolites included in EU RD for RA: • metabolites which can be oxidised to metabolite 2,2-difluoro-2H-1,3-benzodioxole-4-carboxylic acid (CGA 192155) EFSA (2024f): HBGVs of parent apply to CGA192155				

[32]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, pp. 100–104.

[33]Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation. OJ L 44, 18.2.2020, p. 1–14.

5.11.3 | Residue definitions – Fludioxonil

TABLE 51 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	Reg. 396/200 (implementing MRL review): Fludioxonil Peer review (EFSA, 2024f): Primary crops: Fludioxonil – all categories of crops following foliar and seed treatment Rotational crops: Fludioxonil (by default)	Yes
	Animal products	Sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1] dioxole-4-carboxylic acid, expressed as fludioxonil (CGA192155) The residue is fat soluble	Reg. 396/200 (implementing MRL review): Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil (CGA192155) Peer review (EFSA, 2024f): Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-2H-1,3-benzodioxole-4- carboxylic acid (CGA192155), expressed as fludioxonil The residue is fat soluble	Yes
RD RA	Plant products	Fludioxonil	Peer review (EFSA, 2024f): Primary crops: Sum of fludioxonil and its metabolites which can be oxidised to metabolite 2,2-difluoro-2H-1,3-benzodioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil (provisional) Rotational crops: Fludioxonil (by default) (provisional)	No
	Animal products	Sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1] dioxole-4-carboxylic acid, expressed as fludioxonil (CGA192155)	Peer review (EFSA, 2024f) and MRL review EFSA (2011d): Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-2H-1,3-benzodioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil	Yes
Conclusion, comments	The residue definitions for enforcement in plant and animals are identical at JMPR and EU level. For risk assessment, the residue definition for animal is similar; for plant products, the EU residue definition is more comprehensive.			

5.11.4 | Codex MRL proposals – Fludioxonil

TABLE 52 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.15 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.02 (W)	–	The existing CXL is being replaced with the new proposal for the group of eggs.
Group of avian, edible offal of	0.1	0.1	The JMPR confirmed the previous maximum previous poultry maximum dietary burden of 1.9 ppm. Max. residues in liver: 0.095 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of avian fats	0.01*	0.01*	The JMPR confirmed the previous maximum previous poultry maximum dietary burden of 1.9 ppm. Max. residues in fat: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.

TABLE 52 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avian muscle	0.01*	0.01*	The JMPR confirmed the previous maximum previous poultry maximum dietary burden of 1.9 ppm. Max. residues in muscle: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of edible offal (mammalian)	**0.15**	0.1	The JMPR confirmed the previous maximum beef and dairy cattle dietary burden of 38 ppm. Max. residues in liver: 0.14 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None.
Group of eggs	0.02	0.02	The JMPR confirmed the previous maximum previous poultry maximum dietary burden of 1.9 ppm. Max. residues in eggs: 0.011 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of mammalian fats (except milk fats)	0.02	0.02	The JMPR confirmed the previous maximum beef and dairy cattle dietary burden of 38 ppm. Max. residues in fat: 0.016 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None.
Group of milk fats[c]	2	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	**0.07**	0.04	The JMPR confirmed the previous maximum beef and dairy cattle dietary burden of 38 ppm. Max. residues in muscle: 0.06 mg/kg Sufficiently supported by data: Yes Specific comments: The highest residue in milk at the feeding dosing level of 38 ppm is 0.06 mg/kg. Therefore, a CXL for milk at 0.06 mg/kg would be sufficient. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of muscle (from mammals other than marine mammals)	0.02	0.02	The JMPR confirmed the previous maximum beef and dairy cattle dietary burden of 38 ppm. Max. residues in muscle: 0.011 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Mammalian fats (except milk fats)	0.02 (W)	–	The existing CXL is being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.02 (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Melons, except watermelon	**7** (Po)	0.3	cGAP: Brazil, one post-harvest treatment with a solution of 120 g ai/hL fludioxonil, either via spraying, dipping or peduncle/stalk application, 0 days after harvest. Number of trials: 8 Sufficiently supported by data: Yes Specific comments: There were 8 residue trials for dip application, 8 residue trials for spray application and 8 residue trials for peduncle/stalk application. According to the JMPR, the Kruskal–Wallis H-test determined that there was no significant difference between the residue levels of fludioxonil in melon (whole fruit) among the different application methods. Therefore, the JMPR estimated MRLs from the HR from each trial. After spray or stalk/peduncle application, residues in the edible portion (melon pulp) were always below the LOQ of 0.01 mg/kg. The dip application method was the critical technique in terms of peel penetration and gave quantifiable (highest) residues. Therefore, the JMPR used only the dip application data set to estimate the STMR. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None

(Continues)

TABLE 52 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Milks	0.07 (W)	–	The existing CXL is being replaced with the new proposal for the group of milks.
Poultry fats	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian fats.
Poultry meat	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
Poultry, edible offal of	0.1 (W)	–	The existing CXL is being replaced with the new proposal for the group of avian, edible offal.
Subgroup of eggplants	**1**	0.4	cGAP: USA, foliar, 4 × 250 g a.s./ha, 7–10-day RTI, 0-days PHI Number of trials: 19 (JMPR 2025) and 11 (EFSA, 2011d) , see Comments Sufficiently supported by data: See comments Specific comments: In the 2025 JMPR report, it is reported a combined data set of 14 trials on bell (sweet pepper) and non-bell peppers (including chili pepper) from the United States and Canada and five greenhouse trials matching the USA GAP are reported. The JMPR considered that the data indicated that the previously recommended MRL of 1 mg/kg in sweet peppers would accommodate the expected fludioxonil residues resulting in peppers when applied according to the USA GAP. The CXL and current EU MRL of 1 mg/kg was estimated from 11 residue trials supporting an EU indoor GAP assessed in the Art 12 MRL review (EFSA, 2011d). In the EU, the direct extrapolation from pepper to eggplants is not foreseen according to the EU guidance on extrapolation rules. In addition, a PHI of 0 days would not be acceptable at EU level. From the USA GAP for peppers data set, reported in the 2025 JMPR report, the calculated MRL would be 0.5 mg/kg. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Follow-up action: None
Watermelon	**7** (Po)	0.3	cGAP: Brazil, one post-harvest treatment with a solution of 120 g ai/hL fludioxonil, either via dipping or stalk application, 0 days after harvest. Number of trials: 8 Sufficiently supported by data: Yes Specific comments: There were 8 residue trials for dip application, 8 residue trials for spray application and 8 residue trials for peduncle/stalk application. According to the JMPR, the Kruskal–Wallis H-test determined that there was no significant difference between the residue levels of fludioxonil in melon (whole fruit) because of the different application methods. Therefore, the JMPR estimated MRLs from the highest residue among each trial. The dip application method was the critical technique in terms of peel penetration and gave the highest residues. Therefore, the JMPR used only the dip application data set to estimate the STMR. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
General comments			

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended; Po, the recommendation accommodates post-harvest treatment of the commodity.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.11.5 | Consumer risk assessment – Fludioxonil

TABLE 53 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD.	**RA assumptions:** An indicative long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2021h) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. melons, watermelons, eggplants, milk, mammalian edible offal). The calculations are affected by additional, non-standard uncertainties, related to more comprehensive EU RA-RD. The risk assessment was performed with the EU ADI. The calculation is indicative since the RA-RD for plant derived by JMPR is limited to fludioxonil only. It is noted that JMPR performed a separate exposure calculation for CGA 192155, SYN 551031 and CGA 339833 which are covered by the EU residue definition for risk assessment for plant commodities. Details on this calculation are reported in the last column.	**Specific comments:** The JMPR concluded that the threshold of toxicological concern (TTC) Cramer class III approach for chronic exposure (1.5 µg/kg bw per day) and for acute exposure (5 µg/kg bw) should be considered in the dietary risk assessment for metabolites CGA227731, CGA335892 and SYN518580, if necessary. The JMPR concluded that dietary exposure to residues of CGA-227731 is expected to be below the TTC for Cramer class III compounds of 5 µg/kg bw for acute exposure. The JMPR will not consider this metabolite in future assessments. CGA-335892 was only identified and characterised in the hen metabolism study, whereas SYN-518580 was identified and characterised in grape, tomato and wheat metabolism studies. For post-harvest uses and seed treatment uses, the JMPR considered that generally no residues of the metabolites were expected. The maximum chronic and acute dietary exposure estimates for CGA-335892 were 0.0083 µg/kg bw per day (chronic) and 1 µg/kg bw (acute) and for SYN-518580 were 0.0083 µg/kg bw per day (chronic) and 1 µg/kg bw (acute). Based on these results, the JMPR concluded that the estimated dietary exposure to residues of CGA335892 and SYN-518580 from uses considered by the 2025 JMPR is below the TTC for Cramer class III compounds and is unlikely to present a public health concern. The JMPR noted that these conclusions should be revisited if additional uses of fludioxonil are evaluated in the future.
Results: No short-term consumer health risk was identified for the crops under assessment. Watermelons: 1.3% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 21% of the ADI. Among the commodities under consideration, milk was identified as the main contributor, accounting for < 1% the ADI.	**Results:** Long-term exposure: Max 6% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 20% (infants and toddler) GECDE max: Max. 60% (infants and toddler)

5.11.6 | Conclusions – Fludioxonil

TABLE 54 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (peer review finalised by EFSA, discussions ongoing at risk management level).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs for enforcement are identical; for RA, Codex RD-RA for plants is less comprehensive.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	Further discussion with risk managers recommended on the following points: • Codex MRL proposal for eggplants (extrapolation from peppers) • EU position in view of the ongoing renewal process.

5.12 | Trifloxystrobin (213) R

5.12.1 | Background information – Trifloxystrobin

TABLE 55 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	HR	
Approval status in the EU	Approved	Commission Implementing Regulation (EU) 2018/1060[34]
EFSA conclusion available	Yes, see comments	EFSA (2017d)
MRL review performed	Yes, see comments	EFSA (2014b)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2025d) (Art.10 and import tolerance in various crops) EFSA (2023f) (honey) EFSA (2022a) (Art. 12 confirmatory data and Art.10 in various crops) EFSA (2019a) (broccoli) EFSA (2018d) (various crops) EFSA (2016c) (celeriacs) EFSA (2014d) (cane fruit)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP17[35] ECHA (2019b) It is noted that trifloxystrobin is classified for effects on or via laction (Lact.; H362)
Endocrine effects of a.s.	No, see comment	EFSA (2017d): The peer review proposed classifying trifloxystrobin as Repr. 2 and noted endocrine organ effects; therefore, the interim criteria of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 for human health may be met. However, based on the available data, trifloxystrobin is unlikely to be an endocrine disruptor in mammals. ECHA RAC did not classify trifloxystrobin as Repr. 2 ECHA (2019b).
Other relevant information	Trifloxystrobin belongs to the class of PFAS chemicals.	

5.12.2 | Health-Based Guidance Values – Trifloxystrobin

TABLE 56 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.04 mg/kg bw per day	JMPR, 2004	0.1 mg/kg bw per day	EFSA, 2017	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2004	0.5 mg/kg bw	EFSA, 2017	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2017d): ADI based on NOAEL from 2-year rat study, applying a standard uncertainty factor of 100. ARfD based on developmental NOAEL from rabbit developmental toxicity study, applying a standard uncertainty factor of 100. JMPR 2004 (FAO and WHO, 2006b): ADI based on parental NOAEL from multigeneration study of reproductive toxicity in rats, applying a standard uncertainty factor of 100. ARfD not allocated. The multigeneration study used in the JMPR assessment for ADI setting was also available in the EU evaluation, but this study was not used for ADI setting in the EU assessment. The rabbit developmental toxicity study used in the EU assessment for ARfD setting was also available in the JMPR evaluation, but this study was not used for ARfD setting in the JMPR assessment.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • (E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylidene-aminooxymethyl]-phenyl}acetic acid (CGA 321113) The HBGVs of the parent are applicable to metabolite CGA321113 Metabolites included in EU RD for RA: • (E,E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113 - M5) (free and conjugated) • CGA 357262, CGA 357261 and CGA 331409 EFSA (2025d): The HBGVs of the parent are applicable to metabolite CGA321113, CGA 357262, CGA 357261 and CGA 331409.				

[34]Commission Implementing Regulation (EU) 2018/1060 of 26 July 2018 renewing the approval of the active substance trifloxystrobin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 C/2018/4836. OJ L 190, 27.7.2018, pp. 3–7.

[35]Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 188, 28.5.2021, p. 27-43.

5.12.3 | Residue definitions – Trifloxystrobin

TABLE 57 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Trifloxystrobin	Reg. 396/2005 (implementing MRL review): Trifloxystrobin Peer review (EFSA, 2017d): Trifloxystrobin	Yes
	Animal products	Trifloxystrobin and CGA 321113 ((E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylidene-aminooxymethyl]-phenyl}acetic acid), expressed as trifloxystrobin The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Sum of trifloxystrobin and its metabolite (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113), expressed as trifloxystrobin Peer review (EFSA, 2017d): Sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin. The residue is fat soluble	Yes
RD RA	Plant products	Trifloxystrobin and CGA 321113 ((E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylidene-aminooxymethyl]-phenyl}acetic acid) expressed as trifloxystrobin	Peer review (EFSA, 2017d): Primary Crops: Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin Processed commodities: Sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin MRL review (EFSA, 2014b): Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin	No
	Animal products	Trifloxystrobin and CGA 321113 ((E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylidene-aminooxymethyl]-phenyl}acetic acid) expressed as trifloxystrobin	Peer review (EFSA, 2017d): Ruminants: Sum of trifloxystrobin and CGA 321113 (M5) (free and conjugated), expressed as trifloxystrobin Poultry: Sum of trifloxystrobin and CGA 321113 (M5) (only free), expressed as trifloxystrobin MRL review (EFSA, 2014b): Sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin Ruminant liver and kidney: Sum of trifloxystrobin, CGA 321113 and its conjugates, expressed as trifloxystrobin	No
Conclusion, comments	The enforcement residue definitions at JMPR and EU levels for plant and animal commodities are comparable. For plant commodities, the Article 12 MRL review risk assessment residue definition matches the JMPR definition. However, the 2017 EU peer review proposed extending it to include three trifloxystrobin isomers. As the toxicity of these isomers and metabolite CGA 321113 has not yet been fully addressed, this residue definition is not yet fully applicable. For animal commodities, the EU and JMPR risk assessment residue definitions are also comparable. The main difference is that the EU risk assessment residue definitions for ruminants, CGA 321113 includes both free and conjugated forms, whereas for poultry only the free form is considered.			

5.12.4 | Codex MRL proposals – Trifloxystrobin

TABLE 58 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Citrus pulp dried	1.5	–	JMPR used the processing factor of 3.4 derived in 2004 and CXL proposal of 0.4 mg/kg to estimate the residues in pulp dried. Currently, no EU MRLs are established for processed products.
Edible offal (mammalian)	0.09 (W)	–	The existing CXL is proposed to be replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of eggs'.

(Continues)

TABLE 58 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avian, edible offal of	0.04*	0.04	Max. dietary burden (laying hens): EU 5.44 ppm. Max. residues in all poultry tissues: < LOQ (0.04 mg/kg) Sufficiently supported by data: Yes Specific comments: Residues were below LOQ (0.04 mg/kg) in all poultry tissues (edible offal, muscle, fat and eggs) at the feeding level of 15 ppm. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian fats	0.04*	0.04	See group of avian edible offal.
Group of avian muscle	0.04*	0.04	See group of avian edible offal.
Group of edible offal (mammalian)	**0.09**	Liver and edible offals from – swine: 0.04 – ruminants, equine and others: 0.07 Kidney from – swine, ruminants, equine and others: 0.04	Max. dietary burden (beef cattle): EU 16.34 ppm. Max. residues in liver: 0.088 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR updated the DB from 2021 with the residues in citrus pulp dried. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of eggs	0.04*	0.04	See group of avian edible offal.
Group of mammalian fats (except milk fats)	**0.07**	0.04 (pig) 0.06 (bovine, sheep, goat, equine and others)	Max. dietary burden (beef cattle): EU 16.34 ppm. Max. residues in liver: 0.068 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR updated the DB from 2021 with the residues in citrus pulp dried. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milk fats[c]	0.02*	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	0.02*	0.02*	Max. dietary burden (dairy cattle): EU 16.13 ppm. Max. residues in milk: < LOQ (0.02mg/kg) Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	0.04*	0.04	Max. dietary burden (beef cattle): EU 16.34 ppm. Max. residues in muscle: < LOQ (0.04 mg/kg) Sufficiently supported by data: Yes Specific comments: JMPR updated the DB from 2021 with the residues in citrus pulp dried. **Conclusion:** The proposed Codex MRL is acceptable.
Lemon	**0.8**	0.5	cGAP: USA, 4 × 0.135 kg a.s./ha, 7-day RTI, 7-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: The previous CXL of 0.5 mg/kg, implemented in EU legislation was proposed for withdrawal by JMPR 2021. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Mammalian fat (except milk fats)	0.07 (W)	–	The existing CXL is proposed to be replaced with the new proposal for the group of fat (mammalian).
Mango	**0.7**	0.01*	cGAP: Philippines: 2 × 0.25 kg a.s./ha, 7-day RTI, 14-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: Samples were analysed for parent and CGA321113 in the whole fruits and pulp (edible portion). In the pulp, the level of residues was below 0.01 mg/kg in all trials. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Meat (from mammals other than marine mammals)	0.07 (W)	–	The existing CXL is proposed to be replaced with the new proposal for the group of muscle (mammalian).
Milk	0.02* (W)	–	The existing CXL is proposed to be replaced with the new proposal for the group of milks.

TABLE 58 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Orange	0.4	0.5	cGAP: USA, 4 × 0.135 kg a.s./ha, 7-day RTI, 7-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: The previous CXL of 0.5 mg/kg, implemented in EU legislation was proposed for withdrawal by JMPR 2021 due to insufficient number of trials. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: none
Orange oil	60	–	JMPR used the processing factor of 130 derived in 2004 and CXL proposal of 0.4 mg/kg to estimate the residues in orange oil. Currently, no EU MRLs are established for processed products.
Poultry edible offal	0.04* (W)	–	The existing CXL is replaced by the new proposal for group of avian edible offal
Poultry fats	0.04* (W)	–	The existing CXL is proposed to be replaced with the new proposal for the group of avian fats.
Poultry meat	0.04* (W)	–	The existing CXL is replaced by the new proposal for group of avian muscle
General comments	–		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.12.5 | Consumer risk assessment – Trifloxystrobin

TABLE 59 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (lemon, mango, edible offal, liver, kidney and fat of cattle, goats, sheep and pig). For orange, the Codex MRL proposal is lower than the existing EU MRL; however, the EU MRL was based on the CXL no longer supported and withdrawn. For, mammalian fat, edible offals, liver and kidney, the risk assessment values were identical to those values used in the EFSA assessment. The calculations are indicative as affected by additional, non-standard uncertainties, because the risk assessment values do not consider potential contribution of trifloxystrobin isomers CGA 357262, CGA 357261 and CGA 331409 as included in the proposed RD RA by the EU pesticides peer review. The toxicity of these isomers and of CGA 321113 has not been fully addressed.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment performed under Art 10 MRL application on maximum residue levels in various crops (EFSA, 2025d) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. lemon, mango, edible offal, liver, kidney and fat of cattle, goats, sheep and pig). The calculations are indicative as affected by additional, non-standard uncertainties, because the risk assessment values do not consider potential contribution of trifloxystrobin isomers CGA 357262, CGA 357261 and CGA 331409 as included in the proposed RD RA by the EU pesticides peer review. The toxicity of these isomers and of CGA 321113 has not been fully addressed. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** – Long-term dietary intakes were calculated using STMR values for commodities under assessment.

(Continues)

TABLE 59 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for the crops under assessment. Lemons: < 1% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 12% of the ADI. Among the commodities under consideration, lemon was identified as the main contributor, accounting for up to 0.06% of the ADI.	**Results:** Long-term exposure: Max 9% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE max: Max. 360% (e.g. infants and toddler) GECDE mean: Max. 80% (e.g. infants and toddler)

5.12.6 | Conclusions – Trifloxystrobin

TABLE 60 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU (expiry of approval in 2033).
Toxicological assessment	EU HBGV available; toxicological profile of relevant metabolites not fully addressed.
Residue definitions	EU and Codex RDs are identical except the RA for plants where EU includes three additional metabolites (CGA 357262, CGA 357261 and CGA 331409) and for ruminants where includes CGA 321113 free and conjugates
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified. Additional, non-standard uncertainties due to different RD for plants and for ruminants and the open issues on toxicological profile of metabolites
Final conclusion	The final EU position should be discussed/decided by risk managers in the view of additional metabolites included in the risk assessment residue definition and their toxicological profile.

5.13 | Indoxacarb (216) R

5.13.1 | Background information – Indoxacarb

TABLE 61 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2021/2081[36]
EFSA conclusion available	Yes, see comments	EFSA (2018b) EFSA (2019k) (Statement on the updated peer review concerning the risk to mammals and bees)
MRL review performed	Yes, see comments	EFSA (2011e)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2022f) (Art. 43 assessment) EFSA (2013n) (beans with pods and mustard seed) EFSA (2013i) (salad plants and in spinach-like plants) EFSA (2012b) (various crops)
Classification of a.s. (cut-off criteria)	No, see comments	No classification. ATP5[37] ECHA (2011a)

[36]Commission Implementing Regulation (EU) 2021/2081 of 26 November 2021 concerning the non-renewal of approval of the active substance indoxacarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending Commission Implementing Regulation (EU) No 540/2011. C/2021/8467. OJ L 426, 29.11.2021, pp. 28–31.

[37]Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 262, 3.10.2013, p. 5-22.

TABLE 61 (Continued)

		Comments, references
Endocrine effects of a.s.	No, see comment	EFSA (2018b) The EFSA Conclusion was issued before the publication of the ECHA/EFSA guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 and is based on interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009.
Other relevant information	Indoxacarb is used as biocide, belongs to the class of PFAS chemicals and is subject to PIC Regulation.[38]	

5.13.2 | Health-Based Guidance Values – Indoxacarb

TABLE 62 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.01 mg/kg bw per day	JMPR, 2005	0.005 mg/kg bw per day	EFSA, 2018	No See comments on a.s.
ARfD	0.1 mg/kg bw	JMPR, 2005	0.005 mg/kg bw	EFSA, 2018	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2018b): ADI based on NOAEL of developmental toxicity study in rats applying a standard UF of 100. ARfD based on NOAEL of developmental toxicity study in rats applying a standard UF of 100. JMPR 2005 (FAO and WHO, 2006c): ADI based on NOAEL of 1-year dog study, supported by NOAEL of 2-generation reproduction toxicity study in rats applying a standard UF of 100. ARfD based on NOAEL of neurotoxicity study in rats applying a standard UF of 100.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • methyl(4aR)-7-chloro-2-{[4-(trifluoromethoxy)phenyl]carbamoyl}-2,5-dihydroindeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate (IN-JT333) Toxicological data have been reported for IN-JT333 in JMPR 2005, including an acute toxicity study and a short-term (14 days) study in rats. The metabolite has higher acute toxicity than the parent. JMPR did not derive HBGVs for IN-JT333. Given that the residue definition for estimation of dietary intake for animal commodities is the sum of indoxacarb, its R enantiomer, and IN-JT333, expressed as indoxacarb, suggests that HBGVs of the parent are applied for the metabolite. Metabolites included in EU RD for RA: • sodium (4aR)-7-chloro-2-{(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]carbamoyl}-2,5-dihydroindeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate (**IN-KT413**) EFSA (2018b): The metabolite IN-KT413 is considered unlikely to be genotoxic. • Methyl 7-chloro-2-{[4-(trifluoromethoxy)phenyl]carbamoyl}-2,3-dihydroindeno[1,2-e][1,3,4]oxadiazine-1(5H)-carboxylate (**IN-MP819**) EFSA (2018b): The metabolite IN-MP819 is considered unlikely to be genotoxic. • N-[4-(trifluoromethoxy)phenyl]urea (**IN-MK638**) EFSA (2018b): The toxicity profile (including genotoxicity) of metabolite IN-MK638 cannot be concluded. • 4-(trifluoromethoxy)aniline (**IN-P0036**) EFSA (2018b): The metabolite INP0036 is considered as covered by studies performed with the parent compound. HBGVs of the parent apply. • **IN-TMG00** EFSA (2018b): The metabolite IN-TMG00 is considered unlikely to be genotoxic. • methyl (4aR)-7-chloro-2-{[4-(trifluoromethoxy)phenyl]carbamoyl}-2,5-dihydroindeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate (**INJT333**) EFSA (2018b): The metabolite IN-JT333 is considered unlikely to be genotoxic. Metabolite has higher acute toxicity than the parent. Insufficient data are available to conclude on HBGVs. • Met 'F' (**IN-VRN79**) EFSA (2018b): No toxicological assessment available. Structure unknown. • methyl (1Z,2RS)-5-chloro-2-hydroxy-1-(2-{(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazinylidene)-2,3-dihydro-1H-indene-2-carboxylate (**IN-KG433**) EFSA (2018b): The metabolite IN-KG433 is considered unlikely to be genotoxic. • methyl (4aS,5RS)-7-chloro-5-hydroxy-2-{[4-(trifluoromethoxy)phenyl]carbamoyl}-2,5-dihydroindeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate (**5-OH-IN-JT333**) EFSA (2018b): The metabolite 5-OH-IN-JT333 is considered unlikely to be genotoxic.				

[38]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

5.13.3 | Residue definitions – Indoxacarb

TABLE 63 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 indoxacarb and its *R* enantiomer	Reg. 396/2005 (implementing MRL review): Indoxacarb (sum of indoxacarb and its R enantiomer) Peer review (EFSA, 2018b): Primary crops: Indoxacarb (and its R-enantiomer) – All categories of crops Processed commodities: indoxacarb (and its R enantiomer)	Yes
	Animal products	Sum of indoxacarb and its *R* enantiomer The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Indoxacarb (sum of indoxacarb and its R enantiomer) Peer review (EFSA, 2018b): Ruminants: Indoxacarb (and its R-enantiomer) Poultry: Indoxacarb (and its R-enantiomer) and INJT333 The residue is fat soluble	No
RD RA	Plant products	Sum of indoxacarb and its *R* enantiomer	Peer review (EFSA, 2018b): Primary crops: Indoxacarb (and its R-enantiomer) Processed commodities: Indoxacarb (and its R enantiomer) and metabolites IN-KT413, IN-MP819, IN-MK638, IN-P0036, IN-TMG00 (provisional) MRL review EFSA (2011e): Sum of indoxacarb and its *R* enantiomer	Yes, for raw commodities
	Animal products	Sum of indoxacarb, its *R* enantiomer, and IN-JT333, expressed as indoxacarb	Peer review (EFSA, 2018b): Ruminants tissues: Indoxacarb (and its R- enantiomer) Milk: Indoxacarb (and its R-enantiomer) and IN-MP819 (provisional) Poultry: Indoxacarb (and its R-enantiomer) and INJT333, Met 'F', IN-KG433, 5-OH-IN-JT333 (provisional) MRL review (EFSA, 2011e): Ruminants and pigs: Sum of indoxacarb and its *R* enantiomer Poultry: Sum of indoxacarb, its R enantiomer and its N-decarboxylated metabolite (IN-JT333), expressed as indoxacarb (tentative)	No
Conclusion, comments	The residue definition for enforcement and risk assessment (raw plant commodities) is the same in the EU and JMPR. For processed commodities, the EU included several metabolites in the residue definition for risk assessment (provisional). For animal products, the residue definition for enforcement derived at the EU level includes metabolite IN-JT333. The RD-RA derived at the EU level includes several metabolites and is expressed differently for poultry, ruminants and milk.			

5.13.4 | Codex MRL proposals – Indoxacarb

TABLE 64 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.05 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.02 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of eggs.
Group of avian, edible offal	0.01*	0.01*	Max. dietary burden (EU poultry layer): 0.705 ppm (JMPR 2025). Specific comments: The CXL proposal was estimated by the 2009 JMPR based on a dosing level of 1.75 ppm from the hen feeding study and a maximum DB of 1.5 ppm (EU poultry layer). The max DB calculated in 2025 JMPR amounts to 0.705 ppm (EU poultry layer) due to the residue contribution of cabbage heads (not a feed item in the USA, AUS or Japan) at 0.667 mg/kg. The second highest DB is for the US laying poultry (0.094 ppm). Therefore, it is advisable to recalculate the CXLs proposal for poultry eggs and tissues, also considering that the current EU MRL for head cabbages is set at the LOQ of 0.01 mg/kg.

TABLE 64 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
			In the latest MRL regulation (EU Reg. 2024/376),[39] MRLs were lowered to the LOQ for most commodities due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature. The list of commodities lowered to the LOQ, since risks for human health could not be excluded, included poultry tissues and eggs. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Follow-up action: None
Group of avian fats	**0.05**	0.01*	See group of avian edible offal
Group of avian muscle	0.01*	0.01*	See group of avian edible offal
Group of edible offal (mammalian)	**0.06**	0.01*	Max. dietary burden (AUS beef cattle): 72.06 ppm. Max. residues in kidney: 0.047 mg/kg (JMPR 2022). Sufficiently supported by data: See specific comments Specific comments: The proposed Codex MRL is supported by data. However, in the latest MRL regulation (EU Reg. 2024/376), MRLs were lowered to the LOQ for most commodities due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature. The list of commodities lowered to the LOQ, since risks for human health could not be excluded, included liver, kidney and edible offal of swine, bovine, sheep, goat and equine. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. Follow-up action: None
Group of eggs	**0.02**	0.01*	See group of avian edible offal
Group of milk fats[c]	6	–	In the EU, specific MRLs are not set for milk fats.
Group of mammalian fats (except milk fats)	**2**	0.01*	Max. dietary burden (AUS beef cattle): 72.06 ppm. Max. residues in fat: 1.90 mg/kg (JMPR 2022). Sufficiently supported by data: See the specific comments Specific comments: In the latest MRL regulation (EU Reg. 2024/376), MRLs were lowered to the LOQ for most commodities due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature. The list of commodities lowered to the LOQ, since risks for human health could not be excluded, included fat of swine, bovine, sheep, goat and equine. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable. Follow-up action: None
Group of milks	**0.2**	0.01*	Max. dietary burden (AUS dairy cattle): 69.69 ppm. Max residues in milk: 0.155 mg/kg (JMPR 2022). Sufficiently supported by data: see specific comments Specific comments: The proposed Codex MRL is not acceptable since it leads to an acute intake concern for EU consumer (see below results of the consumer risk assessment). Moreover, in the latest MRL regulation (EU Reg. 2024/376), MRLs were lowered to the LOQ for most commodities due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature. The list of commodities lowered to the LOQ, since risks for human health could not be excluded, included milks. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable Follow-up action: None.

(Continues)

[39]Commission Regulation (EU) 2024/376 of 24 January 2024 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for indoxacarb in or on certain products. C/2024/363. OJ L, 2024/376, 25.1.2024.

TABLE 64 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of muscle (from mammals other than marine mammals)	**0.1**	0.01*	Max. dietary burden (AUS beef cattle): 72.06 ppm. Max. residues in muscle: 0.099 mg/kg (JMPR 2022). Sufficiently supported by data: See specific comments Specific comments: The proposed Codex MRL is not acceptable since it leads to an acute intake concern for EU consumer (see below results of the consumer risk assessment). The corresponding MRL for muscle reflecting the estimated dietary burden for Australian beef cattle would be 0.09 mg/kg (highest residue in muscle at dietary burden: 0.089 mg/kg). EFSA calculated the corresponding MRL for muscle (0.09 mg/kg). **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable Follow-up action: None.
Mammalian fats (except milk fats)	2 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	2 (fat) (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milk fat	6 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milk fats.
Milks	0.2 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milks.
Poultry, edible offal of	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian, edible offal.
Poultry meat	0.01* (fat) (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian muscle.
General comments	Although no maximum residue level for crops for feed commodities was estimated in the 2025 JMPR report, the JMPR updated the dietary burden calculations. The JMPR included new estimations for grape pomace and tomato pomace based on the 2022 JMPR report, as well as cotton hulls and pea seed that were not previously included in the DB calculations. The highest and median residue levels in animal commodities are not reported in the 2025 JMPR report; the JMPR referred to the results reported in the JMPR 2022 report (cattle) and JMPR 2009 report (poultry).		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.13.5 | Consumer risk assessment – Indoxacarb

TABLE 65 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. group of avian edible offal, avians fat, avian muscle, eggs, mammalian fats, mammalian muscle, mammalian edible offal, mammalian fat and milk). The calculations are indicative, because the residue definitions for RA derived by JMPR is different to the EU RD. Therefore, the calculations are affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The MRL values from the most recent legislation (EU MRL Reg. 2024/376) were updated, including the STMR values derived by JMPR for the commodities for which the proposed Codex MRL is higher than the EU MRL (i.e. group of avian edible offal, avians fat, avian muscle, eggs, mammalian fats, mammalian muscle, mammalian edible offal, mammalian fat and milk). The calculations are indicative, because the residue definitions for RA derived by JMPR is different to the EU RD. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** The JMPR recommended STMR and HR values for animal commodities according to the update of the revised Codex Classification. JMPR claimed that the STMR and HR are not anticipated to affect the previous dietary risk assessment, therefore no updated risk assessment was performed.

TABLE 64 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: **The calculated short-term exposure exceeded the ARfD for several animal commodities under assessment.** Poultry (muscle/meat): 339% of ARfD Swine (muscle/meat): 242% of ARfD Milk (cattle): 174% of ARfD Bovine (muscle/meat): 144% of ARfD Other farmed animals (Muscle/meat): 138% of ARfD Equine (muscle/meat): 120% of ARfD Sheep (muscle/meat): 109% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 98% of the ADI. Among the commodities under consideration, cattle milk was identified as the main contributor, accounting for up to 84% of the ADI.	**Results:** Dietary exposure calculations were not performed.

5.13.6 | Conclusions – Indoxacarb

TABLE 66 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU.
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs for enforcement are identical; for RA-RD livestock, Codex RDs are less comprehensive.
Codex MRL proposals	The proposed Codex MRLs for several animal commodities are not acceptable since they lead to an acute risk for the EU consumer (see the consumer risk assessment section).
Dietary risk assessment	Acute intake concern was identified by EFSA for several animal commodities.
Final conclusion	Due to intake concerns, and insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing, the final EU position should be discussed by risk managers.

5.14 | Boscalid (221) R

5.14.1 | Background information – Boscalid

TABLE 67 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	SK	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 2008/44/EC[40] Renewal Assessment Report (RAR) submitted, EFSA peer review on clock-stop
EFSA conclusion available	No	EFSA peer review ongoing (additional data requested)
MRL review performed	Yes, see comments	EFSA (2014e)
EU MRL applications or other EU assessments	Yes, see comments	Art.12 confirmatory data application assessed under the peer review (additional data requested) Art.10 in wheat on hold EFSA (2020l) (pomegranates) EFSA (2019l) (honey) EFSA (2015a) (beans and peas with pods)
Classification of a.s. (cut-off criteria)	Not assessed	No classification has been proposed by the EU Pesticides Peer Review (TC189 and TC190)[41]

(Continues)

[40]Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances. OJ L 94, 5.4.2008, pp. 13–20.

[41]https://www.efsa.europa.eu/sites/default/files/2023-12/minutes-ppr-mammalian-toxicity.pdf.

TABLE 67 (Continued)

		Comments, references
Endocrine effects of a.s.	Yes, see comments	ED criteria for T-modality are met (TC203 Experts' consultation 2.12)[41]
Other relevant information	The EU Pesticides Peer Review concluded that boscalid is unlikely to be genotoxic based on the weight of the evidence. However, some uncertainties remain due to study limitations. To address these limitations conduction of a new *in vitro* genotoxicity test battery or alternatively, an *in vivo* oral MN assay combined with a comet assay, was recommended.	

5.14.2 | Health-Based Guidance Values – Boscalid

TABLE 68 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.04 mg/kg bw per day	JMPR, 2006/2019	0.02 mg/kg bw per day –(new) 0.04 mg/kg bw per day (current)	EU Pesticides Peer Review TC189 and TC190 Directive 2008/44/EC	No, compared to the new proposal See comments on a.s.
ARfD	Unnecessary	JMPR, 2006/2019	Not necessary	EU Pesticides Peer Review TC189 and TC190	No See comments on a.s.
Conclusion/ comments on a.s.	EU Pesticides Peer Review (TC189 and TC190, Experts' consultation 2.13 and 2.17)[41]: RMS and EFSA: ADI based on the NOAEL from the 2-year rat study, applying a standard uncertainty factor of 100 and an extra uncertainty factor of 2 related to uncertainties on boscalid's pesticidal mode of action (inhibition succinate dehydrogenase) and its relevance to human, including contribution to neurodegeneration. Other MSs considered application of an extra uncertainty factor of 10 instead of 2 more appropriate. JMPR 2006 and 2019 (FAO and WHO, 2008, 2021): ADI based on the NOAEL from the 2-year rat study, applying a standard uncertainty factor of 100. The reference point for ADI setting is the same in the EU and JMPR evaluation. In the EU evaluation, an extra uncertainty factor was applied for ADI derivation (see explanation above).				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 2-chloro-*N*-(_4_'- chloro-5-hydroxybiphenyl-2-yl)nicotinamide (M510F01) JMPR 2006/2019 (FAO and WHO, 2008, 2021): Although no toxicological assessment of M510F01 was included in the JMPR report, the metabolite is included in the residue definition and expressed as boscalid, indicating that the HBGVs for the parent compound are considered applicable. Metabolites included in EU RD for RA: • 2-chloro-*N*-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (M510F01) (free and conjugated) • *N*-(4'-chlorobiphenyl-2-yl)formamide (M510F52) • *N*-(4'-chlorobiphenyl-2-yl)acetamide (M510F53) EU Pesticides Peer Review (TC189 and TC190, Experts' consultation 2.14)[41]: The genotoxicity assessment remains open for M510F01. Although a major rat metabolite, genotoxicity studies with parent showed limitations and QSAR analysis (untrained) raised a potential concern for chromosome aberration. If concluded unlikely to be genotoxic, HBGVs of parent applicable. The genotoxicity assessment of M510F52 and M510F53 remain open. An assessment of general toxicity has not been performed for these metabolites.				

5.14.3 | Residue definitions – Boscalid

TABLE 69 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Boscalid	Reg. 396/2005 (implementing MRL review): Boscalid	Yes
	Animal products	Boscalid The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Muscle, fat, edible offals (other than liver and kidney), milk and eggs: Boscalid Kidney and liver: Sum of boscalid and its hydroxy metabolite 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (**M510F01**), free and conjugated expressed as boscalid (confirmed during the TC 200 under the peer review of 10 February 2026)[42] The residue is fat soluble	No (for kidney and liver)

[42] https://www.efsa.europa.eu/sites/default/files/2021-10/pesticides-residues-minutes.pdf.

TABLE 69 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Boscalid	MRL review (EFSA, 2014e): Boscalid	Yes
	Animal products	Sum of boscalid, 2-chloro-N-(_4_'- chloro-5-hydroxybiphenyl-2-yl) nicotinamide (M510F01) including its conjugate, expressed as boscalid	**Outcome from peer review (TC 200 of 10 February 2026)[42]:** boscalid, M510F01 (free and conjugated), expressed as boscalid. MRL review (EFSA, 2014e): Muscle, fat, edible offals (other than liver and kidney), milk and eggs: Boscalid Kidney (swine, ruminants) and liver (poultry): Sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid Liver (swine and ruminants): Sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid	See comments
Conclusion, comments	The residue definitions for enforcement and risk assessment in plants are comparable at EU and JMPR levels. For animal commodities, the enforcement residue definitions differ for kidney and liver, as the EU includes M510F01 in its free and conjugated form; which has been confirmed in the ongoing peer review process. Regarding the risk assessment residue definition for livestock, the current EU residue definition is comparable with the JMPR definition only for kidney. However, during the expert consultation held in the context of the renewal peer review, the EU risk assessment residue definition for livestock has been revised and proposed as: **boscalid, M510F01 (free and conjugated), expressed as boscalid, similar to JMPR**.			

5.14.4 | Codex MRL proposals – Boscalid

TABLE 70 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.2 (W)	–	The existing CXL is replaced by the new proposal for 'group of edible offal' (mammalian) as outlined in general considerations, section 2.4 of the 2024 JMPR report (FAO and WHO, 2025).
Eggs	0.02 (W)	–	The existing CXL is replaced by the new proposal for 'group of eggs' as outlined in general considerations, section 2.4 of the 2024 JMPR report (FAO and WHO, 2025).
Group of avian fats	0.02	0.08	Max. dietary burden poultry: EU, 8.8 ppm Max. residues in fats: 0.02 mg/kg Sufficiently supported by data: Yes Specific comments: At EU a higher MRL is applicable. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian muscle	**0.02**	0.01*	Max. dietary burden (poultry): EU, 8.8 ppm Max. residues in muscle: 0.02 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is not acceptable because it leads to an exceedance of the ADI, see the consumer risk assessment. Follow-up action: None
Group of avian, edible offal	0.02	0.15 (liver and edible offals) 0.05*(kidney)	Max. dietary burden (poultry): EU, 8.8 ppm Max. residues in liver: 0.02 mg/kg Sufficiently supported by data: Yes Specific comments: At EU higher MRLs are applicable. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of edible offal (mammalian)	0.2	Liver and kidney from – swine: 0.05* – ruminants, equine and others: 0.2 Edible offals from – swine: 0.07 – ruminants, equine and others: 0.3	Max. dietary burden (dairy cattle): Australia, 98 ppm Mean/max. residues in muscle: 0.07 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR updated the livestock dietary burden which increased significantly from 34.9 to 98 ppm. However, the previous CXLs were maintained because the feeding studies showed non-linear and variable residue transfer (i.e. lower residues at the higher dosing level) indicating that the existing CXLs were sufficiently conservative to cover the updated exposure estimates. **Conclusion:** The proposed Codex MRL is not acceptable because it leads to chronic risk for the EU consumer; in addition, the RD for enforcement is different at EU level. Follow-up action: None

(Continues)

TABLE 70 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of eggs	**0.03**	0.01*	Max. dietary burden (poultry): EU, 8.8 ppm. Max. residues in eggs: 0.025 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is not acceptable because it leads to an exceedance of the ADI, see the consumer risk assessment. Follow-up action: None
Group of mammalian fats (except milk fats)	**0.7**	0.07 (pig) 0.3 (ruminants, equine and others)	Max. dietary burden (dairy cattle): Australia, 98 value ppm Mean/max. residues in fat: 0.7 mg/kg Sufficiently supported by data: Yes Specific comments: see the Group of edible offal (mammalian) **Conclusion:** The proposed Codex MRL is not acceptable because it leads to an exceedance of the ADI, see the consumer risk assessment. Follow-up action: None
Group of milk fats[c]	2	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	**0.1**	0.02	Max. dietary burden (dairy cattle): Australia, 98 ppm Sufficiently supported by data: Yes Specific comments: see the Group of edible offal (mammalian) **Conclusion:** The proposed Codex MRL is not acceptable because it leads to an exceedance of the ADI, see the consumer risk assessment. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	**0.07**	0.01* (swine, bovine, sheep, equine and others) 0.2 (goat)	Max. dietary burden (dairy cattle): Australia, 98 ppm Sufficiently supported by data: Yes Specific comments: see the Group of edible offal (mammalian) **Conclusion:** The proposed Codex MRL is not acceptable because leads to an exceedance of the ADI, see the consumer risk assessment. Follow-up action: None
Mammalian fats (except milk fats)	0.7 (W)	–	The existing CXL is replaced with the new proposal for the group of mammalian fats.
Meat (from mammals other than marine mammals)	0.7 (fat) (W)	–	The existing CXL is replaced with the new proposal for the group of muscle (mammalian).
Milk fat	2 (W)	–	The existing CXL is replaced with the new proposal for the group of milk fats. At EU level no MRL is derived for this commodity.
Milks	0.1 (W)	–	The existing CXL is replaced with the new proposal for the group of milks.
Poultry fats	0.02 (W)	–	The existing CXL is replaced with the new proposal for the group of avian fats.
Poultry meat	0.02 (W)	–	The existing CXL is replaced with the new proposal for the group of avian muscle.
Poultry, edible offal of	0.02 (W)	–	The existing CXL is replaced with the new proposal for the group of avian edible offal of.
General comments	Although the proposed CXLs in mammalian fat, milk, mammalian muscle, poultry muscle and eggs are supported by data they lead to chronic risk for the European consumer.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.14.5 | Consumer risk assessment – Boscalid

TABLE 71 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 and confirmed by the peer review.	**RA assumptions:** The risk assessment was performed with the most recent endpoints on the ADI and RA-RD proposed during the peer review process. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2020l) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. milk muscle (mammalian and poultries), mammalian fat and eggs).	**Specific comments:** –
Results: Not relevant	**Results:** The calculated long-term exposure exceeded the ADI. The overall chronic exposure accounted for 159% of the ADI. Among the commodities under consideration, milk was identified as the main contributor, accounting for up to 15% of the ADI. By using the current EU ADI of 0.04 mg/kg bw per day the chronic exposure account for 80% of the ADI.	**Results:** Long-term exposure: Max 60% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 120% (e.g. infants and toddler) GECDE max: Max. 490% (e.g. infants and toddler)

5.14.6 | Conclusions – Boscalid

TABLE 72 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (currently under clock-stop).
Toxicological assessment	No ARfD was considered necessary at either EU or JMPR level. For the ADI, during expert consultation on mammalian-toxicology under peer review process, the ADI value was lowered from 0.04 mg/kg bw/day to 0.02 mg/kg bw per day.
Residue definitions	EU and Codex residue definitions for enforcement and risk assessment in plants are identical. For animal commodities, the enforcement residue definitions differ for kidney and liver, whereas the newly proposed EU risk assessment residue definition under peer review is aligned with the JMPR definition.
Codex MRL proposals	The proposed Codex MRLs are supported by data; however, they lead to an exceedance of the new proposed EU ADI.
Dietary risk assessment	By using the new proposed ADI, a chronic intake concern was identified by EFSA.
Final conclusion	The Codex MRL proposals are supported by data, but a chronic risk for the EU consumers was identified.

5.15 | Difenoconazole (224) R

5.15.1 | Background information – Difenoconazole

TABLE 73 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 2008/69/EC[43] Renewal Assessment Report (RAR) submitted, EFSA peer review ongoing

(Continues)

[43]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, pp. 9–14.

TABLE 73 (Continued)

		Comments, references
EFSA conclusion available	Yes, see comments	EFSA (2011a) EFSA (2014j) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data) EFSA (2018h) (conclusion on TDMs in light of confirmatory data) EFSA (2023i) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data) EFSA (2024c) (conclusion in light of confirmatory data) EFSA peer review ongoing
MRL review performed	Yes, see comments	EFSA (2024e)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2025f) (import tolerances in various crops)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria
Endocrine effects of a.s.	Assessment ongoing	–
Other relevant information	Difenoconazole belongs to the class of triazole fungicides and it is approved in Europe as candidate for substitution.	

5.15.2 | Health-Based Guidance Values – Difenoconazole

TABLE 74 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		HBGV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.01 mg/kg bw per day	JMPR, 2007	0.01 mg/kg bw per day	Directive 2008/69/EC	Yes
ARfD	0.3 mg/kg bw	JMPR, 2007	0.16 mg/kg bw	Directive 2008/69/EC	No
Conclusion/ comments on a.s.	EFSA (2011a): ADI based on NOAEL of 2-year rat study applying a standard UF of 100. ARfD based on NOAEL of developmental toxicity study in rats applying a standard UF of 100. JMPR 2007 (FAO and WHO, 2009): ADI based on NOAEL of 2-year rat study applying a standard UF of 100. ARfD based on NOAEL of neurotoxicity study in rats applying a standard UF of 100. Metabolites included in JMPR RD for RA: 1- [2- chloro- 4- (4- chloro- phenoxy)- phenyl]- 2- (1,2,4- triazol)- 1- yl- ethanol) (CGA 205375) According to JMPR 2007, this metabolite was also found in rats. The LD50 was > 2000 mg/kg bw and the substance did not show alerts for mutagenic activity. In the peer review (EFSA, 2011a), the toxicological profile of the metabolite was not fully addressed. This point is under discussion in the currently ongoing renewal process. Separate HBGVs were derived for the triazole derivative metabolites.				
Comments on metabolites	Metabolites included in JMPR RD for RA: 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol)(CGA 205375) JMPR: The metabolite is covered by the HBGVs of the parent. EU: For this metabolite, the assessment of genotoxicity remains unresolved, as no assessment for clastogenic and aneugenic potential is available. Their general toxicity profile is considered covered by the parent (if lack of clastogenic and aneugenic potential is confirmed). Metabolites included in EU RD for RA: 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol)(CGA 205375) • TA (triazole alanine) • TLA (triazole lactic acid) • TAA (triazole acetic acid) • 1,2,4-T (1,2,4-triazole)				

5.15.3 | Residue definitions – Difenoconazole

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	Difenoconazole	Reg. 396/2005: Difenoconazole MRL review (EFSA, 2024e): Difenoconazole (sum of isomers) Peer review (EFSA, 2011a): 1. Difenoconazole and 2. provisionally, triazole derivative metabolites	Yes
	Animal products	Sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole The residue is fat soluble	Reg. 396/2005: Difenoconazole MRL review (EFSA, 2024e): Difenoconazole-alcohol (CGA205375), free and conjugated, expressed as difenoconazole Peer review (EFSA, 2011a): Difenoconazole-alcohol The residue is fat soluble	No
RD RA	Plant products	Difenoconazole	MRL review (EFSA, 2024e): 1. Difenoconazole (sum of isomers); 2. TA and TLA; 3. TAA; 4. 1,2,4-triazole Peer review (EFSA, 2011a): 1. difenoconazole and 2. provisionally, triazole derivative metabolites	Yes
	Animal products	Sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole	MRL review (EFSA, 2024e): For all animal commodities: 1. Difenoconazole-alcohol (CGA205375), expressed as difenoconazole; 2. TA and TLA; 3. TAA; 4. 1,2,4-T Peer review (EFSA, 2011a): 1. Difenoconazole-alcohol expressed as difenoconazole and 2. provisionally, Triazole Derivative Metabolites	No
Conclusion, comments	The EU residue definition for MRL enforcement for plant is similar to the JMPR residue definition. For animal commodities, both enforcement and risk assessment residue definitions differ and are not comparable. However, this has no practical impact, as no Codex MRLs are proposed for animal commodities. The renewal process is ongoing and may lead to revised residue definitions. The main difference between the EU and JMPR risk assessment residue definitions is that JMPR does not consider triazole derivative metabolites (TDMs).			

5.15.4 | Codex MRL proposals – Difenoconazole

TABLE 76 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	Existing EU MRL/ new EU MRL[b,c]	Comment
Subgroup of spices, seeds	**0.9**	0.3/0.15	cGAP: No GAP information or residue trials for the use of difenoconazole on cumin seed were provided. Number of trials: The JMPR received monitoring data from India and of the 1319 samples analysed, 92 samples contained residues above 0.1 mg/kg. Sufficiently supported by data: at least 120 samples should have residues above 0.1 mg/kg to estimate upper 95% one-tailed confidence limit of the 95th percentile Specific comments: According to the current Codex procedure (FAO, 2016) more than 120 samples with quantifiable residues are needed to estimate the upper 95% one-tailed confidence limit of the 95th percentile. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable for setting MRLs with 95th percentile at 95% confidence level Follow-up action: It should be discussed with the MSs whether the CXL proposal is acceptable since there are four samples with residue up to 1.89 mg/kg and above the proposed CXL.
General comments	Samples were not analysed for triazole derivative metabolites (TDMs).		

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]New EU MRLs voted in PAFF committee in May 2026, but Regulation not yet published.

5.15.5 | Consumer risk assessment – Difenoconazole

TABLE 77 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for spicy seeds. The calculations are indicative, because the residue definitions for RA derived by JMPR are different to the EU RD, which also includes the triazole derivative metabolites (TDMs). There is no information on the residue levels of TDMs and is it not possible to assess their contribution to the dietary risk assessment, however in this specific case on cumin seeds is not expected to raise a consumer concern.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2024e) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (cumin seed). There is no information on the residue levels of TDMs and is it not possible to assess their contribution to the dietary risk assessment, however in this specific case on cumin seeds is not expected to raise a consumer concern.	**Specific comments:** It is noted that the chronic dietary intake calculated by JMPR already reaches 100% of the ADI. However, as seed spices are very minor commodities and are consumed in small amounts, their contribution is not expected to significantly increase the overall chronic exposure.
Results: No short-term consumer health risk was identified for the crops under assessment. Fennel seed: 0.6% of ARfD For the remaining seed spices, the acute exposure account for less than 0.01% of the ARfD.	**Results:** No long-term consumer health risk was identified in the indicative risk assessment. The overall indicative chronic exposure accounted for 85% of the ADI (NL toddler). Seed spices contribution to overall chronic exposure has not exceeded 0.1% of the ADI.	**Results:** Long-term exposure: Max 100% of the JMPR ADI (children). GECDE mean: Max. 190% (infants and toddlers) GECDE max: Max. 530% (infants and toddlers) Short-term exposure: The IESTI calculation for seed spices accounted for less than 0.01% of the ARfD.

5.15.6 | Conclusions – Difenoconazole

TABLE 78 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing.
Toxicological assessment	EU HBGV available. The values might be revised in the ongoing renewal of the approval.
Residue definitions	EU and Codex RDs are identical for the matrices under discussion. As the renewal process is ongoing, the EU residue definitions might change. However, it should be highlighted that, in the EU, separate residue definitions have been established for triazole derivative metabolites (TDMs).
Codex MRL proposals	More than 120 samples with quantifiable residues are needed to estimate the upper 95% one-tailed confidence limit of the 95th percentile, while here were only 92 samples. In addition, there were samples with residues higher than the proposed CXL.
Dietary risk assessment	No acute and chronic intake concerns were identified for EU consumers; however, the risk assessment for TDMs was not carried out leading to non-standard uncertainties in the dietary risk assessment. Further risk management discussions are required to derive the EU position for the proposed Codex MRLs.
Final conclusion	To be discussed with the MSs whether the CXL proposal is acceptable.

5.16 | Azoxystrobin (229) R

5.16.1 | Background information – Azoxystrobin

TABLE 79 Background information.

	Comments, references
JMPR assessment	JMPR meeting 2025
Type of JMPR evaluation	New compound evaluation
RMS	AT

TABLE 79 (Continued)

		Comments, references
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 98/47/EC[44] Dossier submitted by the applicant
EFSA conclusion available	Yes, see comments	EFSA (2010a) EFSA (2014k) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2013o)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2024g) (import tolerance in melons and watermelons) EFSA (2023d) (hops) EFSA (2022) (rapeseeds and linseeds) EFSA (2021e) (import tolerance in mangoes and oil palm fruits) EFSA (2021) (import tolerance in sugar beet roots) EFSA (2020k) (Art. 12 confirmatory data and MRLs modification) EFSA (2016g) (various crops) EFSA (2016d) (grapes)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ECHA (2018a) ATP15[45]
Endocrine effects of a.s.	Not assessed	–
Other relevant information	Azoxystrobin is used as biocide.	

5.16.2 | Health-Based Guidance Values – Azoxystrobin

TABLE 80 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.03 mg/kg bw per day	JMPR, 2024	0.2 mg/kg bw per day	EFSA, 2010	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2024	Not necessary	EFSA, 2010	Yes
Conclusion/ comments on a.s.	EFSA (2010a): ADI based on NOAEL of 2-year rat study applying a standard UF of 100. In 2024, JMPR lowered the ADI from 0.2 mg/kg bw/d to 0.03 mg/kg bw/d (see details on EFSA CCPR 2025; EFSA, 2025g). The ADI is based on a NOAEL of a two-generation reproductive toxicity study applying a standard UF of 100. At the time of the peer review, the study used by JMPR to lower the ADI was not available at EU level. However, the RMS informed EFSA that an EU toxicological assessment is ongoing and may lead to HBGVs similar to those proposed by JMPR.				
Comments on metabolites	–				

5.16.3 | Residue definitions – Azoxystrobin

TABLE 81 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Azoxystrobin	Reg. 396/2005: Azoxystrobin MRL review (EFSA, 2013o) and Peer review (EFSA, 2010a): Azoxystrobin	Yes
	Animal products	Azoxystrobin The residue is fat soluble	Reg. 396/2005: Azoxystrobin MRL review (EFSA, 2013o) and Peer review (EFSA, 2010a): Azoxystrobin The residue is not fat soluble	Yes

(Continues)

[44]Commission Directive 98/47/EC of 25 June 1998 including an active substance (azoxystrobin) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ L 191, 7.7.1998, pp. 50–52.

[45]Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 261, 11.8.2020, p. 2–15.

TABLE 81 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Azoxystrobin	MRL review (EFSA, 2013o) and Peer review (EFSA, 2010a): Azoxystrobin	Yes
	Animal products	Azoxystrobin	MRL review (EFSA, 2013o): Azoxystrobin Peer review (EFSA, 2010a): Azoxystrobin (provisional)	Yes
Conclusion, comments				

5.16.4 | Codex MRL proposals – Azoxystrobin

TABLE 82 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Broccoli, Chinese	1.5	5	cGAP: Thailand, 3 × 0.094 kg a.s./ha, 7-day RTI, 3-day PHI Number of trials: 6 Sufficiently supported by data: The number of trials is sufficient to support the GAP according to JMPR rules. At EU level a higher MRL is in place. Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None
General comments			

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.16.5 | Consumer risk assessment – Azoxystrobin

TABLE 83 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 risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2024g) were updated, including the STMR values derived by JMPR for broccoli.	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 15% of the ADI (normal mode). The maximum contribution of broccoli to the chronic exposure is 0.35% of the ADI (NL toddler). It is noted that the ADI derived by JMPR in 2024 is lower than the current EU ADI. Using the JMPR ADI for the chronic risk assessment, the exposure accounts for 102% of the ADI (normal and refined mode calculations).	**Results:** Long-term exposure: Max 50% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max.90% infants and toddler GECDE max: Max. 1090% (adults, male, female)

5.16.6 | Conclusions – Azoxystrobin

TABLE 84 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU.
Toxicological assessment	EU HBGV available. In 2024, JMPR lowered the ADI from 0.2 mg/kg bw/d to 0.03 mg/kg bw per day.
Residue definitions	EU and Codex RDs are identical.
Codex MRL proposals	The proposed Codex MRLs is supported by data.

TABLE 84 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Dietary risk assessment	No chronic intake concern was identified for the EU consumer with the current ADI. However, if the EU ADI is lowered it could result in a chronic intake concern. With the ADI derived by JMPR a chronic risk is identified.
Final conclusion	The CXL proposal is acceptable by using the current EU ADI.

5.17 | Spinetoram (233) R

5.17.1 | Background information – Spinetoram

TABLE 85 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	HR	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2025/1092[46] (no application to renew the approval was submitted)
EFSA conclusion available	Yes, see comments	EFSA (2013g)
MRL review performed	Yes, see comments	EFSA (2020d)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2025h) (Art. 12 confirmatory data)
Classification of a.s. (cut-off criteria)	No, see comments	No classification according to notified classification and labelling according to CLP criteria and the EFSA conclusion (EFSA, 2013g)
Endocrine effects of a.s.	Not assessed	–
Other relevant information	–	

5.17.2 | Health-Based Guidance Values – Spinetoram

TABLE 86 Comparison of Health-Based Guidance Values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		HBGV comparable
	Value	Comments	Value	Comments	
ADI	0.05 mg/kg bw per day	JMPR, 2008	0.025 mg/kg bw per day	EFSA, 2013	No
ARfD	Unnecessary	JMPR, 2008	0.1 mg/kg bw	EFSA, 2013	No
Conclusion/comments on a.s.					
Comments on metabolites	Metabolites included in JMPR RD for RA: • N-demethyl metabolite of the major spinetoram component (spinetoram-J) • N-formyl metabolite of the major spinetoram component (spinetoram-J) Metabolites included in EU RD for RA: • 2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-9-ethyl-4,14-dimethyl-13-{[(2R,5S,6R)-6-methyl-5-(methylamino) tetrahydro-2H-pyran-2-yl]oxy}-7,15-dioxo-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranoside (N-demethyl-175-J) • N-[(2R,3S,6R)-6-({(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-13-yl}oxy)-2-methyltetrahydro-2H-pyran-3-yl]-N-methylformamid (N-formyl-175-J)				

[46]Commission Implementing Regulation (EU) 2025/1092 of 2 June 2025 amending Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council. C/2025/3315. OJ L, 2025/1092, 3.6.2025.

5.17.3 | Residue definitions – Spinetoram

TABLE 87 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Spinetoram (sum of spinetoram-J and spinetoram-L)	Reg. 396/2005 (implementing MRL review): Spinetoram (sum of spinetoram-J and spinetoram-L) Peer review (EFSA, 2013g): XDE-175 (sum of XDE-175-J and XDE-175-L)	Yes
	Animal products	Spinetoram (sum of spinetoram-J and spinetoram-L) The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Spinetoram (sum of spinetoram-J and spinetoram-L) Peer review (EFSA, 2013g): no definition agreed upon during peer review The residue is fat soluble	Yes
RD RA	Plant products	Spinetoram (sum of spinetoram-J and spinetoram-L) and N-demethyl and N-formyl metabolites of the major spinetoram component (spinetoram-J)	MRL review (EFSA, 2020d) and Peer review (EFSA, 2013g): Sum of spinetoram (sum of spinetoram-J and spinetoram-L) and the N-demethyl-175-J and N-formyl-175-J metabolites, expressed as spinetoram-J	Yes
	Animal products	Spinetoram (sum of spinetoram-J and spinetoram-L) and N-demethyl and N-formyl metabolites of the major spinetoram component (spinetoram-J)	MRL review (EFSA, 2020d): Sum of spinetoram (sum of spinetoram-J and spinetoram-L) and the -demethyl-175-J and -formyl-175-J metabolites, expressed as spinetoram-J (for ruminants) Peer review (EFSA, 2013g): no definition agreed upon during peer review	Yes
Conclusion, comments	Similar residue definitions in plant and animal are applicable at EU and JMPR levels.			

5.17.4 | Codex MRL proposals – Spinetoram

TABLE 88 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b,c]	Comment
Asparagus, raw	**0.3**	0.02*	cGAP: United States, 4 × 87.5 g a.s./ha, 4-day RTI, 1-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Broccoli, Chinese	**10**	0.02*	cGAP: Thailand, 2 × 3.6 g/hL, 5-day RTI, 3-day PHI Number of trials: 6 Sufficiently supported by data: see specific comments Specific comments: Despite the number of trials is sufficient according to JMPR rules, an EU consumer risk is identified. **Conclusion:** The proposed Codex MRL is not acceptable because there is an acute consumer risk identified. See consumer risk assessment. Follow-up action: None.
Coffee bean, raw (i.e. green coffee)	0.02*	0.1*	cGAP: Brazil, 2 × 18 g a.s./ha, 30-day RTI, 7-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None.

TABLE 88 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b,c]	Comment
Edible offal (mammalian)	0.1 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian)
Eggs	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group of eggs.
Subgroup of eggplants	**0.4**	0.05	cGAP: Brazil, 4 × 50 g a.s./ha, 3-day PHI, RTI: not specified Number of trials: not mentioned Sufficiently supported by data: See comments Specific comments: The JMPR extrapolated the recommendations of the JMPR 2017 (FAO and WHO, 2017a) for peppers to eggplant. In the EU, the extrapolation from peppers to eggplants is not foreseen. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is compatible with the EU policy on setting MRLs because the extrapolation from peppers to eggplants would not be acceptable in the EU. Follow-up action: None.
Group of avian, edible offal of	0.01*	0.02*	Max. dietary burden (Layer hens): Europe 0.06 ppm. Max. residues in liver: 0.00047 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of avian fats	0.01*	0.02*	Max. dietary burden (Layer hens): Europe 0.06 ppm. Max. residues in fat: 0.0053 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of avian muscle	0.01*	0.02*	Max. dietary burden (Layer hens): Europe 0.06 ppm. Max. residues in muscle: 0.00022 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of edible offal (mammalian)	**0.07**	0.02*	Max. dietary burden (cattle): Europe 5.6 ppm. Max. residues in liver: 0.070 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of eggs	0.01*	0.02*	Max. dietary burden (Layer hens): Europe 0.06 ppm. Max. residues in eggs: 0.00047 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of mammalian fats (except milk fats)	**1**	0.02*	Max. dietary burden (cattle): Europe 5.6 ppm. Max. residues in fat: 0.87 mg/kg Sufficiently supported by data: Yes Specific comments: An MRL proposal of 0.9 mg/kg would be sufficient. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of milk fats[c]	0.5	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	**0.03**	0.02*	Max. dietary burden (cattle): Australia 5.5 ppm. Max. residues in milk: 0.032 mg/kg Sufficiently supported by data: Yes Specific comments: Despite HR is 0.032 mg/kg, the CXL proposal is still appropriate. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None.
Group of muscle (from mammals other than marine mammals)	**0.05**	0.02*	Max. dietary burden (cattle): Europe 5.6 ppm. Max. residues in muscle: 0.053 mg/kg Sufficiently supported by data: Yes Specific comments: Despite HR is 0.053 mg/kg, the CXL proposal is still appropriate. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

(Continues)

TABLE 88 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b,c]	Comment
Meat (from mammals other than marine mammals)	1 (fat) (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milk fats	0.15 (W)	–	The existing CXL is being replaced with the new proposal for the group of milk fats.
Milks	0.02 (W)	–	The existing CXL is being replaced with the new proposal for the group of milks.
Poultry, edible offal of	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group avian, edible offal.
Poultry meat	0.01* (fat) (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
Sugar cane	0.02*	0.02*	cGAP: Brazil, 2 × 12 g a.s./ha, interval not specified, 60-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Sugar cane, molasses	–	–	Residues of spinetoram in the RAC were < 0.02 mg/kg with residues in processed commodities (brown sugar and molasses) were also < 0.02 mg/kg. Currently, no EU MRLs are established for processed products.
Sugar cane, refined sugar	–	–	Residues of spinetoram in the RAC were < 0.02 mg/kg with residues in processed commodities (brown sugar and molasses) were also < 0.02 mg/kg. Currently no EU MRLs are established for processed products.
General comments	None of the commodities evaluated by the 2025 JMPR are used as animal feed; however, JMPR updated the dietary burden calculations using the latest OECD livestock dietary burden calculator diets.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.17.5 | Consumer risk assessment – Spinetoram

TABLE 89 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. aubergine, broccoli, asparagus and livestock commodities).	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2020d) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. aubergine, broccoli, asparagus and livestock commodities).	**Specific comments:** –
Results: The calculated short-term exposure exceeded the ARfD for one/several crops under assessment. Broccoli: 324% of ARfD (BE toddlers) Broccoli boiled: 614% of ARfD Aubergines: 10% of ARfD	**Results:** **No long-term consumer health risk was identified**. The overall chronic exposure accounted for 19% of the ADI. Among the crops under consideration, broccoli was identified as the main contributor, accounting for up to 6% of the ADI.	**Results:** Long-term exposure: Max 20% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 170% (female adults) GECDE max: Max. 560% (female adults)

5.17.6 | Conclusions – Spinetoram

TABLE 90 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU (approval expired in June 2024, and no request for renewal was submitted).
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex RDs are identical.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data, except CXL for broccoli which leads to an acute risk for the consumer.
Dietary risk assessment	Acute intake concern identified for broccoli.
Final conclusion	The final EU position should be discussed/decided by risk managers, since the CXL proposal for broccoli exceeds the EU ARfD, and extrapolation from peppers to derive CXL for eggplants is not foreseen in the EU.

5.18 | Metaflumizone (236) R

5.18.1 | Background information – Metaflumizone

TABLE 91 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	SE	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2025/1092[47] (no application to renew the approval was submitted)
EFSA conclusion available	Yes, see comments	EFSA (2013l)
MRL review performed	Yes, see comments	EFSA (2020g)
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Metaflumizone belongs to the class of PFAS chemicals.	

5.18.2 | Health-Based Guidance Values – Metaflumizone

TABLE 92 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	Comments	Value	Comments	HBGV comparable
ADI	0.1 mg/kg bw per day	JMPR, 2009/2019	0.01 mg/kg bw per day	EFSA, 2013 (3- and 12-month dog study and 100×6* UF)	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2009/2019	0.13 mg/kg bw	EFSA, 2013 (rat developmental study and 100×3** UF)	No See comments on metabolites
Conclusion/ comments on a.s.	*Additional factor of 2 (for the uncertainties related to oral absorption) and 3 (for the uncertainties related to bioaccumulation in dogs) **Additional factor of 3 (to cover the likely greater oral absorption of metaflumizone at the levels likely to be encountered by consumers) In the EU evaluation, the ARfD was derived from the rat developmental study, in which adverse effects in dams (reduced body weight gain) were observed after 2 or 3 doses. Based on the available data, it was also concluded that metaflumizone with an E/Z-isomer ratio of 9/1 has the same toxicological profile as the Z-isomer.				

(Continues)

[47]Commission Implementing Regulation (EU) 2025/1092 of 2 June 2025 amending Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council. C/2025/3315. OJ L, 2025/1092, 3.6.2025.

TABLE 92 (Continued)

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
Comments on metabolites	Metabolites included in JMPR RD for RA: – In the JMPR evaluations, M320I23 (4-{5-hydroxy-3-oxo-4-[4-(trifluoromethoxy)phenyl]-6-[3-(trifluoromethyl)phenyl]-2,3,4,5-tetrahydro-1,2,4-triazin-5-yl}benzonitrile) the same toxicological end points as for metaflumizone applies, and therefore would be covered by its ADI. The metabolites M320I04, M320I06 and M320I29 were considered unlikely to be genotoxic and were assessed using the TTC approach for Cramer class III substances (1.5 µg/kg bw per day) for chronic toxicity. Metabolites included in EU RD for RA: Metabolite M320I04 (4-{2-oxo-2-[3-(trifluoromethyl) phenyl]ethyl}benzonitrile): in the EU peer review, no conclusion could be drawn regarding toxicological profile of the plant metabolite M320I04 (including its genotoxic potential).				

5.18.3 | Residue definitions – Metaflumizone

TABLE 93 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Metaflumizone, sum of *E*-isomer and *Z*-isomer	Reg. 396/2005: Metaflumizone (sum of *E*- and *Z*- isomers) MRL review (EFSA, 2020g) Raw commodities: Metaflumizone (sum of *E*- and *Z*- isomers) Processed commodities (tentative, pending toxicological information on metabolite M320I04): Metaflumizone (sum of *E*- and *Z*-isomers) and M320I04, expressed as metaflumizone Peer review (EFSA, 2013l): Sum of metaflumizone *E*- and *Z*-isomers	Yes, except for processing commodities
	Animal products	Metaflumizone, sum of E-isomer and Z-isomer The residue is fat soluble	Reg. 396/2005: Metaflumizone (sum of *E*- and *Z*- isomers) MRL review (EFSA, 2020g) and Peer review (EFSA, 2013l): Metaflumizone (sum of *E*- and *Z*- isomers) The residue is fat soluble	Yes
RD RA	Plant products	Metaflumizone, sum of *E*-isomer and *Z*-isomer	MRL review (EFSA, 2020g): Leafy crops (tentative, pending toxicological information on metabolite M320I04): Metaflumizone (sum of *E*- and *Z*- isomers) All other crops: Metaflumizone (sum of *E*- and *Z*- isomers). Processed commodities (tentative, pending toxicological information on metabolite M320I04): Metaflumizone (sum of *E*- and *Z*- isomers) and M320I04, expressed as metaflumizone Peer review (EFSA, 2013l): Sum of metaflumizone *E*- and *Z*-isomers	Yes, except for leafy and processed commodities
	Animal products	Metaflumizone, sum of *E*-isomer and *Z*-isomer	MRL review (EFSA, 2020g) and Peer review (EFSA, 2013l): Metaflumizone (sum of *E*- and *Z*- isomers)	Yes
Conclusion, comments	During the EU MRL review, broader residue definitions were tentatively proposed for enforcement in processed commodities and for risk assessment in leafy crops, pending clarification of the toxicological profile of metabolite M320I04. The remaining enforcement and risk assessment residue definitions are comparable between the EU and JMPR.			

5.18.4 | Codex MRL proposals – Metaflumizone

TABLE 94 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.02* (W)	–	The existing CXL is replaced with the new proposal for the group of edible offal (mammalian).
Eggplant	0.6 (W)	–	The existing CXL is replaced with the new proposal for the group of eggplants.
Eggs	0.02 (W)	–	The existing CXL is replaced with the new proposal for the group of eggs.
Group of avian, edible offal	0.02*	0.02*	Max. dietary burden (poultry broilers): Europe 0.034 ppm. Max. residues in liver: 0.011 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR 2025 updated the dietary burden calculation, resulting in a slight increase; however, this does not affect the CXL for edible offal. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian fats	**0.2**	0.08	Max. dietary burden (poultry broilers): Europe 0.034 ppm. Max. residues in fat: 0.111 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR 2025 updated the DB calculation which increased from 0.022 to 0.034 mg/kg. This impacted the residue found in fat that slightly increased from 0.08 to 0.111 mg/kg. It is highlighted that a CXL proposal of 0.15 mg/mg would be sufficient. **Conclusion:** The proposed Codex MRL is acceptable; however, a lower CXL would be sufficient. Follow-up action: None
Group of avian muscle	0.02* (fat)	0.02*	Max. dietary burden (poultry broilers): Europe 0.034 ppm. Max. residues in muscle: 0.007 mg/kg Sufficiently supported by data: see specific comments Specific comments: – **Conclusion:** The CXL proposal is acceptable. Follow-up action: None
Group of edible offal (mammalian)	0.02*	0.02*	Max. dietary burden (cattle): Australia 3.30 ppm. Max. residues in liver and kidney: < 0.02 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of eggs	0.02	0.02	Max. dietary burden (poultry layers): Europe 0.033 ppm. Max. residues in eggs: 0.020 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR updated the dietary burden calculation from the 2019 evaluation. Although a slight increase was observed, from 0.022 to 0.033 mg/kg, the existing MRL remains sufficient and no change is needed. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of mammalian fats (except milk fats)	0.15	0.15	Max. dietary burden (beef cattle): Australia 3.30 ppm. Max. residues in fat: 0.13 mg/kg Sufficiently supported by data: Yes Specific comments: In the 2025 JMPR report, the highest residue level in fat is wrongly reported as < 0.02 mg/kg. The current EU MRL is based on the previous CXL. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milks	0.02	0.02	Max. dietary burden (cattle): Australia 3.29 ppm. Max. residues in milk: 0.019 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR 2025 updated the DB that slightly increased, however no impact in the previous CXL. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milk fats[c]	0.3	–	In the EU, specific MRLs are not set for milk fats.

(Continues)

TABLE 94 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of muscle (from mammals other than marine mammals)	0.02* (fat)	0.02*	Max. dietary burden (cattle): Australia 3.30 ppm. Max. residues in muscle: < 0.02 mg/kg Sufficiently supported by data: see specific comments Specific comments: JMPR indicated that the CXL proposal is expressed on a fat basis; however, this may be a reporting error linked to the agreed harmonisation of the Codex food classification. **Conclusion:** The proposed Codex MRL is acceptable without the 'fat' qualifier. Follow-up action: None
Mammalian fats (except milk fats)	0.15 (W)	–	The existing CXL is replaced with the new proposal for the group of mammalian fats (except milk fats)
Meat (from mammals other than marine mammals)	0.02* (fat) (W)	–	The existing CXL is replaced with the new proposal for the group of muscle (from mammals other than marine mammals)
Milks	0.02 (W)	–	The existing CXL is replaced with the new proposal for the group of milks.
Milk fats	0.6 (W)	–	The existing CXL is replaced with the new proposal for the group of milk fats.
Onion, Welsh, dried	3	–	JMPR could not derive a processing factor since the sampling procedure of onions before processing did not follow Codex procedure. Currently, no EU MRLs are established for processed products.
Poultry, edible offal of	0.02* (W)	–	The existing CXL is replaced with the new proposal for the group of avian edible offal of.
Poultry fats	0.08 (W)	–	The existing CXL is replaced with the new proposal for the group of avian fats.
Poultry meat	0.02* (fat) (W)	–	The existing CXL is replaced with the new proposal for the group of avian muscle.
Subgroup of eggplants	0.6	0.7	cGAP: Netherlands, 2 × 0.024 kg a.s./ha, 7-day RTI, 3-day PHI Number of trials: 25 Sufficiently supported by data: Yes Specific comments: JMPR combined residue data from peppers and tomatoes to support the proposal for the subgroup of eggplants. Although the extrapolation to the whole subgroup was not explicitly covered by the label, JMPR considered it acceptable given the limited number of commodities included in the subgroup. It is noted that the application rate reported in the JMPR report as 0.024 mg/kg appears to be a typographical error and should read 0.24 kg a.s./ha. The existing EU MRL is based on a more critical EU cGAP of 2 × 240 g a.s./ha, 7-day RTI and 1-day PHI. The sponsor is encouraged to submit data to JMPR supporting this cGAP. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: –
General comments	The inclusion of metabolite M320I04 in the risk assessment residue definition for leafy crops and in the enforcement residue definition for processed commodities does not affect the current assessment, as no CXLs are proposed for leafy crops or livestock commodities.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.18.5 | Consumer risk assessment – Metaflumizone

TABLE 95 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for poultry fat for which the Codex MRL proposal is higher than the existing EU MRL. Although at EU level a new residue definition was tentatively derived for leafy crops, it has no impact on the current assessment.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2020g) were updated, including the STMR values derived by JMPR for poultry fat where the proposed Codex MRL is higher than the EU MRL. Although at EU level a new residue definition was tentatively derived for leafy crops, it has no impact on the current assessment.	**Specific comments:** – The 2019 Extra JMPR concluded that metabolites M320I04, M320I06 and M320I29 can be assessed using the TTC approach (Cramer class III; 1.5 μg/kg bw/day) and are not expected to pose a consumer health concern. Dietary exposure to M320I04 was estimated at 0.45 μg/kg bw/day, below the applicable TTC threshold, while M320I06 represented < 1% of the parent residue and M320I29 was not detected in edible plant commodities.

TABLE 95 (Continued)

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
Results: No short-term consumer health risk was identified for poultry fat, the IESTI was below 0.001% of ARfD	**Results:** **No long-term consumer health risk was identified**. The overall chronic exposure accounted for 70% of the ADI. The contribution of poultry fat to the overall chronic intake was < 0.04 of the ADI.	**Results:** Long-term exposure: Max 3% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 7% (e.g. children and adolescents) GECDE max: Max. 30% (e.g. infants and toddler)

5.18.6 | Conclusions – Metaflumizone

TABLE 96 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU (approval expired in December 2014, as no request for renewal was submitted).
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex RDs are comparable for the current assessment. The inclusion of M320I04 in the EU risk assessment residue definition for leafy crops and in the enforcement residue definition for processed commodities does not affect the current assessment.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The Codex MRL proposals are supported by data and risk for consumers is unlikely.

5.19 | Clothianidin (238) R

5.19.1 | Background information – Clothianidin

TABLE 97 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	DE	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2022/801[48] In the light of the restrictions defined by Regulation (EU) No 2018/784,[49] the applicant decided to withdraw the application for the renewal of approval of clothianidin. Consequently, the approval expired on 31 January 2019.
EFSA conclusion available	No	The DAR prepared by the RMS was not peer reviewed by EFSA. Therefore, no EFSA conclusion is available For the peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules, an EFSA conclusion is available (EFSA, 2018f)
MRL review performed	No	EFSA (2014i)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2018l) (potatoes) In addition, EFSA assessed a number of emergency authorisations granted by Member States between 2018 and 2021
Classification of a.s. (cut-off criteria)	No, see comments	Clothianidin does not fall under cut-off criteria. ATP01[50] ECHA (2021b)

(Continues)

[48]Commission Implementing Regulation (EU) 2022/801 of 20 May 2022 amending Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council. C/2022/3216. OJ L 143, 23.5.2022, pp. 7–10.

[49]Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin. *OJ L 132, 30.5.2018, p. 35–39*.

[50]Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 235, 5.9.2009, p. 1–439.

TABLE 97 (Continued)

		Comments, references
Endocrine effects of a.s.	Not assessed	A.s. was not peer reviewed
Other relevant information	Clothianidin belongs to the group of neonicotinoids and is subject to the PIC Regulation.[51] It was authorised as biocide.	

5.19.2 | Health-Based Guidance Values – Clothianidin

TABLE 98 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.1 mg/kg bw per day	JMPR, 2010	0.097 mg/kg bw per day	Directive 2006/41/EC	Yes See comments on a.s.
ARfD	0.6 mg/kg bw	JMPR, 2010	0.1 mg/kg bw	Directive 2006/41/EC	No See comments on a.s.
Conclusion/ comments on a.s.	According to JMPR 2010 (FAO and WHO, 2011b), the ADI is based on the NOAEL in the chronic study in the rat of 9.7 mg/kg bw per day for decreased body weight and feed consumption. A safety factor of 100 was applied. The ARfD based on the NOAEL of 60 mg/kg bw in the acute neurotoxicity study in the rat, based on reduced locomotor activity at 100 mg/kg bw. A safety factor of 100 was applied. The EU ADI is based on the same chronic study in rats (with an uncertainty factor of 100). The ARfD was derived from developmental toxicity rat and rabbit, using an uncertainty factor of 100 (European Commission, 2005). The difference is due to rounding. The existing HBGVs have not been peer reviewed by EFSA.				
Comments on metabolites	Metabolites included in JMPR RD for RA: not relevant Metabolites included in EU RD for RA: not relevant				

5.19.3 | Residue definitions – Clothianidin

TABLE 99 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Clothianidin	Reg. 396/2005: Clothianidin MRL review (EFSA, 2014i): Thiamethoxam and clothianidin (considered separately)	Yes
	Animal products	Clothianidin The residue is not fat soluble	Reg. 396/2005: Clothianidin MRL review (EFSA, 2014i): Ruminants and pigs: Thiamethoxam and clothianidin (considered separately) Poultry products: No residue definition proposed The residue is not fat soluble	Yes
RD RA	Plant products	Clothianidin	MRL review (EFSA, 2014i): Thiamethoxam and clothianidin (considered separately)	Yes
	Animal products	Clothianidin	MRL review (EFSA, 2014i): Ruminants and pigs: Thiamethoxam and clothianidin (considered separately) Poultry products: No residue definition proposed	Yes (for poultry - no RD-RA set in the EU)
Conclusion, comments	The EU residue definition for MRL enforcement and risk assessment in plants and livestock is equivalent to the JMPR residue definitions; in the EU, no RD for RA was proposed for poultry.			

[51]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

5.19.4 | Codex MRL proposals – Clothianidin

TABLE 100 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian) (except liver)	0.02* (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Liver of cattle, goats, pigs and sheep	0.4 (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of liver (mammalian).
Eggs	0.01* (c, T) (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of eggs.
Group of avian fats	0.01* (c, T)	0.02*	Max. dietary burden (AUS poultry layer): 11.8 ppm for thiamethoxam and 0.334 ppm for clothianidin. MRL proposals for eggs and poultry tissues were derived from poultry metabolism study where animals were dosed with thiamethoxam at approximately 10N-rate and clothianidin at approximately 500N-rate. Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None
Group of avian muscle	0.01* (c, T)	0.02*	See group of avian fats
Group of avian, edible offal	**0.4** (c, T)	0.02*	See group of avian fats
Group of edible offal (mammalian)	**0.4** (c, T)	0.02*	Max. dietary burden (AUS dairy cattle): 22.6 ppm for thiamethoxam and 1.98 for clothianidin. JMPR 2025 revised the dietary burden calculation, leading to a minor increase for both thiamethoxam (from max 20.6 to 22.6 ppm) and clothianidin (from max 1.14 to 1.98 ppm). Since the increase remains below 10%, the previous residue estimates are not affected. Highest max residues in milk (0.044 mg/kg) were estimated based on the livestock feeding studies performed with thiamethoxam. Highest max residues in liver (0.39 mg/kg) were estimated based on the livestock feeding studies performed with thiamethoxam. Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, several feed items are from crops that are melliferous (e.g. almonds, apples, citrus, rapeseed), and thus potential food source for pollinators. Therefore, it is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs in view of the EU policy for setting MRLs for neonicotinoids, and the appropriate level of protection for pollinators. Follow-up action: None
Group of eggs	0.01* (c, T)	0.01*	See group of avian fats
Group of mammalian fats (except milk fats)	0.02* (c, T)	0.02*	See group of edible offal (mammalian)
Group of milks	**0.05** (c, T)	0.01*	See group of edible offal (mammalian)
Group of muscle (from mammals other than marine mammals)	0.02* (c, T)	0.02*	See group of edible offal (mammalian)
Mammalian fats (except milk fats)	0.02* (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.02* (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milks	0.05 (c, T) (W)	–	The existing CXL is being replaced with the new proposal for group of milks.
Poultry fats	0.01* (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of avian fats.
Poultry meat	0.01* (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
Poultry, edible offal of	0.4 (c, T) (W)	–	The existing CXL is being replaced with the new proposal for the group of avian, edible offal.
General comments	JMPR 2025 updated the DB which were slightly increased however, the CXLs for animal commodities, remain unchanged compared with JMPR 2021. The proposed CXLs from 2021 JMPR were not implemented in the EU Regulation. There was an update of the animal commodities designation and codes, following the update of the Codex Classification.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended; (c,T), clothianidin derived from both clothianidin and thiamethoxam use, residues from thiamethoxam use are higher.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.19.5 | Consumer risk assessment – Clothianidin

TABLE 101 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. avian edible offal, mammalian edible offal, milks). Since clothianidin and thiamethoxam share a common mode of action, the two substances should be considered together in the risk assessment, taking into account the different toxicological potencies. Therefore, clothianidin and thiamethoxam were assessed separately, and in a combined assessment.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1., based on the latest Regulation (EC) 2023/334,[52] where all MRLs are set at the LOQ, and including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. avian edible offal, mammalian edible offal, milks). Since clothianidin and thiamethoxam share a common mode of action, the two substances should be considered together in the risk assessment, taking into account the different toxicological potencies. Therefore, clothianidin and thiamethoxam were assessed separately, and in a combined assessment.	**Specific comments:** The JMPR The JMPR did not change the previous recommendations for STMRs and HRs for animal commodities, and therefore, a new dietary risk assessment was not deemed necessary.
Results: No short-term consumer health risk was identified for the crops under assessment. Milk (cattle): 5% of ARfD **Combined (thiamethoxam and clothianidin)** Highest exposure among the commodities under consideration Milk (cattle): 5% of the ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 3% of the ADI. Among the commodities under consideration, milk (cattle) was identified as the main contributor, accounting for up to 3% of the ADI. **Combined (thiamethoxam and clothianidin)** The overall chronic exposure accounted for 17% of the ADI.	**Results:** A consumer risk assessment was not deemed necessary, since HR and STMR of animal commodities were not changed.

5.19.6 | Conclusions – Clothianidin

TABLE 102 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU (approval expired in January 2019, as the application for renewal was withdrawn).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs for plant commodities (enforcement and risk assessment) are equivalent.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data, but further risk management discussions are recommended in view of the EU policy on protection of pollinators.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	Further risk manager consideration is needed, considering the EU policy for setting MRLs on neonicotinoids.

5.20 | Etoxazole (241) R

5.20.1 | Background information – Etoxazole

TABLE 103 Background information.

	Comments, references
JMPR assessment	JMPR meeting 2025
Type of JMPR evaluation	New use
RMS	EL

[52]Commission Regulation (EU) 2023/334 of 2 February 2023 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products. C/2023/214. OJ L 47, 15.2.2023, pp. 29–45.

TABLE 103 (Continued)

		Comments, references
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Implementing Regulation (EU) 2020/2105[53] Dossier admissible, RMS assessment ongoing
EFSA conclusion available	Yes, see comments	EFSA (2017c) EFSA (2024h) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory information) EFSA (2025e) (conclusion in light of confirmatory data on the endocrine disruption assessment)
MRL review performed	Yes, see comments	EFSA (2012c)
EU MRL applications or other EU assessments	Yes, see comments	Import tolerance in oranges and grapefruits (additional data requested) EFSA (2012d) (cherry, plum and banana)
Classification of a.s. (cut-off criteria)	No, see comments	No classification No ECHA RAC assessment. No classification according to CLP00.[54]
Endocrine effects of a.s.	No, see comment	EFSA (2017c) The EFSA Conclusion was issued before the publication of the ECHA/EFSA guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 and is based on interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009.
Other relevant information	Etoxazole is approved in Europe as candidate for substitution.	

5.20.2 | Health-Based Guidance Values – Etoxazole

TABLE 104 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.05 mg/kg bw per day	JMPR, 2010	0.04 mg/kg bw per day	EFSA, 2017	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2010	Not necessary	EFSA, 2017	Not applicable
Conclusion/comments on a.s.	EFSA (2017c): ADI based on NOAEL of 2-year rat study applying a standard UF of 100. JMPR 2010 (FAO and WHO, 2011b): ADI based on overall NOAEL of 90-day and 1-year studies in dogs applying a standard UF of 100.				
Comments on metabolites					

5.20.3 | Residue definitions – Etoxazole

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	Etoxazole	Reg. 396/2005: Etoxazole Peer review (EFSA, 2017c) and MRL review (EFSA, 2012c): Fruit and fruiting vegetables, pulses and oilseeds following foliar treatment: Etoxazole (sum of isomers)	Yes
	Animal products	Etoxazole The residue is fat soluble	Reg. 396/2005: Etoxazole Peer review (EFSA, 2017c): not required MRL review (EFSA, 2012c): Etoxazole The residue is fat soluble	Yes

(Continues)

[53]Commission Implementing Regulation (EU) 2020/2105 of 15 December 2020 renewing the approval of the active substance etoxazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2020/8809. OJ L 425, 16.12.2020, pp. 96–100.

[54]Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

TABLE 105 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Etoxazole	Peer review (EFSA, 2017c): Primary crops: Etoxazole (sum of isomers) – restricted to fruit crops, pulses and oilseeds – Foliar application. Processed commodities: Etoxazole, R-4 and R-7 (provisional) Rotational crops: open MRL review (EFSA, 2012c): Fruit and fruiting vegetables, pulses and oilseeds: Etoxazole	No, for processed products
	Animal products	Etoxazole	Peer review (EFSA, 2017c): not required MRL review (EFSA, 2012c): Etoxazole	Yes
Conclusion, comments	The residue definitions for plant and animal commodities are comparable between the EU and JMPR assessments. For processed commodities, the EU residue definition for risk assessment also includes two metabolites; however, this difference is not relevant for the current assessment, as avocado is mainly consumed without thermal processing.			

5.20.4 | Codex MRL proposals – Etoxazole

TABLE 106 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Avocado	**0.15**	0.01*	cGAP: USA, 1 × 0.151 kg a.s/ha, 1-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: Residues in avocado were determined in the edible portion (peel and pulp) without the pit and recalculated to a whole-fruit basis using a factor of 0.85 to account for the pit (≈15% of fruit weight). **Conclusion:** The proposed Codex MRL is supported by data Follow-up action: –
Edible offal (mammalian)	0.01* (W)	–	The existing CXL is replaced with the new proposal for the group of edible offal (mammalian).
Group of avian, edible offal of	0.01*	0.01*	No relevant feed items contribute to poultry dietary exposure; thus, JMPR consider that residues are not expected in avian commodities and decide to set CXLs at the LOQ (0.01 mg/kg).
Group of avian fats	0.01*	0.01*	See group of avian edible offal.
Group of avian muscle	0.01*	0.01*	See group of avian edible offal.
Group of edible offal (mammalian)	0.01*	0.01*	Max. dietary burden (beef cattle): Australia: 2.69 ppm. Max. residues in animal tissues except fats: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of eggs	0.01*	0.01*	See group of avian edible offal.
Group of mammalian fats (except milk fats)	**0.03**	0.01*	Max. dietary burden (beef cattle): Australia: 2.69 ppm. Max. residues in fat: 0.03 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milk fats[c]	0.02	–	In the EU, specific MRLs are not set for milk fats.
Group of milks	0.01*	0.01*	Max. dietary burden (dairy cattle): Australia: 1.24 ppm. Sufficiently supported by data: Yes Specific comments: Feeding studies were available at three dietary levels (1, 3 and 10 ppm). At the maximum dietary burden, residues in milk were below 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	0.01*	0.01*	See group of edible offal.

TABLE 106 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Meat (from mammals other than marine mammals)	0.01* (W)	–	The existing CXL is replaced with the new proposal for the group of muscle (from mammals other than marina mammals).
Milks	0.01* (W)	–	The existing CXL is replaced with the new proposal for the group of milks.
Sweet corn (corn-on-the-cob) (kernels plus cob with husk removed)	0.01*	0.01*	cGAP: USA, 1 × 0.151 kg a.s./ha, 21-day PHI Number of trials: 13 Sufficiently supported by data: Yes Specific comments: In all samples, the residues were below 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: –
Sweet corn, stover	6 (dw)	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
General comments	–		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.
Abbreviation: dw, dry weight.
*Indicates that the input value is proposed at the limit of quantification.
[a]Commodity description according to Codex food classification.
[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.
[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.20.5 | Consumer risk assessment – Etoxazole

TABLE 107 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 risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2012d) were updated, including the STMR values derived by JMPR for avocado and mammalian fats.	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 3% of the ADI, avocado contributed with less than 0.01%.	**Results:** Long-term exposure: Max 1% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 6% (adults female) GECDE max: Max. 20% (e.g. adults male and female; children and adolescents)

5.20.6 | Conclusions – Etoxazole

TABLE 108 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (dossier admissible, RMS assessment ongoing).
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex RDs for enforcement are identical; for risk assessment, the EU-RD differs for processed commodities.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No chronic intake concern identified.
Final conclusion	The Codex MRL proposals are sufficiently supported by data and risk for consumers is unlikely.

5.21 | Flubendiamide (242) R

5.21.1 | Background information – Flubendiamide

TABLE 109 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	EL	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2025/1092[55] (no application to renew the approval was submitted)
EFSA conclusion available	Yes, see comments	EFSA (2013j)
MRL review performed	Yes, see comments	EFSA (2020h)
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Flubendiamide belongs to the class of PFAS chemicals.	

5.21.2 | Health-Based Guidance Values – Flubendiamide

TABLE 110 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.02 mg/kg bw per day	JMPR, 2010	0.017 mg/kg bw per day	EFSA, 2013	Yes See comments on a.s.
ARfD	0.2 mg/kg bw	JMPR, 2010	0.1 mg/kg bw	EFSA, 2013	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2013j): ADI based on long-term rat study and application of a standard UF of 100. ARfD based on developmental neurotoxicity study and application of a standard UF of 100. The JMPR ADI is based on a 2-year study in rats (NOAEL 50 ppm = 1.7 mg/kg bw per day), and on a 1-year study in dogs (NOAEL 100 ppm = 2.2 mg/kg bw per day) and an UF of 100. ARfD based on one- and two-generation studies of reproductive toxicity, developmental neurotoxicity study in rat with UF 100. The ADIs derived by JMPR and EU are based on the same study. Differences in the value are most likely the result of different policy on rounding.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • flubendiamide-iodo-phthalimide Metabolites included in EU RD for RA: flubendiamide-iodo-phthalimide: no further data available to conclude if HBGVs from parent could apply to this metabolite at JMPR and EU level.				

5.21.3 | Residue definitions – Flubendiamide

TABLE 111 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Flubendiamide	Reg. 396/2005 (implementing MRL review): Flubendiamide Peer review (EFSA, 2013j): Flubendiamide	Yes
	Animal products	Flubendiamide The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Flubendiamide Peer review (EFSA, 2013j): Flubendiamide (representative uses) The residue is fat soluble	Yes

[55]Commission Implementing Regulation (EU) 2025/1092 of 2 June 2025 amending Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council. C/2025/3315. OJ L, 2025/1092, 3.6.2025.

TABLE 111 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Flubendiamide	MRL review (EFSA, 2020h) and Peer review (EFSA, 2013j): Flubendiamide	Yes
	Animal products	Flubendiamide and flubendiamide-iodophthalimide	MRL review (EFSA, 2020h): Sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide Peer review (EFSA, 2013j): Sum of parent flubendiamide (NNI-0001) and NNI-0001-iodo-phthalimide expressed as flubendiamide	Yes
Conclusion, comments	Residue definitions in plants and livestock in the EU and JMPR are comparable.			

5.21.4 | Codex MRL proposals – Flubendiamide

TABLE 112 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of edible offal (mammalian)	0.6	Liver and kidney from – swine, ruminants, equine and others: 1 Edible offals from from – swine, ruminants, equine and others: 2	Max. dietary burden (AUS beef cattle): 47.92 ppm. Max. residues in liver/kidney: 0.57 mg/kg Sufficiently supported by data: Yes Specific comments: STMRs and HRs were based on the calculated residues of flubendiamide + iodo-phthalimide in milk and cattle tissues. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of mammalian fats (except milk fats)	1.5	2	Max. dietary burden (AUS beef cattle): 47.92 ppm. Max. residues in fat: 1.15 mg/kg Sufficiently supported by data: Yes Specific comments: STMRs and HRs based on the calculated residues of flubendiamide + iodo-phthalimide in milk and cattle tissues **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milks	**0.15**	0.1	Max. dietary burden (AUS dairy cattle): 40.72 ppm. Max. residues in milk: 0.101 mg/kg Sufficiently supported by data: Yes Specific comments: A CXL for milk at 0.1 mg/kg would be sufficient. In the absence of information on the lipid content of the cream sample used in the original assessment, JMPR assumed a milk fat content of 4% and complete partitioning of flubendiamide and flubendiamide-iodophthalimide residues into the fat fraction, resulting in a concentration factor of 25. STMRs and HRs were based on the calculated residues of flubendiamide + iodo-phthalimide in milk and cattle tissues. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of milk fats[c]	4	–	In the EU, specific MRLs are not set for milk fats.
Group of muscle (from mammals other than marine mammals)	0.15	2	Max. dietary burden (AUS beef cattle): 47.92 ppm. Max. residues in muscle: 0.13 mg/kg Sufficiently supported by data: Yes Specific comments: STMRs and HRs were based on the calculated residues of flubendiamide + iodo-phthalimide in milk and cattle tissues. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

(Continues)

TABLE 112 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Onion, Welsh, dried	7	–	The JMPR could not estimate a processing factor for Welsh onion since in the fresh RAC the outer layer was removed (not following the Codex procedure). Currently, no EU MRLs are established for processed products.
General comments	At CCPR 56, the EU made a reservation for the proposed animal products since a new dietary burden calculation should have been performed to derive the MRL proposals. In the 2025 JMPR report, the JMPR calculated the dietary burden estimations using the OECD feed calculator 2018, rev 5, and presented the results in Annex 5. The 2010 and 2024 JMPR did not estimate MRLs, STMR or HR values for poultry tissues and eggs as the poultry dietary burden exceeded the highest dosing level in the poultry feeding study by more than 30%. No new feeding study was received, and the 2025 JMPR could not make any estimation for poultry commodities. The only CXL proposal for livestock higher than the current EU MRL is for milk.		

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.21.5 | Consumer risk assessment – Flubendiamide

TABLE 113 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. A risk assessment was performed, with the proposed Codex MRL for milk.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (EFSA, 2020h), reflecting the current EU MRLs (some of them based on previously implemented CXLs) and the proposed Codex MRL for milk.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the commodities under assessment. Cattle milk: 10% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 68% of the ADI. The main contributor was milk (cattle) accounting for up to 29% of the ADI.	**Results:** Long-term exposure: Max 20% of the JMPR ADI. Short-term exposure: Highest result for milks: 5% of ARfD GECDE mean: Max. 70% (female adults; infants and toddlers) GECDE max: Max. 280% (female adults; children and adolescents)

5.21.6 | Conclusions – Flubendiamide

TABLE 114 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU (approval expired in August 2024, as no request for renewal was submitted).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs are identical.
Codex MRL proposals	The proposed CXLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The Codex MRL proposals are sufficiently supported by data and risk for consumers is unlikely.

5.22 | Fluopyram (243) R

5.22.1 | Background information – Fluopyram

TABLE 115 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	AT	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Implementing Regulation (EU) No 802/2013[56] Renewal Assessment Report (RAR) submitted, EFSA peer review ongoing
EFSA conclusion available	Yes, see comments	EFSA (2013a) EFSA (2018s) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data) EFSA peer review ongoing
MRL review performed	Yes, see comments	EFSA (2020f)
EU MRL applications or other EU assessments	Yes, see comments	Art.12 confirmatory data assessment (ongoing) Art. 10 in lime (ongoing) EFSA (2023b) (Art.10 and import tolerance in various crops)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not fall under cut-off criteria ECHA (2014); ATP09[57]
Endocrine effects of a.s.	Not assessed	Not assessed under the new criteria established by Regulation (EU) 2018/605 (EFSA, 2013a)
Other relevant information	Fluopyram belongs to the class of PFAS chemicals based on its chemical structure.	

5.22.2 | Health-Based Guidance Values – Fluopyram

TABLE 116 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.01 mg/kg bw per day	JMPR, 2010	0.012 mg/kg bw per day	EFSA, 2013	No, minor difference due to rounding
ARfD	0.5 mg/kg bw	JMPR, 2010	0.5 mg/kg bw	EFSA, 2013	Yes
Conclusion/comments on a.s.	–				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 2- (trifluoromethyl)benzamide • N-(E)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2- trifluoromethyl)benzamide • N-(Z)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide No toxicological information was reported for the three metabolites. However, according to the WHO toxicological evaluation (JMPR 2011; FAO and WHO, 2012), all three metabolites were identified as major metabolites in rats. The inconsistent coding of metabolites across JMPR assessments, however, prevents verification of the reported results. Metabolites included in EU RD for RA: • fluopyram-benzamide (M25) • fluopyram-E/Z-olefine (M02/M03) No data was available on the three metabolites, M25, M02 or M03. However, the peer review process is at initial phase and this information may become available.				

[56]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, pp. 13–16.

[57]Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 195, 20.7.2016, p. 11–25.

5.22.3 | Residue definitions – Fluopyram

TABLE 117 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	Reg. 396/2005 (implementing MRL review): Fluopyram Peer review (EFSA, 2013a): Fluopyram	Yes
	Animal products	Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram The residue is not fat soluble	Reg. 396/2005 (implementing MRL review): Sum of fluopyram and fluopyram-benzamide (M25) expressed as fluopyram Peer review (EFSA, 2013a): Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram The residue is not fat soluble	Yes
RD RA	Plant products	Fluopyram	MRL review (EFSA, 2020f) and Peer review (EFSA, 2013a): Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram	No
	Animal products	Sum of fluopyram, 2- (trifluoromethyl) benzamide and the combined residues of N-(E)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl] ethenyl)-2- trifluoromethyl) benzamide and N-(Z)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl] ethenyl)-2-trifluoromethyl) benzamide, all expressed as fluopyram.	MRL review (EFSA, 2020f) and Peer review (EFSA, 2013a): Sum fluopyram, fluopyram-benzamide (M25), fluopyram-E/Z-olefine (M02/M03), expressed as fluopyram	Yes
Conclusion, comments	The EU RD for RA comprises an additional metabolite (M25). This metabolite was found only in few commodities, such as rape seeds. It was also observed in rotational crops e.g. cereal straw. M25 is a common metabolite with flutolanil. The peer review for the renewal is ongoing.			

5.22.4 | Codex MRL proposals – Fluopyram

TABLE 118 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	8 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	2 (W)	–	The existing CXL is being replaced with the new proposal for the group of eggs.
Group of avian, edible offal	**5**	0.3 (liver and edible offals) 0.02* (kidney)	Max. dietary burden (EU poultry layer): 8.5 ppm. Max residues in liver: 3.1 mg/kg. Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. A slightly lower value of 4 mg/kg might be sufficient. Follow-up action: None
Group of avian fats	**1**	0.07	Max. dietary burden (EU poultry layer): 8.5 ppm. Max. residues in fat: 0.9 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None

TABLE 118 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avian muscle	**1.5**	0.07	Max. dietary burden (EU poultry layer): 8.5 ppm. Max. residues in muscle: 0.97 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. A slightly lower value of 1 mg/kg might be sufficient. Follow-up action: None
Group of edible offal (mammalian)	**8**	Liver from – swine: 0.5 – ruminants, equine and others: 0.8 Kidney from – swine: 0.08 – ruminants, equine and others: 0.15 Edible offals from – swine: 0.5 – ruminants, equine and others: 0.8	Max. dietary burden (AUS beef cattle): 65 ppm. Max residues in liver: 7.2 mg/kg Sufficiently supported by data: Yes Specific comments: **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Group of eggs	**2**	0.15	Max. dietary burden (EU poultry layer): 8.5 ppm. Max. residues in eggs: 1.5 mg/kg Sufficiently supported by data: Yes Specific comments: The HR of 1.3 mg/kg (RD for MRL enforcement) was rounded up to 2 mg/kg derive the Codex MRL proposal. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. A slightly lower value of 1.5 mg/kg might be sufficient. Follow-up action: None
Group of mammalian fats (except milk fats)	**1.5**	0.09 (pig) 0.15 (ruminants, equine and others)	Max. dietary burden (AUS beef cattle): 65 ppm. Max residues in fat: 1 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Group of milks	**0.8**	0.07 (cattle, horse) 0.06 (sheep, goat)	Max. dietary burden (AUS beef cattle): 55 ppm. Max residues in milk: 0.72 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	**1.5**	0.1 (swine) 0.15 (ruminants, equine and others)	Max. dietary burden (AUS beef cattle): 65 ppm. Max residues in muscle: 1 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Mammalian fats (except milk fats)	1.5 (W)	–	The existing CXL is being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	1.5 (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milks	0.8 (W)	–	The existing CXL is being replaced with the new proposal for the group of milks.
Mint	0.6	60	cGAP: USA, foliar, 2 × 250 g a.s./ha, 21-day RTI, 28-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.

(Continues)

TABLE 118 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Mint oil	–	–	The JMPR derived a processing factor of 0.53. Currently no EU MRLs are established for processed products.
Onion, bulb	**0.4**	0.07	cGAP: USA, foliar, 2 × 250 g a.s./ha, 7-day RTI, 7-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Pineapple	0.01*	0.01*	cGAP: Mexico, two drench/drip applications each at 250 g a.s./ha, with the first application 30-days after transplanting and a second application 13 days after, 180 days PHI. Number of trials: 14 Sufficiently supported by data: Yes Specific comments: Combined data set of 8 residue trials with a single foliar application of 500 g a.s./ha and 6 trials with two foliar applications of 250 g a.s./ha done 165–209 days apart. Residues in the whole fruit were always below the LOQ of 0.01 mg/kg. The JMPR considered that the foliar application would lead to higher residues when compared soil application as per the GAP under assessment. Therefore, the JMPR estimated the MRL at the LOQ of 0.01 mg/kg. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Poultry, edible offal	5 (W)	–	The existing CXL is being replaced with the new proposal for the group of avian, edible offal.
Poultry, fats	1 (W)	–	The existing CXL is being replaced with the new proposal for the group of avian fats.
Poultry, meat	1.5 (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
Squash, summer	0.3	0.6	cGAP: USA, foliar, 2 × 250 g a.s/ha, 5-day RTI, 0-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Subgroup of fruiting vegetables, cucurbits – melons, pumpkins and winter squashes	**0.6**	0.9 (melons) 0.4 (pumpkins and watermelons)	cGAP: USA, foliar, 2 × 250 g a.s/ha, 5-day RTI, 0-day PHI Number of trials: 25 Sufficiently supported by data: Yes Specific comments: Combined data set of field-grown melons (15), watermelon (4) and glasshouse grown melons (6). In the EU indoor and outdoor trials are not combined, since outdoor trials are not representative for indoor/protected conditions. In addition, a PHI of 0 days would not be acceptable at EU level. The CXL calculated from the outdoor trials results in a 0.7 mg/kg proposal while using the results from the indoor trials leads to a CXL of 0.5 mg/kg. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs because of using a combined data set of indoor and outdoor trials. The calculated long-term exposure exceeded the ADI Follow-up action: None.

TABLE 118 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
General comments			The JMPR noted that none of the commodities for which the current meeting is making recommendations on are animal feeds and residues in pineapple process waste are expected to be below limits of quantification; therefore, no changes to the dietary burdens were expected. The maximum dietary burdens and CXL proposals are in line with the 2023 JMPR report, apart from the slight difference in the max DB reported for the EU layer poultry (8.5 in the Annex 5 of the 2025 JMPR compared to the max DB of 9.1 ppm reported in the chapter for fluopyram). It is noted that, for some animal commodities (eggs, avian muscle and avian edible offal), lower CXLs may be proposed.

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.22.5 | Consumer risk assessment – Fluopyram

TABLE 119 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. (i.e. onion, pumpkins, watermelons, and livestock commodities). The calculations are indicative, because the EU residue definition is wider than the residue definition of Codex. Therefore, the calculations are affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment scenario 2 (EFSA, 2023b) were updated, including the STMR values derived by JMPR for the commodities for which the proposed Codex MRL is higher than the EU MRL (i.e. onion, pumpkins, watermelons and livestock commodities). The calculations are indicative, because the EU residue definition is wider than the residue definition of Codex. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Bovine liver: 12% of ARfD Cattle milk: 12% of ARfD	**Results:** **The calculated long-term exposure exceeded the ADI**. The overall chronic exposure accounted for 329% of the ADI. Among the commodities under consideration, cattle milk was identified as the main contributor, accounting for up to 239% of the ADI, when the STMR of 0.48 mg/kg from the CXL proposal in the 2025 JMPR was used in the calculations.	**Results:** Long-term exposure: Max 80% of the JMPR ADI. Short-term exposure: Highest result for milks, edible offal: 10% of ARfD GECDE mean: Max. 270% (infants and toddler) GECDE max: Max. 690% (infants and toddler)

5.22.6 | Conclusions – Fluopyram

TABLE 120 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (RAR submitted, EFSA peer review has not started yet).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs are identical, except the RD for RA for plant products, where the EU RD is wider.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	A chronic intake concern was identified by EFSA.
Final conclusion	The final EU position should be discussed by risk managers.

5.23 | Thiamethoxam (245) R

5.23.1 | Background information – Thiamethoxam

TABLE 121 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	FR	
Approval status in the EU	Not approved	Commission Implementing Regulation (EU) 2022/801[58] In the light of the restrictions defined by Regulation (EU) No 2018/785,[59] the applicant decided to withdraw the application for the renewal of approval of thiamethoxam. Consequently, the approval expired on 30 April 2019.
EFSA conclusion available	No, see comments	The DAR prepared by the RMS was not peer reviewed by EFSA. Therefore, no EFSA conclusion is available For the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering the uses as seed treatments and granules, an EFSA conclusion is available (EFSA, 2018g)
MRL review performed	Yes, see comments	EFSA (2014i)
EU MRL applications or other EU assessments	Yes, see comments	EFSA assessed a number of emergency authorisations granted by Member States between 2018 and 2021
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2019c); ATP17[60]
Endocrine effects of a.s.	Not assessed	
Other relevant information	Thiamethoxam belongs to the group of neonicotinoids, is used as biocide and is subject to the PIC regulation[61].	

5.23.2 | Health-Based Guidance Values – Thiamethoxam

TABLE 122 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.08 mg/kg bw per day	JMPR, 2010	0.026 mg/kg bw per day	Directive 2007/6/EC	No See comments on metabolites
ARfD	1 mg/kg bw	JMPR, 2010	0.5 mg/kg bw	Directive 2007/6/EC	No See comments on metabolites
Conclusion/comments on a.s.	At JMPR level: An ADI of 0.08 mg/kg bw per day was derived from a NOAEL of 8.23 mg/kg bw per day in a 90-day dog study, based on prolonged thromboplastin time, applying a safety factor of 100. This ADI was considered protective for hepatotoxic/hepatocarcinogenic effects in mice and marginal effects in a multigeneration rat study. An ARfD of 1 mg/kg bw was derived from a NOAEL of 100 mg/kg bw in an acute neurotoxicity study in rats, based on transient functional changes, applying a safety factor of 100 and supported by an acute toxicity study in mice. At EU level: The ADI of 0.026 mg/kg bw per day was derived from a 18-month study mice applying a safety factor of 100. The ARfD of 0.5 mg/kg bw was derived from a rabbit development toxicity study applying a safety factor of 100 (European Commission, 2006).				

[58]Commission Implementing Regulation (EU) 2022/801 of 20 May 2022 amending Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council. C/2022/3216. OJ L 143, 23.5.2022, pp. 7–10.

[59]Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin. OJ L 132, 30.5.2018, pp. 35–39.

[60]Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 188, 28.5.2021, p. 27–43.

[61]Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast). OJ L 201, 27.7.2012, p. 60–106.

TABLE 122 (Continued)

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
Comments on metabolites	Metabolites included in JMPR RD for RA: • CGA 265307 (N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine) Metabolite was mentioned to be a minor rat metabolite, but found at much higher concentration in mouse than in rats (JMPR report 2010). No toxicological studies reported. • MU3 (amino-([(2-chlorothiazol-5-ylmethyl)-amino]-methylene)- hydrazide, metabolite in poultry meat) No information provided on the toxicological profile of either metabolite. Metabolites included in EU RD for RA: • Clothianidin See chapter on clothianidin				

5.23.3 | Residue definitions – Thiamethoxam

TABLE 123 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	HBGV comparable
RD enf	Plant products	Thiamethoxam	Reg. 396/2005 (implementing MRL review): Thiamethoxam MRL review (EFSA, 2014i): Thiamethoxam and clothianidin (considered separately)	Yes
	Animal products	Thiamethoxam and clothianidin (considered separately) The residue is not fat soluble	Reg. 396/2005: Thiamethoxam MRL review (EFSA, 2014i): Ruminants and pigs: Thiamethoxam and clothianidin (considered separately). Poultry products: No residue definition proposed Fat solubility not specified	Yes
RD RA	Plant products	Thiamethoxam	MRL review (EFSA, 2014i): Thiamethoxam and clothianidin (considered separately)	Yes
	Animal products	All animal commodities except poultry: Thiamethoxam and clothianidin (considered separately) For poultry: Sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam; and clothianidin (clothianidin to be considered separately from thiamethoxam)	MRL review (EFSA, 2014i): Ruminants and pigs: Thiamethoxam and clothianidin (considered separately). Poultry products: No residue definition proposed	Yes; for poultry no RD-RA set in the EU
Conclusion, comments	The EU residue definition for MRL enforcement and risk assessment in plants and livestock is equivalent to the JMPR residue definitions, except the RD for RA for poultry.			

5.23.4 | Codex MRL proposals – Thiamethoxam

TABLE 124 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.05 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group of eggs.
Group of avian fats	0.01*	0.02*	See group of avian muscle.

(Continues)

TABLE 124 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avian muscle	**0.03**	0.02*	Max. dietary burden (AUS poultry layer): 11.8 ppm for thiamethoxam and 0.334 ppm for clothianidin. MRL proposals for eggs and poultry tissues were derived from poultry metabolism study where animals were dosed with thiamethoxam at approximately 10N-rate and clothianidin at approximately 500N-rate. Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None
Group of avian, edible offal	0.01*	0.02*	See group of avian muscle.
Group of edible offal (mammalian)	**0.05**	0.02*	Max. dietary burden (AUS dairy cattle): 22.6 ppm for thiamethoxam and 1.14 for clothianidin. Highest max residues in milk (0.044 mg/kg) were estimated based on the livestock feeding studies performed with thiamethoxam. Highest max residues in liver (0.39 mg/kg) were estimated based on the livestock feeding studies performed with thiamethoxam. Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. However, several feed items are from crops that are melliferous (e.g. almonds, apples, citrus, rapeseed), and thus potential food source for pollinators. Therefore, it is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs in view of the EU policy for setting MRLs for neonicotinoids, and the appropriate level of protection for pollinators.
Group of eggs	0.01*	0.01*	See group of avian muscle.
Group of mammalian fats (except milk fats)	0.01*	0.02*	See group of edible offal (mammalian).
Group of milks	**0.15**	0.01*	See group of edible offal (mammalian).
Group of muscle (from mammals other than marine mammals)	**0.07**	0.02*	See group of edible offal (mammalian).
Mammalian fats (except milk fats)	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.07 (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle.
Milks	0.15 (W)	–	The existing CXL is being replaced with the new proposal for group of milks).
Poultry fats	0.01* (W)	–	The existing CXL is being replaced with the new proposal for group of avian fats
Poultry meat	0.03 (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
Poultry, edible offal of	0.01* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian edible offal.
General comments	JMPR 2025 updated the DB which were slightly increased; however, the CXLs for animal commodities, remain unchanged compare with JMPR 2021. The proposed CXLs from 2021 JMPR were not implemented in the EU Regulation. There was an update of the animal commodities designation and codes, following the update of the Codex Classification.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.23.5 | Consumer risk assessment – Thiamethoxam

TABLE 125 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. avian edible offal, mammalian edible offal, milks). Since clothianidin and thiamethoxam share a common mode of action, the two substances should be considered together in the risk assessment, taking into account the different toxicological potencies. Therefore, clothianidin and thiamethoxam were assessed separately, and in a combined assessment.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1., based on the latest Regulation (EC) 2023/334,[62] where all MRLs are set at the LOQ, and including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. avian edible offal, mammalian edible offal, milks). Since clothianidin and thiamethoxam share a common mode of action, the two substances should be considered together in the risk assessment, taking into account the different toxicological potencies. Therefore, clothianidin and thiamethoxam were assessed separately, and in a combined assessment.	**Specific comments:** The JMPR The JMPR did not change the previous recommendations for STMRs and HRs for animal commodities, and therefore, a new dietary risk assessment was not deemed necessary.
Results: No short-term consumer health risk was identified for the crops under assessment. Milk (cattle): 1% of the ARfD **Combined (thiamethoxam and clothianidin)** Highest exposure among the commodities under consideration Milk (cattle): 5% of the ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 12% of the ADI. Among the crops under consideration, milk (cattle) was identified as the main contributor, accounting for up to 9% of the ADI. **Combined (thiamethoxam and clothianidin)** The overall chronic exposure accounted for 17% of the ADI.	**Results:** A consumer risk assessment was not deemed necessary, since HR and STMR of animal commodities were not changed.

5.23.6 | Conclusions – Thiamethoxam

TABLE 126 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. no longer approved in the EU (approval expired in January 2019, as the application for renewal was withdrawn).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs for plant commodities (enforcement and risk assessment) are equivalent.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data, but further risk management discussions are recommended in view of the EU policy on protection of pollinators.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	Further risk manager consideration is needed, considering the EU policy for setting MRLs on neonicotinoids.

5.24 | Dinotefuran (255) R

5.24.1 | Background information – Dinotefuran

TABLE 127 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	No RMS assigned	DE volunteered to act as RMS for this a.s.
Approval status in the EU	Not approved	Never notified and authorised in the EU

(Continues)

[62]Commission Regulation (EU) 2023/334 of 2 February 2023 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products. C/2023/214. OJ L 47, 15.2.2023, pp. 29–45.

TABLE 127 (Continued)

	Comments, references	
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No, see comments	Art. 10 import tolerance in various crops (additional data requested) EFSA (2024b) (Scientific support for preparing an EU position in the 55th Session of CCPR)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2023a)
Endocrine effects of a.s.	No, see comment	Peer review meeting (TC 110)[63]: ED criteria are not met EATS modalities.
Other relevant information	Dinotefuran is an a.s. belonging to the group of neonicotinoids. It is approved as biocide for controlling insects, ants, etc. by means other than repulsion or attraction.	

5.24.2 | Health-Based Guidance Values – Dinotefuran

TABLE 128 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		HBGV comparable
	Value	**Comments**	**Value**	**Comments**	
ADI	0.2 mg/kg bw per day	JMPR, 2012	0.22 mg/kg bw per day	Peer Review Meeting TC114	Yes
ARfD	1 mg/kg bw	JMPR, 2012	1.25 mg/kg bw	Peer Review Meeting TC114	Yes
Conclusion/ comments on a.s.	Peer review meeting (TC 114)[63]: ADI based on NOAEL from oral dietary 52-week study conducted in dogs, applying a standard uncertainty factor of 100. ARfD based on maternal NOAEL from developmental toxicity study in rabbits, applying a standard uncertainty factor of 100. JMPR 2012 (FAO and WHO, 2013b): ADI based on NOAEL from oral dietary 52-week study conducted in dogs, applying a standard uncertainty factor of 100. ARfD based on maternal NOAEL from developmental toxicity study in rabbits, applying a standard uncertainty factor of 100. The reference points for setting the HBGVs in the EU and JMPR assessments are the same. Differences in HBGVs related to different rounding approaches applied.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • UF (1-methyl-3-(tetrahydro-3-furylmethyl) urea) • DN (1-methyl-3-(tetrahydro-3- furylmethyl) guanidium dihydrogen) In the 2012 JMPR report (first evaluation of the a.s. dinotefuran), no toxicological studies are reported for the two metabolites included in the RD for risk assessment. As in the JMPR report (2025) the definition of residue for estimation of dietary intake in plant commodities includes the sum of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF) and 1-methyl-3-tetrahydro-3-furylmethyl)guanidium dihydrogen (DN), expressed as dinotefuran, this implies that metabolites would be covered by the HBGVs established for the parent. However, a related tox assessment is not presented. In the EU assessment, these metabolites are not considered covered by the HBGVs of the parent. Although they were proposed as covered by the toxicity profile of the parent compound, since they were found in significant amount (e.g. > 10%) in several tissues in the rat metabolism study, these percentages represent those of the total radioactivity detected in the tissues and not the percentages of the administered dose of dinotefuran. These tissue values are much lower than 10% of the administered dinotefuran dose which is the cut-off typically applied to consider a metabolite as present in significant amount in a rat metabolism study. Based on the available information, it cannot be concluded whether the HBGVs of the parent compound are applicable to the metabolites (peer review meeting (TC 114[63]). Metabolites included in EU RD for RA: • No EU residue definition for risk assessment is established. However, dinotefuran was discussed at the residues peer review meeting TC 192[64] (December 2025) in the framework of the Art 10. According to the conclusions of the peer-review meeting, the following compounds were identified as relevant for the inclusion into the risk assessment residue definition (RA-RD): - Dinotefuran - UF - DN - PHP The following information was required: Genotoxicity and general toxicity need to be addressed for PHP; valid residue field trials are needed to address the levels of PHP under real conditions; genotoxicity of MNG metabolite needs to be addressed (to potentially excluded it from the RD). This toxicological information is required to finally conclude on the expression of the RD-RA. The residue definition for enforcement was proposed as: – dinotefuran				

[63] https://www.efsa.europa.eu/sites/default/files/2023-12/minutes-ppr-mammalian-toxicity.pdf.

[64] https://www.efsa.europa.eu/sites/default/files/2021-10/pesticides-residues-minutes.pdf.

5.24.3 | Residue definitions – Dinotefuran

TABLE 129 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	Plant products	Dinotefuran	Dinotefuran by default No EU peer review and no MRL review	Yes, see comments
	Animal products	Sum of dinotefuran and 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF), expressed as dinotefuran The residue is not fat soluble	Dinotefuran by default No EU peer review and no MRL review	Yes, see comments
	Plant products	Sum of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF) and 1-methyl-3-tetrahydro-3-furylmethyl)guanidium dihydrogen (DN), expressed as dinotefuran	No EU peer review and no MRL review	Not applicable
	Animal products	Sum of dinotefuran and 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF), expressed as dinotefuran	No EU peer review and no MRL review	Not applicable
Conclusion, comments	The a.s. was never notified and authorised in the EU. There is no EU peer review or MRL review available. The current EU RD for enforcement for plants and livestock is dinotefuran.			

5.24.4 | Codex MRL proposals – Dinotefuran

TABLE 130 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Durian	0.7	–	cGAP: Thailand, Foliar, 2 × 1.5 g a.s./tree, 7-day RTI, 3-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: The STMR (< 0.036 mg/kg) and HR (0.036 mg/kg) used by the JMPR were from the residues in durian pulp (3 × < 0.036 mg/kg; 0.036 mg/kg). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Edible offal (mammalian)	0.1 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.02* (W)	–	The existing CXL is being replaced with the new proposal for the group of eggs.
Group of avian, edible offal	0.02*	0.02	Max. dietary burden (AUS poultry layer): 2.35 ppm. A feeding study for poultry was not available. However, the maximum dietary burden calculated by the JMPR for broiler and layer poultry (2.35 ppm) was lower than the level in the animal metabolism study on laying hen (10 ppm), and residue of dinotefuran was detected only in egg white at 0.013 mg/kg. Therefore, the JMPR considered that the residues of sum of dinotefuran, UF and DN at the maximum dietary burden were expected to occur at levels < 0.01 mg eq/kg in poultry commodities. Sufficiently supported by data: Yes Specific comments: The CXLs for poultry tissues and eggs were estimated at the LOQ of 0.02* mg/kg in JMPR report 2012 (FAO and WHO, 2013a) based on the combined LOQ for dinotefuran and UF. These CXLs were implemented in the EU Regulation 491/2014[65] but at the level of 0.02 mg/kg (without asterisk). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. MS to consider if the CXLs for poultry commodities should be expressed with an asterisk (i.e. 0.02* mg/kg). See also general comments on the RD enforcement livestock. Follow-up action: None
Group of avian fats	0.02*	–	See group of avian, edible offal.

(Continues)

[65]Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ L 146, 16.5.2014, pp. 1–91.

TABLE 130 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avian muscle	0.02*	0.02	See group of avian, edible offal.
Group of edible offal (mammalian)	0.1	0.1	Max. dietary burden (AUS dairy cattle): 15.36 ppm. Max. residues in kidney: 0.080 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Group of eggs	0.02*	0.02	See group of avian, edible offal
Group of mammalian fats (except milk fats)	0.1	–	Max. dietary burden (AUS dairy cattle): 15.36 ppm. Max. residues in fat: 0.067 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Group of milk	0.1	0.1	Max. dietary burden (AUS dairy cattle): 15.36 ppm. Max. residues in milk: 0.084 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	0.1	0.1	Max. dietary burden (AUS dairy cattle): 15.36 ppm. Max. residues in muscle: 0.065 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Mango	0.6	–	cGAP: Thailand, Foliar, 2 × 0.5 g a.s./tree, 7-day RTI, 3-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: The JMPR used a pulp: whole fruit ratio (x 0.54) to estimate residues in mango pulp from those in mango whole fruit: STMR (0.12 mg/kg) and HR of (0.16 mg/kg). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Meat (from mammals other than marine mammals)	0.1 (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milk	0.1 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milks.
Poultry, edible offal of	0.02* (W)	–	The existing CXL being replaced with the new proposal for the group of avian, edible offal.
Poultry meat	0.02* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
General comments	No commodities evaluated by the 2025 JMPR are used as animal feed. However, the JMPR estimated the animal dietary burden for dinotefuran based on the residues estimated by previous JMPR and using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual. In 2014, the CXLs for several plant and animal products have been taken over in the EU legislation (Reg (EU) 491/2014. However, the residue definition for animal products was not aligned with the Codex residue definition for animal products. Hence, a reconsideration of the MRLs that are currently set for animal products, based on CXLs, would be necessary. It is also noted that the metabolites included in the RD-RA by JMPR were not reviewed toxicologically at the EU level.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.24.5 | Consumer risk assessment – Dinotefuran

TABLE 131 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the JMPR ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. durian, mango and livestock fat). The calculations are indicative, because no definitive EU residue definitions and HBGVs are available. Therefore, the calculations are affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the JMPR ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2024b) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. durian, mango and livestock fat). The risk assessment is indicative, since the substance was never assessed in the EU, and therefore, no definitive EU residue definitions and HBGVs are available. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Mango: 2% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 7% of the ADI. Among the crops under consideration, mango was identified as the main contributor, accounting for up to 0.03% of the ADI.	**Results:** Long-term exposure: Max 3% of the JMPR ADI. Short-term exposure: Highest result for mango: 1% of ARfD GECDE mean: Max. 10% (Adults, female) GECDE max: Max. 20% (Adults, female; infants and toddler)

5.24.6 | Conclusions – Dinotefuran

TABLE 132 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU under pesticide legislation; however, the a.s. is approved for biocidal uses. The EU assessment of an import tolerance is currently ongoing.
Toxicological assessment	No EU HBGVs available.
Residue definitions	EU and Codex RDs for enforcement are identical; for RA, Codex RDs are more comprehensive.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified (using the HBGVs derived by the JMPR).
Final conclusion	The final EU position should be discussed/decided by risk managers, since the a.s. was never approved in the EU, there is an import tolerance ongoing, no EU HBGVs available, and no RD-RA set at the EU level.

5.25 | Cyantraniliprole (263) R

5.25.1 | Background information – Cyantraniliprole

TABLE 133 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	ES	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Implementing Regulation (EU) 2016/1414[66] Dossier admissible, RMS assessment expected by the end of 2027

[66]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. C/2016/5372. OJ L 230, 25.8.2016, pp. 16–19.

TABLE 133 (Continued)

		Comments, references
EFSA conclusion available	Yes, see comments	EFSA (2014f)
MRL review performed	Yes, see comments	EFSA (2017e) (Statement; no MRL review required)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2022) (apricots and import tolerances in various crops) EFSA (2021d) (olives) EFSA (2019m) (Chinese cabbages, blackberries and raspberries) EFSA (2018a) (leeks)
Classification of a.s. (cut-off criteria)	Not assessed	–
Endocrine effects of a.s.	Not assessed	–
Other relevant information	–	

5.25.2 | Health-Based Guidance Values – Cyantraniliprole

TABLE 134 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.03 mg/kg bw per day	JMPR, 2013/2023	0.01 mg/kg bw per day	EFSA, 2014	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2013/2023	Not necessary	EFSA, 2014	Yes Not applicable.
Conclusion/ comments on a.s.	EFSA (2014f): ADI based on NOAEL from 1-year dog study applying a standard uncertainty factor of 100. JMPR 2013 and 2023 (FAO and WHO, 2014, 2024): ADI based on NOAELs from 90-day and 1-year toxicity studies in dogs applying a standard uncertainty factor of 100.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38] • 2-[3-Bromo-1-(3- chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84] • 3-Bromo-1-(3- chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN-N7B69] • 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H- pyrazole-5-carboxamide [IN-MYX98] JMPR 2013 (FAO and WHO, 2014): IN-MLA84, IN-MYX98 and IN-J9Z38 have been tested in rodents through their formation from the parent compound and are, therefore, covered by the ADI for cyantraniliprole. As the estimated exposure to IN-N7B69 is below the threshold of toxicological concern for Cramer class III compounds, there is no concern for this metabolite. EFSA (2014f): IN-J9Z38 is covered by HBGVs of the parent. Although no specific toxicological assessment data are available for IN-MLA84 and IN-N7B69, these metabolites are major rat metabolites and are therefore considered covered by the HBGVs of the parent compound. Metabolites included in EU RD for RA: • 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile (IN-J9Z38) • 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-8-methyl-4-oxo-1,4-dihydroquinazoline-6-carbonitrile (IN-MLA84) • 3-bromo-1-(3-chloropyridin-2-yl)-N-[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1H-pyrazole-5-carboxamide (IN-N7B69) EFSA (2014f): IN-J9Z38 is covered by HBGVs of the parent.				

5.25.3 | Residue definitions – Cyantraniliprole

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	Cyantraniliprole	Reg. 396/2005: Cyantraniliprole Peer review (EFSA, 2014f): Cyantraniliprole	Yes
	Animal products	Cyantraniliprole The residue is not fat soluble	Reg. 396/2005: Reg. 396/2005: Cyantraniliprole Peer review (EFSA, 2014f): Cyantraniliprole The residue is not fat soluble	Yes

TABLE 135 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Cyantraniliprole For processed commodities: Sum of cyantraniliprole and 2- [3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], expressed as cyantraniliprole	Peer review (EFSA, 2014f): Cyantraniliprole For processed commodities: Sum cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole	Yes
	Animal products	Sum of cyantraniliprole, 2-[3-bromo-1-(3- chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3- chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3- chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl] phenyl]-1H-pyrazole-5-carboxamide [IN-N7B69] and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino] carbonyl]-6-methylphenyl]-1H- pyrazole-5-carboxamide [IN-MYX98], expressed as cyantraniliprole	Peer review (EFSA, 2014f): Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole	No
Conclusion, comments	**EU plant:** Metabolism studies in four crop groups showed a similar metabolic profile across application methods, with cyantraniliprole as the main residue. Therefore, the enforcement and risk assessment RDs were proposed as cyantraniliprole. **Processed commodities:** Cyantraniliprole was stable under pasteurisation and sterilisation but degraded under boiling, mainly to IN-J9Z38, also confirmed in processing studies. The RDs were proposed as cyantraniliprole for enforcement and the sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole, for risk assessment. JMPR proposed similar RDs for plant and processed products. **EU animal:** Goat and poultry metabolism studies showed extensive excretion and limited residues in tissues, milk and eggs. The EU RD-RA was proposed as the sum of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole, with a conversion factor of 2 except for meat and honey. JMPR assessed the same studies but also included IN-MYX98 in the risk assessment RD, as it occurred at significant levels in muscle and milk.			

5.25.4 | Codex MRL proposals – Cyantraniliprole

TABLE 136 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	1.5 (W)	–	The existing CXL is replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.3 (W)	–	The existing CXL is replaced with the new proposal for the group of eggs.
Group of avian, edible offal of	0.15	0.15	The CXL was proposed by JMPR in 2015 and considered acceptable. 2025 JMPR meeting aligned the CXL with the revised commodity classification, as described in section 2.4 of the general considerations of the 2024 JMPR report (FAO and WHO, 2025).
Group of avian fats	0.04	0.04	See group of avian edible offal.
Group of avian muscle	0.02	0.02	See group of avian edible offal.
Group of edible offal (mammalian)	1.5	1.5	The CXL was proposed by JMPR in 2015 and considered acceptable. The 2025 JMPR aligned the CXL with the revised commodity classification, as described in section 2.4 of the general considerations of the 2024 JMPR report (FAO and WHO, 2025).
Group of eggs	0.3	0.3	See group of avian edible offal.
Group of mammalian fats (except milk fats)	0.5	0.5	See group of edible offal (mammalian).

(Continues)

TABLE 136 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of milks	**0.6**	0.02	This CXL proposal, originally recommended by JMPR in 2015, was already assessed by EFSA in 2016 and found unacceptable due to an identified chronic consumer risk. Besides a CXL of 0.5 mg/kg would be sufficient which also leads to a chronic risk for EU consumer. **Conclusion:** The proposed Codex MRL is not acceptable as it leads to an exceedance of the ADI. Follow-up action: None.
Group of muscle (from mammals other than marine mammals)	0.2	0.2	See group of edible offal (mammalian).
Subgroup of herbs	**40**	15 (land cresses) 0.02* (celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers and tarragon) 20 (parsley)	cGAP: USA, 3 × 0.149 kg a.s./ha, 5-day RTI, 1-day PHI Number of trials: 16, basil (6), dill (6), mint (4) Sufficiently supported by data: Yes Specific comments: The US GAP covers subgroup 027A. Although medians differed by less than fivefold, the fresh mint data set was statistically different from basil and dill and gave the highest residues. The JMPR therefore used the data on fresh mint to estimate the CXL and the STMR for subgroup 027A, Herbs (HH 2095). **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: –
Subgroup of herbs, dried	150	–	JMPR derived the CXL from the combined dried basil, dillweed and mint data sets, which were not statistically different. No EU MRLs are currently established for processed products.
Hops, dried	**70**	0.05*	cGAP: USA, 3 × 0.149 kg a.s/ha, 5-day RTI, 1-day PHI Number of trials: 6 (5 USA + 1 Canada) Sufficiently supported by data: Yes Specific comments: Samples were analysed for cyantraniliprole and IN-J9Z38, the metabolite relevant for processed commodities, to derive the STMR. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Mammalian fats (except milk fats)	0.5 (W)	–	The existing CXL is replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.2 (W)	–	The existing CXL is replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milks	0.6 (W)	–	The existing CXL is replaced with the new proposal for the group of milks.
Papaya	**1.5**	0.01*	cGAP: USA, 3 × 0.149 kg a.s/ha, 14-day RTI, 1-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: –
Poultry fats	0.04 (W)	–	The existing CXL is replaced with the new proposal for the group of avian fats.
Poultry meat	0.02 (W)	–	The existing CXL is replaced with the new proposal for the group of avian muscle.
Poultry, edible offal for of	0.15 (W)	–	The existing CXL is replaced with the new proposal for the group of avian edible offal.

TABLE 136 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Subgroup of spices, seeds	**80**	0.05*	cGAP: USA, 3 × 0.149 kg a.s/ha, 5-day RTI, 1-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: The JMPR estimated a CXL and an STMR for dill seeds (HS 0730) and extrapolated to subgroup 028A, Spices, seeds (HS 0190). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
General comments	The CXL proposal for milk is not acceptable since it leads to a chronic risk.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.25.5 | Consumer risk assessment – Cyantraniliprole

TABLE 137 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 risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2022e) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. papaya, hops, spices seeds, herbs and milk). The calculations are indicative, because the residue definition for risk assessment derived by JMPR for animal commodities is wider than the EU RD. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: Not relevant	**Results:** The calculated long-term exposure exceeded the ADI. The overall chronic exposure accounted for 191% of the ADI. Among the commodities under consideration, cattle milk was identified as the main contributor, accounting for up to 125% of the ADI.	**Results:** Long-term exposure: Max 50% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 110% (e.g. infants and toddler) GECDE max: Max. 390% (e.g. infants and toddler)

5.25.6 | Conclusions – Cyantraniliprole

TABLE 138 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (dossier admissible, RMS assessment ongoing).
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex residue definitions are comparable for enforcement and for risk assessment in plant commodities. For animal commodities, the risk assessment residue definitions differ, as JMPR included an additional metabolite.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data for herbs, hops, papaya and spices, seeds. The CXL proposal in milk is not acceptable since it leads to chronic risk for EU consumer.
Dietary risk assessment	A chronic intake concern was identified by EFSA.
Final conclusion	The final EU position should be discussed/decided by risk managers.

5.26 | Pyriofenone (310) R

5.26.1 | Background information – Pyriofenone

TABLE 139 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	LV	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Implementing Regulation (EU) No 833/2013[67] Renewal Assessment Report (RAR) submitted, EFSA peer review has not started yet
EFSA conclusion available	Yes, see comments	EFSA (2013d) EFSA (2013k) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2019d)
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	No, see comments	Carcinogen cat. 2, Aquatic Chronic 1 ECHA (2019a)
Endocrine effects of a.s.	No, see comment	No endocrine disruptor assessment was performed during the peer review, as it was finalised before Regulation (EU) 2018/605 and the 2018 EFSA/ECHA guidance became applicable. EFSA (2013d)
Other relevant information	–	

5.26.2 | Health-Based Guidance Values – Pyriofenone

TABLE 140 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.09 mg/kg bw per day	JMPR, 2018	0.07 mg/kg bw per day	EFSA, 2013	No See comments on a.s.
ARfD	Unnecessary	JMPR, 2018	Not necessary	EFSA, 2013	Yes See comments on a.s.
Conclusion/ comments on a.s.	The EFSA ADI is slightly lower than the JMPR value, but both are in the same order of magnitude. Both assessments used the 2-year rat study and the same nominal NOAEL of 200 ppm; the difference reflects the expression of the intake in mg/kg bw per day, with EFSA using the male value (7.25 mg/kg bw per day) and JMPR the female value (9.13 mg/kg bw per day). No acute reference values were considered necessary by JMPR and EFSA at the time of evaluation.				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Metabolites included in EU RD for RA: • (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3,4-dihydroxy-2-methoxy-6-methylphenyl)methanone (2MDPM) (free and conjugated). In the EU peer review, 4HDPM was considered non-mutagenic, and the parent reference values were deemed applicable to this metabolite. No further information is available for other metabolites.				

[67]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, pp. 7–10.

5.26.3 | Residue definitions – Pyriofenone

TABLE 141 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Pyriofenone	Reg. 396/2005: Pyriofenone MRL review (EFSA, 2019d): Fruits and cereals and processed commodities: Pyriofenone Peer review (EFSA, 2013d): Pyriofenone	Yes
	Animal products	Pyriofenone Not determined due to insufficient information	Reg. 396/2005: Pyriofenone MRL review (EFSA, 2019d): Ruminants tissues and milk: Pyriofenone Peer review (EFSA, 2013d): Not required, considering the representative uses (Provisionally, EFSA proposal: pyriofenone for ruminant products) The residue is not fat soluble	Yes
RD RA	Plant products	Pyriofenone	MRL review (EFSA, 2019d): Fruits and cereals and processed commodities: Pyriofenone Peer review (EFSA, 2013d): Pyriofenone	Yes
	Animal products	Pyriofenone	MRL review (EFSA, 2019d): Ruminants tissues and milk: Pyriofenone Peer review (EFSA, 2013d): Not required, considering the representative uses Provisional RD proposed for ruminant products: Sum of pyriofenone and 2MDPM (free and conjugated)	No, compared with the provisional RD
Conclusion, comments	For plant commodities, the EU and JMPR residue definitions are the same. For animal products, no definitive residue definitions have been derived in the EU, since no significant dietary intake is expected for livestock. In 2018, the JMPR proposed the parent compound as the residue definition for animal products. The same RD is proposed in 2025 JMPR report.			

5.26.4 | Codex MRL proposals – Pyriofenone

TABLE 142 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of eggs.
Group of avian fats	0.01*	0.01*	Sufficiently supported by data: Yes Specific comments: JMPR updated the DB with residues levels in tomato pomace. Since residues of pyriofenone are not expected in poultry, JMPR maintained the previous CXL at the LOQ of 0.01 mg/kg for eggs or poultry tissues and align them with the new classification of animal commodities. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian muscle	0.01*	0.01*	See group of avian fats.
Group of avian, edible offal of	0.01*	0.01*	See group of avian fats.
Group of edible offal (mammalian)	0.01*	0.01*	Sufficiently supported by data: Yes Specific comments: JMPR updated the DB with residues levels in tomato pomace, with no resulting changes. Considering the goat metabolism study performed with 10 ppm (actual levels 7.8–13 ppm; 13–21 N), pyriofenone is not expected to be present at levels higher than the LOQ of 0.01 mg/kg in any matrix. The previous CXL derived by JMPR 2019 are confirmed and they are aligned with the new classification. **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None

(Continues)

TABLE 142 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of eggs	0.01*	0.01*	See group of avian fats.
Group of mammalian fats (except milk fats)	0.01*	0.01*	See group of edible offal (mammalian).
Group of milks	0.01*	0.01*	See group of edible offal (mammalian).
Group of milk fats[c]	0.01	–	In the EU, specific MRLs are not set for milk fats.
Group of muscle (from mammalians other than marine mammals)	0.01*	0.01*	See group of edible offal (mammalian).
Mammalian fats (except milk fats)	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammalians other than mammals)	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milks	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milks.
Peppers, chili, dried	15	–	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 chilli peppers.
Poultry fats	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian fats.
Poultry meat	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian muscle.
Poultry, edible offal of	0.01* (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of avian edible offal.
Subgroup of eggplants	**1.5**	0.01*	cGAP: USA, Foliar (outdoor or indoor), 3 × 110 g a.s./ha, 7-day RTI, 0-day PHI; USA, Foliar (outdoor or indoor), 4 × 89 g a.s./ha, 7-day RTI, 0-day PHI Number of trials: 8 Sufficiently supported by data: See comments Specific comments: Twelve independent trials were performed outdoor in the USA with four applications (bell and non-bell peppers). In Mexico there are 8 (side-by-side) indoor trials done either with 3 or 4 applications with peppers (variety not specified). In Canada four trials indoor were performed with 4 applications (bell and non-bell peppers). Since the Kruskal-Wallis H-test indicates that the residue populations from outdoor-grown and greenhouse-grown peppers were significantly different, the JMPR used the indoor trials to estimate the MRL. The highest residue from each side-by-side trial on Mexico and the four residue trials from Canada were then used by the JMPR to estimate an MRL for the subgroup of peppers (VO 0051), the JMPR extrapolated this estimate to the subgroup of eggplants (VO 2046). This extrapolation would not be accepted in the EU. In addition, a PHI of 0 days would not be acceptable at EU level either. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs because the extrapolation rules guidance in the EU does not foresee direct extrapolation from peppers to eggplants. It is noted that an extrapolation from tomatoes would be acceptable in the EU. Follow-up action: None.
Subgroup of low growing berries	0.5 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of low growing berries, except strawberry.

TABLE 142 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Subgroup of low growing berries, except strawberry	0.5	0.5	cGAP: USA, 3 × 110 g a.s./ha, 7-day RTI, 0-day PHI (MPR, 2018) Number of trials: 8 Sufficiently supported by data: Yes Specific comments: A PHI of 0 days would not be acceptable at EU level. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Subgroup of peppers	**1.5**	0.01*	cGAP: USA, Foliar (outdoor or indoor), 3 × 110 g a.s./ha, 7-day RTI, 0-day PHI; USA, Foliar (outdoor or indoor), 4 × 89 g a.s./ha, 7-day RTI, 0-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: Twelve independent trials were performed outdoor in the USA with four applications (bell and non-bell peppers). In Mexico there are 8 indoor trials (side-by-side) done either with 3 or 4 applications with peppers (variety not specified). In Canada four trials indoor were performed with 4 applications (bell and non-bell peppers). Since the Kruskal–Wallis H-test indicates that the residue populations from outdoor-grown and greenhouse-grown peppers were significantly different, the JMPR used the indoor trials to estimate the MRL. The highest residue from each side-by-side trial on Mexico and the four residue trials from Canada were then used to estimate an MRL for the subgroup of peppers (VO 0051) and the JMPR extrapolated this estimate to the subgroup of eggplants (VO 2046). A PHI of 0 days would not be acceptable at EU level. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Subgroup of tomatoes	**0.2**	0.01*	cGAP: USA, Foliar, outdoor and indoor (greenhouse-grown), 4 × 88 g a.s./ha, 7-day RTI, 0-day PHI; Number of trials: 28 Sufficiently supported by data: Yes Specific comments: There are 23 trials done outdoor in the USA (with tomato and cherry tomato) and 5 trials indoor performed in Canada. Since the Kruskal–Wallis H-test showed that the residue populations from outdoor-grown and greenhouse-grown tomatoes were not significantly different, the JMPR decided to combine these data sets. In the EU, indoor and outdoor trials should not be combined, since outdoor trials are normally not representative for indoor/protected conditions. The MRL calculated separately from the outdoor and indoor data sets lead to the same estimated value (0.2 mg/kg). However, the indoor data set is incomplete (only 5 trials available). In addition, a PHI of 0 days would not be acceptable at EU level. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable/compatible with the EU policy on setting MRLs. Follow-up action: None
Strawberry	**2**	0.5	cGAP: Japan, 3 × 8.9 g a.s./hL (3000-fold dilution), RTI not specified, 1-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Tomato, juice	–	–	JMPR derived a processing factor of 10. Currently no EU MRLs are established for processed products.

(Continues)

TABLE 142 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Tomato, paste	–	–	JMPR derived a processing factor of 0.032. Currently, no EU MRLs are established for processed products.
Tomato pomace, dried	7	–	JMPR derived a processing factor of 33. Currently, no EU MRLs are established for processed products.
Tomato, puree	–	–	JMPR derived a processing factor of 0.33. Currently, no EU MRLs are established for processed products.
General comments	According to the 2025 JMPR report, the new median residue for tomato pomace did not change the dietary burden and the meeting confirmed the 2019 JMPR recommendations for animal commodities (FAO and WHO, 2020).		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.26.5 | Consumer risk assessment – Pyriofenone

TABLE 143 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: Not relevant as no ARfD was allocated.	**RA assumptions:** A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2019d) were updated, including the Codex MRL proposals derived by JMPR for strawberries, tomatoes and peppers. The risk assessment was performed with the EU ADI. The calculations are indicative, because a final decision on the appropriate RD for animal commodities for risk assessment has not been derived in the EU. However, considering the low dietary burden and the fact that no significant residues are expected in animal products, the open issue regarding the residue definition is not expected to have a major impact on the results of the exposure calculation.	**Specific comments:**
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 4% of the ADI. Among the commodities under consideration, milk (cattle) was identified as the main contributor, accounting for up to 0.9% of the ADI.	**Results:** Long-term exposure: Max 1% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 3% (infants and toddler) GECDE max: Max. 20% (infants and toddler)

5.26.6 | Conclusions – Pyriofenone

TABLE 144 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (RAR submitted, EFSA peer review has not started yet).
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs for enforcement are identical; for RA livestock, Codex RDs less comprehensive.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position regarding the CXLs proposed for eggplants and tomatoes should be discussed/decided by risk managers.

5.27 | Metconazole (313) R

5.27.1 | Background information – Metconazole

TABLE 145 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	BE	
Approval status in the EU	Approved	Commission Implementing Regulation (EU) 2024/1749[68]
EFSA conclusion available	Yes, see comments	EFSA (2018h) (conclusion on TDMs in light of confirmatory data) EFSA (2023e)
MRL review performed	Yes, see comments	EFSA (2011g)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2016f) (various crops) EFSA (2013e) (barley and oats)
Classification of a.s. (cut-off criteria)	No, see comments	No classification No classification according to ATP01[69] No evaluation performed by ECHA RAC.
Endocrine effects of a.s.	No, see comment	It does not meet the endocrine disruptor criteria (EFSA, 2013e)
Other relevant information	Metconazole belongs to the class of triazole fungicides and it is approved in Europe as candidate for substitution	

5.27.2 | Health-Based Guidance Values – Metconazole

TABLE 146 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.04 mg/kg bw per day	JMPR, 2019	0.01 mg/kg bw per day	EFSA, 2023	No
ARfD	0.04 mg/kg bw	JMPR, 2019	0.01 mg/kg bw	EFSA, 2023	No
Conclusion/comments on a.s.	The HBGVs of the parent compound are comparable.				
Comments on metabolites	Metabolites included in JMPR RD for RA for animal commodities: • (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (M1) • (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (M12) The metabolites M1 and M12 are adequately covered by the toxicological profile of metconazole. Metabolites included in EU RD for RA: • TA (triazole alanine) • TLA (triazole lactic acid) • TAA (triazole acetic acid) • 1,2,4-T (1,2,4-triazole) M1 and M12 belong to the group of monohydroxylated metconazole derivatives, which are **provisionally** included in the EU residue definition for risk assessment (RD-RA) for plants (primary crops, processed commodities and rotational crops). This inclusion is pending confirmation of the presence and ratio of M11 and M21 among the monohydroxylated compounds recovered as a group, and their general toxicity profile (cf. EU confirmatory information requested).				

[68]Commission Implementing Regulation (EU) 2024/1749 of 24 June 2024 renewing the approval of the active substance metconazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011. C/2024/4221. OJ L, 2024/1749, 25.6.2024.

[69]Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 235, 5.9.2009, p. 1–439.

5.27.3 | Residue definitions – Metconazole

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	Metconazole (sum of cis and trans isomer)	Reg. 396/2005: Metconazole (sum of isomers) Peer review (EFSA, 2023e): Metconazole (sum of isomers)	Yes
	Animal products	Metconazole (sum of cis and trans isomer) The residue is not fat soluble	Reg. 396/2005: Metconazole (sum of isomers) Peer review (EFSA, 2023e): Metconazole (sum of isomers) The residue is fat soluble	Yes
RD RA	Plant products	Metconazole (sum of cis and trans isomer)	Peer review (EFSA, 2023e): 1. Metconazole (sum of isomers) and its monohydroxylated derivatives (free and conjugated), expressed as metconazole (provisionally) 2. TA and TLA 3. TAA 4. 1,2,4-triazole MRL review (EFSA, 2011g): Metconazole	No
	Animal products	Sum of metconazole (sum of cis and trans isomer) and metabolites (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol (M1) and (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanecarboxylic acid (M12), expressed as metconazole	Peer review (EFSA, 2023e): 1. Metconazole (sum of isomers) 2) TA and TLA 2. TAA 3. 1,2,4-triazole MRL review (EFSA, 2011g): Pigs and ruminants: metconazole	No
Conclusion, comments	At both EU and JMPR levels, the enforcement residue definitions for plant and animal commodities are compatible. However, the risk assessment residue definitions differ. In the EU, the risk assessment residue definitions for both plant and animal commodities also include triazole derivative metabolites (TDMs), whereas JMPR does not consider TDMs for any commodity. Besides, during the peer review finalised in 2023, metconazole monohydroxylated derivatives (free and conjugates) were also included in the plant RA-RD on provisional basis. In contrast, for animal commodities, JMPR includes metabolites M1 and M12 in the risk assessment, while these metabolites were not considered relevant at EU level during the peer review.			

5.27.4 | Codex MRL proposals – Metconazole

TABLE 148 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of edible offal' (mammalian) as outlined in general considerations, section 2.4 of the 2024 JMPR report (FAO and WHO, 2025).
Eggs	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of eggs' as outlined in general considerations, section 2.4 of the 2024 JMPR report (FAO and WHO, 2025).

TABLE 148 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avian muscle	**0.04***	0.02*	Max. dietary burden (EU poultry layer): 2.4 ppm. Max. residues in eggs and poultry tissues: < 0.04 mg/kg Sufficiently supported by data: Yes Specific comments: The CXLs for poultry tissues were assessed by JMPR in 2019. In the current assessment, the dietary burden increased slightly from 2.2 ppm to 2.4 ppm. The residues of metconazole in poultry tissues at the 20 ppm feeding level were < 0.02 mg/kg and JMPR maintained the previous CXL proposals of 0.04* mg/kg for all tissues. However, the rationale for proposing a CXL of 0.04 mg/kg rather than 0.02 mg/kg is unclear, given that residues were not detectable and analytical methods capable of enforcing a CXL of 0.02 mg/kg were available at JMPR level (JMPR 2019; FAO and WHO, 2020). At EU level, comparable feeding studies supported the lower MRL of 0.02 mg/kg. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None
Group of avian, edible offal	**0.04***	0.02*	See group of avian muscle.
Group of avian fats	**0.04***	0.02*	See group of avian muscle.
Group of edible offal (mammalian)	**0.04***	0.02*	Max. dietary burden (AUS beef cattle): 15 ppm. Max. residues in muscle/liver/muscle and milk: < 0.04 mg/kg Sufficiently supported by data: Yes Specific comments: The CXLs in beef and dairy cattle were assessed by JMPR in 2019 and the dietary burdens remained unchanged in the 2025 JMPR assessment. However, the rationale for proposing a CXL of 0.04 mg/kg rather than 0.02 mg/kg is unclear, given that residues were not detectable and analytical methods capable of enforcing a CXL of 0.02 mg/kg were available at JMPR level (JMPR 2019; FAO and WHO, 2020). At EU level, comparable feeding studies supported the lower MRL of 0.02 mg/kg. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None
Group of eggs	**0.04***	0.02*	See group of avian muscle.
Group of mammalian fats (except milk fats)	**0.04***	0.02*	See group of edible offal (mammalian).
Group of milks	**0.04***	0.02*	See group of edible offal (mammalian).
Group of muscle (from mammals other than marine mammals)	**0.04***	0.02*	See group of edible offal (mammalian).
Mammalian fats (except milk fats)	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of mammalian fats' as outlined in general considerations, section 2.4 of the 2024 JMPR report.
Meat (from mammals other than marine mammals)	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of muscle (from mammals other than marine mammals)'.
Milks	0.04* (W)		The existing CXL is replaced by the new proposal for 'group of milks'
Onion, Welsh, dried	1.5	–	JMPR estimated the CXL from 6 trials following drying of Welsh onion. Fresh Welsh onions were trimmed, washed and air-dried until the moisture content was 8.1%–19%. Currently, no EU MRLs are established for processed products.
Poultry, edible offal of	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of avian edible offal'
Poultry fats	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of avian fats'
Poultry meat	0.04* (W)	–	The existing CXL is replaced by the new proposal for 'group of avian muscle'
General comments	In animal commodities, metconazole residues are not stable in muscle and liver, while storage stability in fat was demonstrated only for 3 months at –20°C (JMPR 2019; FAO and WHO, 2020). JMPR did not propose a CXL for fresh Welsh onion, for which the EU MRL is set at the LOQ of 0.02* mg/kg (code 0220040).		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.27.5 | Consumer risk assessment – Metconazole

TABLE 149 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for animal commodities, for which the Codex MRL proposal is higher than the existing EU MRL. The inputs values used in the calculations were the proposed CXL (LOQ). The calculations are indicative, because the risk assessment derived by JMPR do not include the triazole derivatives. Therefore, the calculations are affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (normal mode). The input values of the most recent long-term risk assessment (EFSA, 2016f) were updated with CXL proposals (LOQ) for animal commodities The calculations are indicative, because the risk assessment derived by JMPR do not include the triazole derivatives. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the commodities under assessment. The maximum acute exposure account for 50% of ARfD (cattle milk). For all the remaining commodities assessed, the acute exposure was less than 7% of ARfD.	**Results:** **No long-term consumer health risk was identified**. The overall chronic exposure accounted for 50% of the ADI. Among the commodities under consideration, cattle milk was identified as the main contributor, accounting for up to 24% of the ADI (NL toddler).	**Results:** Long-term exposure: Max 2% of the JMPR ADI. Short-term exposure: JMPR did not calculate the acute exposure since no consumption data for Welsh onion were available and the HR for animal commodities were estimated at 0 mg/kg. GECDE mean: Max. 3% (e.g. infants and toddler) GECDE max: Max. 10% (e.g. infants and toddler)

5.27.6 | Conclusions – Metconazole

TABLE 150 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU.
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex RDs for enforcement are identical, but RA-RDs differ: In the EU, TDMs were included in both RA-RD for plant and animals and provisionally monohydroxylated metconazole derivatives in plants; JMPR includes M1 and M12 for animal commodities.
Codex MRL proposals	Further discussion is needed with the risk managers on the CXL proposals for animal commodities.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers.

5.28 | Mefentrifluconazole (320) R

5.28.1 | Background information – Mefentrifluconazole

TABLE 151 Background information.

	Comments, references
JMPR assessment	JMPR meeting 2025
Type of JMPR evaluation	New use
RMS	ES

TABLE 151 (Continued)

		Comments, references
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Implementing Regulation (EU) 2019/337[70] Dossier submitted by the applicant
EFSA conclusion available	Yes, see comments	EFSA (2018i)
MRL review performed	Yes, see comments	EFSA (2018i) also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005
EU MRL applications or other EU assessments	Yes, see comments	Art.10 in pomegranates, table grapes, grape leaves and animal commodities (ongoing) EFSA (2023h) (various crops) EFSA (2020j) (various crops)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ECHA (2018b) ATP15[71]
Endocrine effects of a.s.	No, see comment	The EFSA Conclusion was issued before the publication of the ECHA/EFSA guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 and is based on interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009.
Other relevant information	Mefentrifluconazole belongs to the class of triazole fungicides and to the class of PFAS chemicals.	

5.28.2 | Health-Based Guidance Values – Mefentrifluconazole

TABLE 152 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.04 mg/kg bw per day	JMPR, 2021	0.035 mg/kg bw per day	EFSA, 2018	Yes See comments on a.s.
ARfD	0.3 mg/kg bw	JMPR, 2021	0.15 mg/kg bw	EFSA, 2018	No
Conclusion/comments on a.s.	EFSA (2018i): ADI based on NOAEL from long-term mouse study, applying a standard uncertainty factor of 100. ARfD based on maternal and developmental NOAEL from rabbit developmental toxicity study, applying a standard uncertainty factor of 100. JMPR 2021 (FAO and WHO, 2022): ADI based on NOAEL from long-term mouse study, applying a standard uncertainty factor of 100. ARfD based on maternal and developmental NOAEL from rabbit developmental toxicity study, applying a standard uncertainty factor of 100. JMPR and EU used the same reference point for ADI setting, but EU did not apply rounding. JMPR and EU used the same study for ARfD setting but selected a different NOAEL.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • M750F022 (2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]propane-1,2-diol) • M750F022 free and conjugated (it comprises M750F023, M750F024 and M750F025) EFSA (2018i): The HBGVs of parent mefentrifluconazole are applicable to the metabolite M750F022 and also to its fatty acid conjugates (M750F023, M750F024 and M750F025), given that these are enzymatically cleaved to the unconjugated metabolite. JMPR 2021 (FAO and WHO, 2022): The HBGVs of parent mefentrifluconazole are also applicable to the metabolite M750F022. The HBGVs of parent mefentrifluconazole are not applicable to M750F023, M750F024 and M750F025, since the additional fatty acid side chains may cause differences in kinetics compared to metabolite M750F022. JMPR used TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day) for these metabolites. Metabolites included in EU RD for RA: • TDMs, • M750F022, • Fatty acid conjugates of M750F022, i.e. ○ M750F023, ○ M750F024, ○ M750F025; EFSA (2018i): The HBGVs of parent mefentrifluconazole are applicable to the metabolite M750F022 and also to its fatty acid conjugates (M750F023, M750F024 and M750F025), given that these are enzymatically cleaved to the unconjugated metabolite. Separate HBGVs have been derived for triazole derivative metabolites (EFSA, 2018h).				

[70]Commission Implementing Regulation (EU) 2019/337 of 27 February 2019 approving the active substance mefentrifluconazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. C/2019/1477. OJ L 60, 28.2.2019, pp. 12–16.

[71]Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 261, 11.8.2020, p. 2–15.

5.28.3 | Residue definitions – Mefentrifluconazole

TABLE 153 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Mefentrifluconazole	Reg. 396/2005: Mefentrifluconazole Peer review (EFSA, 2018i): Mefentrifluconazole	Yes
	Animal products	Mefentrifluconazole (free and conjugated) The residue is fat soluble	Reg. 396/2005: Mefentrifluconazole The residue is fat soluble	No
RD RA	Plant products	Mefentrifluconazole	Peer review (EFSA, 2018i): (a) Mefentrifluconazole (b) triazole derivative metabolites (TDMs): with a separate assessment of: 1. TA and TLA 2. TAA 3. 1,2,4-Triazole	No
	Animal products	Sum of mefentrifluconazole (free and conjugated) + 2-[4-(4-chlorophenoxy)-2-(trifluoromethyl) phenyl]propane-1,2-diol (M750F022), free and conjugated, expressed as mefentrifluconazole equivalent	Peer review (EFSA, 2018i): Animal except poultry: a. Mefentrifluconazole b. triazole derivative metabolites (TDMs) with a separate assessment of: 1. 1,2,4-triazole 2. TA and TLA 3. TAA for ruminant matrices Poultry: a. Sum of mefentrifluconazole, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent triazole derivative metabolites (TDMs) with b. triazole derivative metabolites (TDMs) with a separate assessment of: 1. 1,2,4-triazole 2. TA and TLA 3. TAA	No
Conclusion, comments	Plant commodities**:** The residue definitions for enforcement and risk assessment derived by JMPR and at EU level are identical. However, in the EU, additional risk assessment residue definitions comprising the TDMs were set. Animal commodities: **JMPR proposed** the residue definition for enforcement **as mefentrifluconazole, free and conjugated**, whereas the **EU residue definition** includes only **the free form of the parent**. The JMPR residue definition is not considered appropriate for EU enforcement because the individual conjugates are not sufficiently defined, analytical standards and enforcement methods are not available and the conjugates are of minor relevance. Therefore, the parent compound is considered an appropriate marker for enforcement. **For risk assessment, the JMPR and EU residue definitions are not comparable**, as the JMPR residue definition includes parent conjugates and M750F022, free and conjugated, whereas **the EU residue definition** includes M750F022 and, for poultry only, also the fatty acid conjugates of M750F022; **TDMs are included separately by EU**. Since feeding study samples were not analysed for conjugates, JMPR derived correction factors from metabolism studies.			

5.28.4 | Codex MRL proposals – Mefentrifluconazole

TABLE 154 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Broccoli	0.15	0.7	cGAP: Mexico, 3 × 0.12 kg a.s./ha, 7-day RTI, 14-day PHI Number of trials: 8 Specific comments: In EU, a comparable GAP is available resulting in higher residue levels. **Conclusion:** The proposed Codex MRL is supported by data. However, at EU a higher EU MRL is applicable. Follow-up action: –
Cauliflower	0.01*	0.7	cGAP: Mexico, 3 × 0.12 kg a.s./ha, 7-day RTI, 14-day PHI Number of trials: 8 Specific comments: All the residues were below 0.01 mg/kg. In EU, a comparable GAP is available resulting in higher residue levels. **Conclusion:** The proposed Codex MRL is supported by data. However, at EU, a higher EU MRL is applicable. Follow-up action: –

TABLE 154 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	2 (W)	–	The existing CXL is replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.04 (W)	–	The existing CXL is replaced with the new proposal for the group of eggs.
Grapes	**3**	0.9 (table grapes) 2 (wine grapes)	cGAP: China, 3 × 0.18 kg a.s./ha, 7-day RTI, 7-day PHI Number of trials: 10 Specific comments: The current EU MRL for wine grapes is based on a previous CXL derived from a less critical GAP. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Grape, dried (currants, raisins and sultanas)	15	–	JMPR derived a processing factor of 3.7. Currently, no EU MRLs are established for processed products.
Grape pomace, dried	15	–	JMPR derived a processing factor of 4.26 in 2022 and a CXL of 9 mg/kg. Based on the same PF, the CXL was increased to 15 mg/kg. Currently, no EU MRLs are established for processed products.
Group of avian, edible offal	**0.7**	0.03	Max. dietary burden for poultry layers: 12 ppm Max. residues in liver: 0.67 mg/kg. Sufficiently supported by data: Yes Specific comments: JMPR updated the 2022 dietary burden with the highest residue of the new uses; no increase observed in the DB. The previous CXL proposal was maintained. **Conclusion:** The proposed Codex MRL is supported by data, but the EU and Codex residue definitions are not fully compatible, see general comment on MRL proposals for animal products Follow-up action: None
Group of avian fats	**0.2**	0.03	Max. dietary burden for poultry layers: 12 ppm Mean/max. residues in fats: 0.187 mg/kg Sufficiently supported by data: Yes Specific comments and conclusion: see group of avian edible offal
Group of avian muscle	**0.03**	0.015	Max. dietary burden for poultry layers: 12 ppm. Max. residues in eggs: 0.024 mg/kg. Sufficiently supported by data: Yes Specific comments and conclusion: see group of avian edible offal
Group of edible offal (mammalian)	**2**	Liver from – swine: 0.02 – bovine and equine: 0.4 – sheep and goat: 0.7 – others: 0.01* Kidney from – swine and others: 0.01* – bovine: 0.15 – sheep and goat: 0.3 – equine: 0.1 Edible offals from – swine and others: 0.01* – bovine and equine: 0.1 – sheep and goat: 0.3	Max. dietary burden for dairy cattle: 67 ppm. Max. residues in liver: 1.87 mg/kg and in kidney: 1.20 mg/kg Sufficiently supported by data: Yes Specific comments: JMPR updated the 2022 dietary burden with the highest residue of the new uses; no increase observed in the DB. The previous CXL proposal is maintained. **Conclusion**: The proposed Codex MRL is supported by data, but the EU and Codex residue definitions are not fully compatible, see general comment on MRL proposals for animal products Follow-up action: None
Group of eggs	**0.04**	0.015	Max. dietary burden for poultry layers: 12ppm Max. residues in eggs: 0.031 mg/kg. Sufficiently supported by data: Yes Specific comments and conclusion: see group of avian edible offal; Follow-up action: None
Group of mammalian fats (except milk fats)	**1.5**	0.01* (pig and others) 0.2 (bovine and equine) 0.4 (sheep and goat)	Max. dietary burden for dairy cattle: 67 ppm. Max. residues in fat: 1.14 mg/kg; Sufficiently supported by data: Yes Specific comments and conclusion: (see group of edible offal (mammalian) Follow-up action: None

(Continues)

TABLE 154 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of milks	**0.1**	0.03 (cattle) 0.04 (sheep and goat) 0.02 (horse)	Max. dietary burden for dairy cattle: 67 ppm. Maximum residue level in milk: 0.08 mg/kg Sufficiently supported by data: Yes Specific comments and Conclusion: (see group of edible offal (mammalian) Follow-up action: None
Group of milk fats[c]	3	–	In the EU, specific MRLs are not set for milk fats.
Group of muscle (from mammals other than marine mammals)	**0.15**	0.01* (swine and others) 0.04 (bovine and equine) 0.06 (sheep and goat)	Max. dietary burden for dairy cattle: 67 ppm. Maximum residues level in milk: 0.13 mg/kg Sufficiently supported by data: Yes Specific comments and Conclusion: (see group of edible offal (mammalian) Follow-up action: None
Mammalian fats (except milk fats)	1.5 (W)	–	The existing CXL is replaced with the new proposal for the group of mammalian fats
Meat (from mammals other than marine mammals)	0.15 (fat) (W)	–	The existing CXL is replaced with the new proposal for the group of muscle (mammalian).
Milks	0.10 (W)	–	The existing CXL is replaced with the new proposal for the group of milk.
Pineapple	**0.5**	0.01*	cGAP: Guatemala, 3 × 0.5 kg a.s./ha, 60-day RTI, 15-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: Samples were analysed as a whole fruit. Residue levels in pulp were recalculated from whole-fruit residues using the processing factor of 0.02. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Pineapple, dried	–	–	JMPR derived a processing factor of 0.13. Currently, no EU MRLs are established for processed products.
Pineapple, juice	–	–	JMPR derived a processing factor of 0.26. Currently, no EU MRLs are established for processed products.
Pineapple, process residue	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose.
Poultry edible offal	0.7 (W)	–	The existing CXL is replaced with the new proposal for the group of avian edible offal.
Poultry, fats	0.2 (W)	–	The existing CXL is replaced with the new proposal for the group of avian fats.
Poultry, meat	0.03 (fat) (W)	–	The existing CXL is replaced with the new proposal for the group of avian muscle.
Sugar beet	**0.3**	0.06	cGAP: USA, 2 × 0.146 kg a.s./ha, 14-day RTI, 7-day PHI Number of trials:16 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –
Sugar beet pulp, dry	1.5	–	JMPR derived a processing factor of 4.75. Currently, no EU MRLs are established for processed products.
Sugar, refined	–	–	JMPR derived a processing factor of 0.06. Currently, no EU MRLs are established for processed products.
Tomatoes, subgroup of	**1.5**	0.7	cGAP: China, 3 × 0.15 kg a.s./ha, 7-day RTI, 3-day PHI Number of trials:12 (combined data set) Sufficiently supported by data: Yes Specific comments: In the EU, indoor and outdoor trials are not combined for MRL derivation. A separate MRL could not be derived based on the indoor data set since only five trials are available. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: –

TABLE 154 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Tomato, sun dried	15	–	JMPR derived a processing factor of 9.17. Currently, no EU MRLs are established for processed products.
Tomato, canned	–	–	JMPR derived a processing factor of 0.06. Currently, no EU MRLs are established for processed products.
Tomato, juice	–	–	JMPR derived a processing factor of 0.08. Currently, no EU MRLs are established for processed products.
Tomato, paste	–	–	JMPR derived a processing factor of 0.49. Currently, no EU MRLs are established for processed products.
Tomato, wet pomace	–	–	JMPR derived a processing factor of 2.93. Currently, no EU MRLs are established for processed products.
Tomato, puree	–	–	JMPR derived a processing factor of 0.28. Currently, no EU MRLs are established for processed products.
General comments	**General comment**: In the JMPR report, no information is provided on the magnitude of TDMs. Hence, the EU risk assessment for the TDMs could not be updated for the uses assessed by JMPR. Animal products: As the Codex residue definition for enforcement, which comprises also the conjugates, is wider than the EU residue definition, Codex MRLs are not compatible with the EU residue definition.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.28.5 | Consumer risk assessment – Mefentrifluconazole

TABLE 155 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment PRIMo rev. 3.1 (normal mode) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (see table on CXL proposals). The risk assessment is indicative, because information on the residue concentrations related to the TDMs is not available. The calculations are affected by additional, non-standard uncertainties, since the JMPR risk assessment residue definitions are different to the EU residue definitions.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (normal mode). The input values of the most recent long-term risk assessment (EFSA, 2023h) were updated, including the STMR values derived by JMPR for the crops for which the proposed Codex MRL is higher than the EU MRL (i.e. see the table on CXL proposals). The risk assessment is indicative, because information on the residue concentrations related to the TDMs is not available. The calculations are affected by additional, non-standard uncertainties, since the JMPR risk assessment residue definitions are different compared to the EU residue definitions.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Table grapes: 83% of ARfD Tomatoes: 30.3% of ARfD Wine grapes: 27% of ARfD Pineapple (whole fruit): 0.1% of ARfD	**Results:** **No long-term consumer health risk was identified**. The overall chronic exposure accounted for 34% of the ADI. Among the crops under consideration, cattle milk was identified as the main contributor, accounting for up to 12% of the ADI.	**Results:** Long-term exposure: Max 40% of the JMPR ADI. Short-term exposure: Highest result for grapes: 40% of ARfD derived by JMPR GECDE mean: Max. 110% (e.g. infants and toddler) GECDE max: Max. 420% (e.g. infants and toddler)

5.28.6 | Conclusions – Mefentrifluconazole

TABLE 156 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU. It belongs to the class of triazoles and to the class of PFAS chemicals
Toxicological assessment	EU HBGV are available.
Residue definitions	For plant products, the enforcement RD set at EU level and by JMPR are identical. For animal products, the enforcement RDs are not compatible. Residue definitions for RA set by JMPR and at EU level are also different, leading to additional uncertainties in the risk assessment.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	Further discussion at management level is required to derive the EU position.

5.29 | Broflanilide (326) R

5.29.1 | Background information – Broflanilide

TABLE 157 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	No RMS assigned	
Approval status in the EU	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Broflanilide belongs to the class of PFAS chemicals.	

5.29.2 | Health-Based Guidance Values – Broflanilide

TABLE 158 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		HBGV comparable
	Value	Comments	Value	Comments	
ADI	0.02 mg/kg bw per day	JMPR, 2022	–	No EU assessment	Not applicable
ARfD	Unnecessary	JMPR, 2022	–	No EU assessment	Not applicable
Conclusion/comments on a.s.					
Comments on metabolites	Metabolites included in JMPR RD for RA: • 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM- 8007) Based on the results of experimental studies and the structural similarity to broflanilide, the JMPR concluded that metabolite DM-8007 is not of greater toxicity than broflanilide and would be covered by the HBGVs for the parent. (JMPR 2022; FAO and WHO, 2023). Metabolites included in EU RD for RA: –				

5.29.3 | Residue definitions – Broflanilide

TABLE 159 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Broflanilide	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
	Animal products	Sum of broflanilide plus 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM- 8007), expressed as broflanilide The residue is fat soluble	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
RD RA	Plant products	Broflanilide	No EU peer review and no MRL review	Not applicable
	Animal products	Sum of broflanilide plus 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM- 8007), expressed as broflanilide	No EU peer review and no MRL review	Not applicable
Conclusion, comments	This active substance was never notified and authorised in the EU. No residue definitions are derived at the EU level. JMPR assessed plant metabolism with labelled broflanilide in cabbages, tomatoes, soya beans, Japanese radish, rice, wheat and tea. Broflanilide was the major residue in all matrices, while DM-8007 was only a minor metabolite and occurred at much lower levels than the parent. Therefore, JMPR considered broflanilide an appropriate marker for enforcement and risk assessment in plants (JMPR 2022). In livestock metabolism studies with lactating goats and laying hens, parent broflanilide was only present at minor levels, whereas DM-8007 was the main residue in tissues, milk and eggs. JMPR therefore derived the residue definition for enforcement and risk assessment in livestock as the sum of broflanilide and DM-8007, expressed as broflanilide. JMPR also concluded that broflanilide is not very persistent under field conditions, has no potential to accumulate in soil, and is stable under processing (JMPR 2022). The a.s. contains three C-CF3 moieties in its chemical structure. In the studies assessed by the JMPR 2022, there was no information on potential formation of trifluoroacetic acid (TFA) in either plants or livestock from the use of broflanilide.			

5.29.4 | Codex MRL proposals – Broflanilide

TABLE 160 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Broccoli	**0.6**	0.01* default MRL Art.18(1)(b)	cGAP: Australia, foliar, 2 × 25 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Cherry tomato	**0.15**	0.01* default MRL Art.18(1)(b)	See tomatoes.
Cucumber	**0.2**	0.01* default MRL Art.18(1)(b)	cGAP: China, foliar (indoor use), 2 × 18.5 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 12 Sufficiently supported by data: See specific comments Specific comments: Combined data set of six trials performed indoor (all below the LOQ of 0.01 mg/kg) and six trials performed outdoor (3 × < 0.01 mg/kg, 0.046, 0.062 and 0.18 mg/kg). Since residue populations were not significantly different according to the Kruskal–Wallis H-test, the JMPR combined the two data sets. The JMPR applied a scaling factor of 0.74, since trials were performed at 25 g a.s./ha. In the EU, indoor and outdoor trials should not be combined, since outdoor trials are normally not representative for indoor/protected conditions. It is noted that the MRL from the indoor data set would lead to an MRL estimated at the LOQ (0.01* mg/kg), while the outdoor data set would lead to a tentative (due to an incomplete data set) MRL estimated at 0.3 mg/kg. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is acceptable with the EU policy on setting MRLs. Follow-up action: None

(Continues)

TABLE 160 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.03 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.03 (W)	–	For broiler and laying poultry, the JMPR estimated a maximum and mean dietary burden of 1.5 ppm and 0.19 ppm, respectively. The JMRP noted that the dietary burden exceeded the highest feed level of 0.5 ppm from the poultry feeding study. Therefore, the JMPR proposed the withdrawal of the existing CXLs for eggs, poultry edible offal, poultry meat and poultry fats.
Group of edible offal (mammalian)	**0.1**	0.01* default MRL Art.18(1)(b)	Max. dietary burden (AUS beef cattle): 9.6 ppm. Max. residues in kidney: 0.09 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Group of mammalian fats (except milk fats)	**1**	0.01* default MRL Art.18(1)(b)	Max. dietary burden (AUS beef cattle): 9.6 ppm. Max. residues in fat: 0.75 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Group of milks	**0.05**	0.01* default MRL Art.18(1)(b)	Max. dietary burden (AUS dairy cattle): 4.5 ppm. Max. residues in milk: 0.038 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	**0.05**	0.01* default MRL Art.18(1)(b)	Max. dietary burden (AUS beef cattle): 9.6 ppm. Max. residues in muscle: 0.046 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Mammalian fats	0.15 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.15 (fat) (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Group of milk fats[c]	1	–	In the EU, specific MRLs are not set for milk fats.
Lettuce, head	**0.8**	0.01* default MRL Art.18(1)(b)	cGAP: Canada, foliar, 2 × 12.5 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: The JMPR applied a scaling factor of 0.5, since trials were performed at 2 × 25 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Lettuce, leaf	**1.5**	0.01* default MRL Art.18(1)(b)	cGAP: Canada, foliar, 2 × 12.5 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: The JMPR applied a scaling factor of 0.5, since trials were performed at 2 × 25 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Milk fats	0.4 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milk fats.
Milks	0.015 (W)	–	The existing CXL is proposed for withdrawal, being replaced with the new proposal for the group of milks.

TABLE 160 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Mung bean (dry)	**0.04**	0.01* default MRL Art.18(1)(b)	cGAP: Indonesia, foliar, 2 × 25 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: The JMPR applied a scaling factor of 1.4 to the residue trials that were performed at 2 × 18 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Peppers, chili	**0.3**	0.01* default MRL Art.18(1)(b)	cGAP: Indonesia, foliar, 2 × 25 g a.s./ha, 7-day RTI, 14-days PHI Number of trials: 14 Sufficiently supported by data: See specific comments Specific comments: Combined data set of trials performed indoor (6) and outdoor (8). In the EU, indoor and outdoor trials should not be combined, since outdoor trials are normally not representative for indoor/protected conditions. It is noted that the MRL from the indoor data set would lead to an MRL estimated of 0.2 mg/kg, while the outdoor data set would lead to an estimated MRL of 0.3 mg/kg. **Conclusion:** It is recommended to discuss with MS whether the proposed Codex MRL is compatible with the EU policy on setting MRLs. Follow-up action: None
Peppers, chili, dried	3	–	Proposed MRL was derived from residue trials in peppers, applying the default dehydration factor of 7. At EU level, MRLs are set only for fresh products, but not for processed chilli peppers.
Peppers, sweet	**0.07**	0.01* default MRL Art.18(1)(b)	cGAP: Canada, foliar, 2 × 18.75 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 10 Sufficiently supported by data: Yes Specific comments: The JMPR applied a scaling factor of 0.75, since trials were performed with two applications of 25 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Poultry, edible offal of	0.03 (W)	–	See Eggs
Poultry meat	0.02 (W)	–	See Eggs
Poultry fats	0.15 (W)	–	See Eggs
Soya bean (dry)	**0.06**	0.01* default MRL Art.18(1)(b)	cGAP: Indonesia, foliar, 2 × 25 g a.s./ha, 7-day RTI, 14-days PHI Number of trials: 23 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Soya bean, flour	–	–	JMPR derived a processing factor of 0.03. Currently, no EU MRLs are established for processed products.
Soya bean, forage	–	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Soya bean, hay and/or straw	15 (dw)	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Soya bean, hulls	0.3	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Soya bean, miso	–	–	JMPR derived a processing factor of 0.14. Currently, no EU MRLs are established for processed products.
Soya bean oil, refined	–	–	JMPR derived a processing factor of 0.11. Currently, no EU MRLs are established for processed products.
Soya bean, pollard	–	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose.
Soya bean, tofu	–	–	JMPR derived a processing factor of 0.11. Currently, no EU MRLs are established for processed products.
Soya bean, soy sauce	–	–	JMPR derived a processing factor of 0.02. Currently no EU MRLs are established for processed products.

(Continues)

TABLE 160 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Spinach	**2**	0.01* default MRL Art.18(1)(b)	cGAP: Canada, foliar, 2 × 12.75 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 12 Sufficiently supported by data: Yes Specific comments: Residue trials performed with mustard greens. The JMPR applied a scaling factor of 0.5, since trials were performed at 25 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Subgroup of eggplants	**0.15**	0.01* default MRL Art.18(1)(b)	cGAP: India, foliar, 2 × 25 g a.s./ha, RTI not stated, 1-day PHI Number of trials: 20 Sufficiently supported by data: Yes Specific comments: The JMPR decided to consider extrapolation of residue data from either tomato or pepper, sweet to eggplant, whichever leads to the higher maximum residue level estimate (JMPR report, 2018). The JMPR proposed an MRL based on extrapolation from residue data on tomato (higher residue than sweet peppers). **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Subgroup of leaves of Brassicaceae	**2**	0.01* default MRL Art.18(1)(b)	cGAP: Canada, foliar, 2 × 12.75 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 9 Sufficiently supported by data: Yes Specific comments: Residue trials performed with mustard greens. The JMPR applied a scaling factor of 0.5, since trials were performed at 25 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Subgroup of stems and petioles	**0.8**	0.01* default MRL Art.18(1)(b)	cGAP: Canada, foliar, 2 × 12.75 g a.s./ha, 7-day RTI, 1-day PHI Number of trials: 9 Sufficiently supported by data: Yes Specific comments: Residue trials performed with celery. The JMPR applied a scaling factor of 0.5, since trials were performed at 25 g a.s./ha. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Tomato	**0.15**	0.01* default MRL Art.18(1)(b)	cGAP: India, foliar, 2 × 25.2 g a.s./ha, RTI not stated, 1-day PHI Number of trials: 20 Sufficiently supported by data: Yes Specific comments: Combined data set of trials performed with tomato (17) and cherry tomatoes (3). Since median residues were within a five-fold range, the JMPR combined the residue populations of tomatoes and cherry tomatoes. The JMPR noted that RTI of 7–10 days is considered commercial practice in India. **Conclusion:** The proposed Codex MRL is supported by data. See results of the consumer risk assessment. Follow-up action: None
Tomato, canned	–	–	JMPR derived a processing factor of 0.12. Currently, no EU MRLs are established for processed products.
Tomato, juice	–	–	JMPR derived a processing factor of 0.24. Currently, no EU MRLs are established for processed products.
Tomato ketchup	0.3	–	JMPR derived a processing factor of 2. Currently, no EU MRLs are established for processed products.
Tomato, pomace	1.5	–	JMPR derived a processing factor of 2.8. Currently no EU MRLs are established for processed products.
Tomato, puree (paste)	0.4	–	JMPR derived a processing factor of 2.2. Currently, no EU MRLs are established for processed products.
Tomato, sun-dried	1	–	JMPR derived a processing factor of 6.8. Currently, no EU MRLs are established for processed products.

TABLE 160 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
General comments	The JMPR estimated a maximum DB for broiler and laying poultry of 1.5 ppm and 0.19 ppm, respectively. The JMPR noted that the dietary burden exceeded the highest feed level of 0.5 ppm from the poultry feeding study, evaluated by the JMPR in 2022 (FAO and WHO, 2023) and agreed to withdraw the previous maximum MRLs for all poultry commodities.		

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.
Abbreviation: dw, dry weight.
*Indicates that the input value is proposed at the limit of quantification.
[a]Commodity description according to Codex food classification.
[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.
[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.29.5 | Consumer risk assessment – Broflanilide

TABLE 161 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:** An indicative long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values used were derived by JMPR for the crops for which there is a proposed Codex MRL. The risk assessment was performed with the JMPR ADI. The risk assessment is indicative, since the substance was never assessed in the EU, and therefore, no definitive EU RD and HBGVS are available. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 4% of the ADI. Among the crops under consideration, spinaches were identified as the main contributor, accounting for up to 2% of the ADI.	**Results:** Long-term exposure: Max 3% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 2% (infants and toddler) GECDE max: Max. 10% (infants and toddler)

5.29.6 | Conclusions – Broflanilide

TABLE 162 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU; no EU assessment available.
Toxicological assessment	No EU HBGVs available.
Residue definitions	No RDs are established at EU level; The JMPR RDs for plant commodities contain only the parent. The JMPR RDs for animal products contain also a metabolite.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	Acute risk assessment not performed (no ARfD derived by JMPR). No chronic intake concern identified in indicative risk assessment performed with JMPR ADI.
Final conclusion	To discuss the EU position for this a.s. that has never been assessed in the EU.

5.30 | Acynonapyr (333) R

5.30.1 | Background information – Acynonapyr

TABLE 163 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	No RMS assigned	
Approval status in the EU	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	Acynonapyr belongs to the class of PFAS chemicals.	

5.30.2 | Health-Based Guidance Values – Acynonapyr

TABLE 164 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.1 mg/kg bw per day	JMPR, 2024	–	No EU assessment	Not applicable
ARfD	0.1 mg/kg bw*	JMPR, 2024	–	No EU assessment	Not applicable
Conclusion/ comments on a.s.	No toxicological assessment performed in the EU. The JMPR ADI is based on the overall NOAEL of 10 mg/kg bw per day in the 13-week and 52-week studies in dogs, supported by the NOAEL of 12.3 mg/kg bw per day in the 2-year study in rats and applying a safety factor of 100. *ARfD is not necessary for the parent but established an ARfD of 0.1 mg eq/kg bw for the metabolites AY, AY-Glu and AP-2, expressed as parent				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 5-(trifluoromethyl)-2- pyridinol (AY) • 5-(trifluoromethyl)-2-pyridon-3-yl ß-D-glucopyranoside (AY-1-Glc) • 5-(trifluoromethyl)-2-pyridyl ß-D-glucopyranosiduronic acid (AY-Glu) JMPR suggested that the ADI derived for parent compound also applies to the following metabolites: • AP-2 • AP-4-gluc/AP-1-OH-gluc • AY • AY-gluc • AY-1 • AY-1-gluc. For the following metabolites, ARfD values were derived: • AP (0.03 mg/kg bw) • AP-2 (0.1 mg/kg bw) • AP-8 (0.03 mg/kg bw) • AY (0.1 mg/kg bw) • AY-glucuronide (0.1 mg/kg bw) Chronic exposure assessment against Cramer class III threshold of 1.5 µg/kg bw (TTC approach) is proposed for the following metabolites: • AP • AP-8 • AY-5 • AH Metabolites included in EU RD for RA: –				

5.30.3 | Residue definitions – Acynonapyr

TABLE 165 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 parent acynonapyr plus 5-(trifluoromethyl)-2-pyridinol (AY), expressed as acynonapyr	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
	Animal products	Sum of parent acynonapyr plus 5-(trifluoromethyl)-2-pyridinol (AY), expressed as acynonapyr The residue is not fat soluble	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
RD RA	Plant products	Sum of parent plus 5-(trifluoromethyl)-2- pyridinol (AY) and 5-(trifluoromethyl)-2-pyridon-3-yl ß-D-glucopyranoside (AY-1-Glc), expressed as acynonapyr (chronic exposure)	No EU peer review and no MRL review	Not applicable
	Animal products	Sum of parent acynonapyr plus 5-(trifluoromethyl)-2-pyridinol (AY) and 5-(trifluoromethyl)-2-pyridyl ß-D-glucopyranosiduronic acid (AY-Glu), expressed as acynonapyr	No EU peer review and no MRL review	Not applicable
Conclusion, comments	Acynonapyr has never been notified or authorised in the EU; consequently, no EU peer review or MRL review is available. Therefore, no EU RDs for enforcement and risk assessment have been established at the EU level. The metabolism of acynonapyr after foliar indoor and outdoor applications was evaluated in apple, cucumber (fruit and foliage) and lettuce, covering fruits and leafy crops. Acynonapyr was the predominant residues in all investigated crops (19%–96% TRR or 0.0051–7.3 mg/kg). A similar metabolic pattern was observed across the two crop groups with formation of metabolites AP (range 4.4%–36% TRR or ≤ 0.005–1.8 mg eq/kg) and AY (3.5%–34% TRR, 0.003–1.1 mg eq/kg). AP was further metabolised to AP-2 (0.59%–5.5% TRR or ≤ 0.005–0.21 mg eq/kg) in all crops, while AY was metabolised to AY-1-Glc in lettuce and cucumber (3.1%–23% TRR (0.002–0.54 mg eq/kg). Confined and field rotational crop studies were not submitted. JMPR considered these studies not required for the uses assessed which are limited to permanent crops (citrus and pome fruit) and indoor grown eggplants, which JMPR considered to be usually grown on soil substitutes. However, such studies may be needed for future uses involving crops grown into rotation. Aqueous hydrolysis studies performed at pH 4, 7 and 9 showed formation of AP, AH and AY as major hydrolysis products. No studies investigating the nature of residues upon processing (high temperature hydrolysis studies), although they were available. Photolytic degradation studies showed that acynonapyr degrades rapidly in water and moderately fast in soil, mainly forming AP and AY, with further photodegradation of AY to AY-4 in water. Based on these findings JMPR considered acynonapyr an adequate marker for enforcement, as it was present at relevant levels in all crops. As degradation of parent into AP and AY may occur during storage, AY included in the enforcement residue definition, as is covered by the toxicity of acynonapyr and supports dietary exposure assessment based on monitoring results. For risk assessment residue definition, JMPR considered AY, AY-1-Glc, AP and AP-2 observed in the metabolism studies and AH identified in the aqueous hydrolysis study. AY and AY-1-Glc were included in the risk assessment residue definition as they are covered by the HBGV of acynonapyr and are relevant in primary and processed commodities. AP-2 was considered sufficiently covered by the inclusion of AY and AY-1-Glc, whereas AP and AH were assessed separately using the TTC approach (see consumer risk assessment). For AP, a separate end point for acute toxicity was established. In lactating goats, parent acynonapyr was detected only at low levels in milk and was not found in tissues. AY was the main residue in tissues and was therefore selected as the enforcement marker for livestock. AY-Glu was observed mainly in kidney, while AP and AP-8 occurred only in milk at very low absolute levels. For animal commodities, JMPR included AY and AY-Glu in the residue definition for dietary risk assessment, as both are covered by the toxicological profile of acynonapyr for chronic exposure; for the acute exposure an ARfD was set by JMPR. AP and AP-8 were assessed separately using the TTC approach and, for acute exposure they were considered more toxic and an ARfD specific for AP was set at level of 0.03 mg/kg bw. The a.s. contains two C-CF3 moieties in its chemical structure. In the studies assessed by the JMPR 2022, there was no information on potential formation of trifluoroacetic acid (TFA) in either plants or livestock from the use of acynonapyr.			

5.30.4 | Codex MRL proposals – Acynonapyr

TABLE 166 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Apple	**3**	0.01* default MRL Art.18(1)(b)	cGAP: Japan, foliar, 1 × 20 g a.s./hL (1000-fold dilution), 1-day PHI Number of trials: 6 Sufficiently supported by data: See comments Specific comments: According to the JMPR report, in Japan, the application concentration is the critical application parameter, and the trials were selected based on that criterium. In the EU for a major crop, 8 residue trials would be required. **Conclusion:** The proposed Codex MRL is supported by data according to FAO rules for the number of trials. Follow-up action: None.
Apple pomace, wet	15 (dw)	–	JMPR derived a processing factor of 1.7. Currently, no EU MRLs are established for processed products.
Apple, juice	–	–	JMPR derived a processing factor of 0.12. Currently, no EU MRLs are established for processed products.
Mandarins, oil, edible	100	–	JMPR derived a processing factor of 46. Currently, no EU MRLs are established for processed products.
Pear	**0.9**	0.01* default MRL Art.18(1)(b)	cGAP: Japan, foliar, 1 × 10 g a.s./hL (2000-fold dilution), 1-day PHI Number of trials: 6 Sufficiently supported by data: See comments Specific comments: According to the JMPR report, in Japan, the application concentration is the critical application parameter, and the trials were selected based on that criterion. In the EU for a major crop, 8 residue trials would be required. **Conclusion:** The proposed Codex MRL is supported by data according to FAO rules for the number of trials. Follow-up action: None.
Pear, juice	–	–	JMPR derived a processing factor of 0.12. Currently, no EU MRLs are established for processed products.
(Satsuma) mandarin, peel fresh	–	–	JMPR derived a processing factor of 2.6. Currently, no EU MRLs are established for processed products.
Subgroup of eggplants	**0.5**	0.01* default MRL Art.18(1)(b)	cGAP: Japan, foliar, 2 × 10 g a.s./hL (2000-fold dilution), 7-day RTI, 1-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: According to the JMPR report, in Japan, the application concentration is the critical application parameter, and the trials were selected based on that criterion. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None.
Subgroup of mandarins	**1.5**	0.01* default MRL Art.18(1)(b)	cGAP: Japan, foliar, 1 × 10 g a.s./hL (2000-fold dilution), 1-day PHI Number of trials: 6 Sufficiently supported by data: Yes Specific comments: According to the JMPR report, in Japan, the application concentration is the critical application parameter, and the trials were selected based on that criterion. **Conclusion:** The proposed Codex MRL is supported by data. Follow-up action: None.
Subgroup of mandarins, juice	–	–	JMPR derived a processing factor of 0.23. Currently, no EU MRLs are established for processed products.
General comments	Storage stability was investigated for acynonapyr and metabolites AP, AP-2, AY, AY-3 and AY-1-Glc in raw and processed plant commodities. Under frozen conditions, residues were stable for at least 10 months in apples and 6 months in oranges, grapes, almonds and hops when samples were fortified with formulated acynonapyr or individual metabolites. In contrast, samples fortified with technical acynonapyr showed degradation of parent to AP and AY after approximately one month in apples, oranges and grapes. As no information was provided on the possible addition of stabilising compounds in commercial formulations preventing degradation to AY and AP, JMPR could not conclude on the general storage stability of parent acynonapyr. For the uses assessed, storage stability was considered sufficiently addressed, as it was investigated concurrently in the Japanese residue trials and demonstrated when parent was considered together with AP or AY. Since there were no animal feeding studies, analytical methods and storage stability data for residues of acynonapyr in animal matrices, the JMPR did not recommend MRLs for animal commodities.		

Abbreviation: dw, dry weight.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.30.5 | Consumer risk assessment – Acynonapyr

TABLE 167 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The JMPR did not allocate an ARfD for acynonapyr but allocated an ARfD to metabolites AY and AY-Glu, and an ARfD to AP and AP-8.	**RA assumptions:** The risk assessment was performed with the JMPR ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1 and using as input values the STMR values derived by JMPR for the crops for which Codex MRLs were proposed (i.e. apples, pear, mandarins, eggplants). The risk assessment is indicative, since the substance was never assessed in the EU, and therefore, no definitive EU residue definitions and toxicological reference values are available. Therefore, the calculations are affected by additional, non-standard uncertainties. The calculations are indicative, because no agreed toxicological reference values are established in the EU. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** The JMPR estimated the chronic exposure to metabolites AP and AP-8 and the potential degradation product AH using the TTC approach for Cramer class III compounds against the threshold of 1.5 µg/kg bw per day. AP (plus AP-8 for milks): The dietary intake calculations resulted in a maximum estimated intake of 12.6 µg per person or 0.21 µg/kg bw (bw of 60 kg), which is below the threshold of 1.5 µg/kg bw indicating that it does not present a public health concern. AH: Assuming 100 percent conversion of the residue expressed in parent equivalents to AH in processed commodities, the dietary intake calculations resulted in a maximum estimated intake of 6.5 µg per person or 0.11 µg/kg bw (bw of 60 kg), which is below the threshold of 1.5 µg/kg bw indicating that it does not present a public health concern. Based on these TTC calculations, the JMPR concluded that the estimated chronic intake to residues of acynonapyr metabolites AP, AP-8 and AH from uses considered by the 2025 JMPR do not present a public health concern.
Results: No short-term consumer health risk was identified for the crops under assessment. ***AY and AY-Glu*** The IESTIs for AY (plant commodities and animal commodities) and for AY plus AY-Glu (kidney) were up to 30% of the ARfD of 0.1 mg/kg bw for acynonapyr for children and up to 20% of the ARfD for the general population. ***AP and AP-8*** The IESTIs for AP (all commodities) and for AP plus AP-8 (milk only) ranged up to 30% of the ARfD of 0.03 mg/kg bw for children and up to 10% of the ARfD for the general population. It is noted that the results of these acute dietary calculations are not shown in Annex 4 of the 2025 JMPR report. Table A4.1 International Estimate of Short-term Intakes (IESTIs) of pesticide residues starts with the results for bifenthrin.	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 12% of the ADI. Among the crops under consideration, apple was identified as the main contributor, accounting for up to 11% of the ADI.	**Results:** Long-term exposure: Max 3% of the JMPR ADI. Short-term exposure: Not relevant for acynonapyr (JMPR did not derive an ARfD for the parent). GECDE mean: Max. 10% (e.g. infants and toddler) GECDE max: Max. 20% (e.g. infants and toddler)

5.30.6 | Conclusions – Acynonapyr

TABLE 168 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU; no EU assessment available.
Toxicological assessment	No EU HBGVs available.
Residue definitions	No RDs derived at the EU level.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers since this a.s. was never approved in the EU.

5.31 | Mepiquat chloride (336) R

5.31.1 | Background information – Mepiquat chloride

TABLE 169 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New use	
RMS	FI	
Approval status in the EU	Approved	Commission Implementing Regulation (EU) 2025/150[72]
EFSA conclusion available	Yes, see comments	EFSA (2024d)
MRL review performed	Yes, see comments	EFSA (2015e)
EU MRL applications or other EU assessments	Yes, see comments	Art.10 in honey (ongoing) EFSA (2024e) (temporary MRLs in fungi and oyster mushrooms) EFSA (2019f) (temporary MRL in oyster mushrooms) EFSA (2018m) (cotton seeds and animal commodities) EFSA (2018j) (various oilseeds and animal commodities) EFSA (2018e) (cotton seeds) EFSA (2016a) (temporary MRL in cultivated fungi)
Classification of a.s. (cut-off criteria)	No, see comments	A.s. does not meet cut-off criteria ECHA (2021a)
Endocrine effects of a.s.	No, see comment	EFSA (2024d)
Other relevant information	Mepiquat chloride is authorised for use in veterinary medicine.	

5.31.2 | Health-Based Guidance Values – Mepiquat chloride

TABLE 170 Comparison of Health-Based Guidance Values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.3 mg/kg bw per day	JMPR, 2023	0.065 mg/kg bw per day	EFSA, 2024	No See comments on a.s.
ARfD	0.6 mg/kg bw	JMPR, 2023	0.3 mg/kg bw	EFSA, 2024	No See comments on a.s.
Conclusion/ comments on a.s.	EFSA (2024d): ADI based on LOAEL of 2-year rat study applying a standard UF of 100 and an extra UF of 2 to account for the extrapolation of the NOAEL from the LOAEL. ARfD based on NOAEL of developmental neurotoxicity study in rats applying a standard UF of 100. JMPR 2023 (FAO and WHO, 2024): ADI based on NOAELs of 90-day and 1-year dog studies applying a standard UF of 100. ARfD based on NOAEL of rat acute neurotoxicity study in rats applying a standard UF of 100.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat cation, free and conjugated) EFSA (2024d): 4-hydroxymepiquat chloride is covered by the HBGVs of the parent. JMPR 2023 (FAO and WHO, 2024): Hydroxy-mepiquat chloride is toxicologically relevant, and of no greater potency than the parent. HBGVs of the parent are applicable. Metabolites included in EU RD for RA: 4-hydroxy mepiquat chloride • 4-hydroxy mepiquat chloride (free and conjugated) and their salts				

[72]Commission Implementing Regulation (EU) 2025/150 of 29 January 2025 renewing the approval of the active substance mepiquat chloride in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011. C/2025/513. OJ L, 2025/150, 30.1.2025.

5.31.3 | Residue definitions – Mepiquat chloride

TABLE 171 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Mepiquat cation	Reg. 396/2005 (implementing MRL review): Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) Peer review (EFSA, 2024d): Sum of mepiquat and its salts, expressed as mepiquat chloride	No, but MRLs can be recalculated
	Animal products	Mepiquat cation The residue is not fat soluble	Reg. 396/2005 (implementing MRL review): Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) Peer review (EFSA, 2024d): Sum of mepiquat and its salts, expressed as mepiquat chloride The residue is not fat soluble	No, but MRLs can be recalculated
RD RA	Plant products	Mepiquat cation	Peer review (EFSA, 2024d) and MRL review (EFSA, 2015e): Sum of mepiquat and its salts, expressed as mepiquat chloride	No
	Animal products	Sum of mepiquat cation and 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat cation, free and conjugated), expressed as mepiquat cation	Peer review (EFSA, 2024d) and MRL review (EFSA, 2015e): Sum of mepiquat and 4-hydroxy mepiquat chloride (free and conjugated) and their salts, expressed as mepiquat chloride	No
Conclusion, comments	The EU residue definition for MRL enforcement for the relevant matrix groups is not fully comparable with the JMPR residue definition, but a recalculation of the Codex MRLs to match with the EU residue definition would be possible. To recalculate a Codex MRL to match with the current EU residue definition, the unrounded Codex MRL proposal derived with the OECD calculator needs to be multiplied with a correction factor of 1.31 before rounding the result to the next MRL class.			

5.31.4 | Codex MRL proposals – Mepiquat chloride

TABLE 172 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Cotton seed	**30**	6	cGAP: Brazil, Foliar, 10 × 50 g a.s./ha, 7-day RTI, plus an additional final spraying of 500 g a.s./ha, 40-day PHI Number of trials: 5 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: If risk managers decide to take over the Codex MRL for cotton seed, which is higher than the current EU MRL, the Codex MRL needs to be recalculated to match with the EU residue definition. The corresponding EU MRL would be 40 mg/kg.
Cotton seed meal	60	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose. It is noted that default processing factors were used by JMPR for the estimation of the dietary burden whilst magnitude of residue trials in processed commodities would have been required at EU level since the residue is > 0.1 mg/kg in cotton seed.
Cotton seed oil, crude	–	–	JMPR derived a processing factor of 1.9. Currently, no EU MRLs are established for processed products.
Cotton seed oil, edible	–	–	JMPR derived a processing factor of 0.04. Currently, no EU MRLs are established for processed products.

(Continues)

TABLE 172 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Edible offal (mammalian)	0.04 (W)	–	The existing CXL is being replaced with the new proposal for the group of edible offal (mammalian).
Eggs	0.008* (W)	–	The existing CXL is, being replaced with the new proposal for the group of eggs.
Group of avian fats	0.008*	0.05	Max. dietary burden (US/Canada poultry layer): 4.3 ppm. Max. residues in muscle, liver, kidney, and fat: < 0.038 mg/kg Sufficiently supported by data: Yes Specific comments: There is a method of analysis for mepiquat chloride with an LOQ of 0.01 mg/kg (0.008 mg mepiquat cation/kg), therefore the JMPR agreed to recommend maximum residue levels for mepiquat cation of 0.008* mg/kg for the group of avian muscle, group of avian (edible offal and group of avian fats). **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian muscle	0.008*	0.05	See group of avian fats.
Group of avian, edible offal	0.008*	0.05 (liver) 0.05* (kidney and edible offals)	See group of avian fats.
Group of edible offal (mammalian)	**0.2**	Liver from – swine: 0.07 – bovine, equine and others: 0.5 – sheep and goat: 0.6 Kidney from – swine: 0.07 – ruminants, equine and others: 0.8 Edible offals from – swine: 0.05* – ruminants, equine and others: 0.8	Max. dietary burden (AUS beef cattle): 10.9 ppm. Max. residues in kidney: 0.17 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Group of eggs	0.05	0.07	Max. dietary burden (US/Canada poultry layer): 4.3 ppm. Max. residues in eggs: 0.041 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of mammalian fats (except milk fats)	0.04	0.05 (pig) 0.06 (bovine, sheep, goat, equine and others)	Max. dietary burden (AUS beef cattle): 10.9 ppm. Max. residues in fat: 0.038 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None
Group of milks	0.03	0.07 (cattle and horse) 0.15 (sheep and goat)	Max. dietary burden (AUS dairy cattle): 6.5 ppm. Max. residues in milk: 0.025 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	0.04	0.05 (swine) 0.09 (bovine, sheep, goat, equine and others)	Max. dietary burden (AUS beef cattle): 10.9 ppm. Max. residues in fat: 0.039 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Mammalian fats (except milk fats)	0.01 (W)	–	The existing CXL is being replaced with the new proposal for the group of mammalian fats (except milk fats).
Meat (from mammals other than marine mammals)	0.01 (W)	–	The existing CXL is being replaced with the new proposal for the group of muscle (from mammals other than marine mammals).
Milks	0.008* (W)	–	The existing CXL is being replaced with the new proposal for the group of milks.

TABLE 172 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Poultry, edible offal of	0.008* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian, edible offal.
Poultry fats	0.008* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian fats.
Poultry meat	0.008* (W)	–	The existing CXL is being replaced with the new proposal for the group of avian muscle.
General comments			

Note: W, the previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.
*Indicates that the input value is proposed at the limit of quantification.
[a]Commodity description according to Codex food classification.
[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.31.5 | Consumer risk assessment – Mepiquat chloride

TABLE 173 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. cotton seed, swine liver and swine kidney). The HR value derived by JMPR was recalculated to match with the EU residue definition for risk assessment.	**RA assumptions:** The risk assessment was performed with the EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1. The input values of the most recent long-term risk assessment (EFSA, 2024a) were updated, including the STMR values derived by JMPR for the commodities for which the proposed Codex MRL is higher than the EU MRL (i.e. cotton seed, swine liver and swine kidney). The STMR value derived by JMPR was recalculated to match with the EU residue definition for risk assessment. Concentrations in liver of swine and ruminants were multiplied by a conversion factor for risk assessment of 1.7 derived from the metabolism study in ruminants (EFSA, 2015e).	**Specific comments:** The 2023 JMPR meeting noted that the metabolite methylpiperidine (found in animal metabolism study but not in plant metabolism study) was not considered to be genotoxic. As no further information was available, the 2025 JMPR agreed to apply the TTC approach (Cramer class III, 1.5 µg/kg bw/d) for toxicity. The dietary intake of methylpiperidine calculated using the 17 GEMS/Food cluster diets were up to 0.14 µg/kg bw, significantly lower than the TTC for Cramer class III. The JMPR concluded that the chronic dietary exposure of methylpiperidine, arising from uses of mepiquat chloride, assessed in JMPR 2025, is unlikely to present a public health concern.
Results: No short-term consumer health risk was identified for the crops under assessment. Cotton seed, swine (liver, kidney): < 1% of ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 23% of the ADI. Among the crops under consideration, cotton seed was identified as the main contributor, accounting for up to 6% of the ADI.	**Results:** Long-term exposure: Max 2% of the JMPR ADI. Short-term exposure: Highest result for milks: 1% of ARfD GECDE mean: Max. 3% (children and adolescents) GECDE max: Max. 10% (infants and toddler)

5.31.6 | Conclusions – Mepiquat chloride

TABLE 174 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU.
Toxicological assessment	EU HBGVs available.
Residue definitions	EU and Codex RDs are not fully comparable, but the Codex MRLs can be recalculated to match with the EU RD.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data. If the CXL proposal is implemented in EU a recalculation of the residue levels to align the EU residue definition is needed.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The Codex MRL proposals are sufficiently supported by data and risk for consumers is unlikely.

5.32 | Acequinocyl (343) R/T

5.32.1 | Background information – Acequinocyl

TABLE 175 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	DE	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Implementing Regulation (EU) No 496/2014[73] Renewal Assessment Report (RAR) submitted, EFSA peer review has not started yet
EFSA conclusion available	Yes, see comments	EFSA (2013f) EFSA (2018t) (outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment in light of confirmatory data)
MRL review performed	Yes, see comments	EFSA (2020a)
EU MRL applications or other EU assessments	Yes, see comments	Art.10 in celeries, Florence fennel and rhubarbs (ongoing) EFSA (2026b) (small berries) EFSA (2025i) (various crops) EFSA (2025a) (strawberries) EFSA (2022d) (sweet peppers/bell peppers)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP03[74]
Endocrine effects of a.s.	Not assessed	
Other relevant information	–	

5.32.2 | Health-Based Guidance Values – Acequinocyl

TABLE 176 Comparison of Health-Based Guidance Values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.02 mg/kg bw per day	JMPR, 2025	0.023 mg/kg bw per day	EFSA, 2013	Slightly, based rounding See comments on a.s.
ARfD	0.2 mg/kg bw	JMPR, 2025	0.08 mg/kg bw	EFSA, 2013	No See comments on a.s.
Conclusion/comments on a.s.	JMPR 2025 (FAO and WHO, 2026): ADI based on NOAEL from 2-year rat study, supported by NOAEL from 18-month mouse study, applying a standard uncertainty factor of 100. ARfD based on NOAEL from mechanistic study on coagulation effects in rats, applying a standard uncertainty factor of 100. EFSA (2013f): ADI based on NOAEL from 2-year study in rats, applying a standard uncertainty factor of 100. ARfD based on NOAEL from mechanistic study on coagulation effects in rats, applying a standard uncertainty factor of 100. In re-evaluation of acequinocyl, RMS indicated to propose the same HBGVs, indicating the ADI also to be supported by the NOAEL of 18-month mouse study.				
Comments on metabolites	Metabolite, AKM-05 (acequinocyl-OH), was considered not more toxic than the parent and covered by the parent HBGVs by JMPR and EU.				

[73]Commission Implementing Regulation (EU) No 496/2014 of 14 May 2014 approving the active substance acequinocyl, 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 143, 15.5.2014, p. 1–5.

[74]Commission Regulation (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 179, 11.7.2012, p. 3–10.

5.32.3 | Residue definitions – Acequinocyl

TABLE 177 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Acequinocyl	Reg. 396/2005: Acequinocyl • MRL review (EFSA, 2020a): Fruit crop group: Acequinocyl Processed commodities (tentative, to be confirmed by the hydrolysis studies): acequinocyl and acequinocyl-OH, expressed as acequinocyl Peer review (EFSA, 2013f): Acequinocyl	Yes, see the comments below
	Animal products	Acequinocyl The residue is not fat soluble	Reg. 396/2005: Acequinocyl MRL review (EFSA, 2020a): Ruminants and swine: Acequinocyl Peer review (EFSA, 2013f): not required The residue is fat soluble	Yes
RD RA	Plant products	Sum of acequinocyl and 2-dodecyl-3-hydroxy-1.4-naphtoquinone (AKM-05), expressed as acequinocyl.	• MRL review (EFSA, 2020a): Fruit crop group: Acequinocyl Processed commodities (tentative, to be confirmed by the hydrolysis studies): Acequinocyl and acequinocyl-OH, expressed as acequinocyl Peer review (EFSA, 2013f): Acequinocyl	No, see the comments
	Animal products	Acequinocyl	MRL review (EFSA, 2020a): Ruminants and swine: Acequinocyl Peer review (EFSA, 2013f): not required	Yes
Conclusion, comments	Metabolism studies in fruit and fruiting vegetables (orange, apple and eggplant) and hops showed a comparable pathway, with parent acequinocyl as the predominant residue (28%–95% TRR) and metabolites mainly formed by hydrolysis. The major metabolites were AKM-05 (generally < 0.1%–4% TRR, up to 10% TRR in eggplant), AKM-18 (≤ 7% TRR) and phthalic acid (typically ≤ 10%–17% TRR, but present at lower levels than the parent compound). In livestock, metabolism was limited and residue transfer to tissues and milk was very low. Parent acequinocyl was detected at low levels, while metabolites AKM-05, AKM-15 and AKM-18 were present only as minor components. On this basis, JMPR established acequinocyl as the residue definition for enforcement in both plant and animal commodities. For risk assessment, the plant residue definition includes the sum of acequinocyl and AKM-05, whereas the livestock residue definition includes acequinocyl only. Although leaves were harvested at 5 and 21 days after application (DAA), the residues were not characterised in leaves, but only in dried hop cones. Therefore, the available metabolism data should not be sufficient to support coverage of leafy crops. At EU level, similar plant and livestock metabolism studies were assessed. The residue definitions for enforcement and risk assessment in plants and livestock include only acequinocyl, except for processed commodities, for which acequinocyl-OH (AKM-05) was tentatively included as a hydrolysis metabolite. EFSA requested additional standard hydrolysis studies to conclude on the relevance of this metabolite in the residue definition for processed commodities.			

5.32.4 | Codex MRL proposals – Acequinocyl

JMPR did not derive CXL proposals because no reliable residue data for AKM-05 were available.

5.32.5 | Consumer risk assessment – Acequinocyl

STMRs/HRs could not be derived because the residue data were unreliable, with instability and insufficient storage stability for AKM 05, which is included in the risk assessment residue definition by JMPR.

5.32.6 | Conclusions – Acequinocyl

TABLE 178 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (RAR submitted, EFSA peer review has not started yet).
Toxicological assessment	EU HBGV available.

(Continues)

TABLE 178 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Residue definitions	The EU and Codex residue definitions are identical, except for plant risk assessment, where the JMPR residue definition is broader. It is comparable to the EFSA residue definition tentatively proposed for processed commodities.
Codex MRL proposals	No new Codex MRL proposals under discussion.
Dietary risk assessment	Not relevant, no Codex MRL proposals were derived by JMPR.
Final conclusion	–

5.33 | Dimpropyridaz (344) R/T

5.33.1 | Background information – Dimpropyridaz

TABLE 179 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	AT	
Approval status in the EU	Approval process ongoing	Draft Assessment Report (DAR) submitted, EFSA peer review has not started yet
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	–	

5.33.2 | Health-Based Guidance Values – Dimpropyridaz

TABLE 180 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	Comments	Value	Comments	HBGV comparable
ADI	0.2 mg/kg bw per day	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
ARfD	1 mg/kg bw	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
Conclusion/comments on a.s.	JMPR derived the ADI based on 2-year chronic toxicity/carcinogenicity study in rats, while the ARfD based on acute neurotoxicity study in rats.				
Comments on metabolites	JMPR also concluded that the HBGV derived for dimpropyridaz applies to the metabolites M550I002, M550I004, M550I006, M550I014, M550I015, M550I051 and M550I052.				

5.33.3 | Residue definitions – Dimpropyridaz

TABLE 181 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 dimpropyridaz and methyl 5-methyl-1-(3-methylbutan-2-yl)-1H-pyrazole-4-carboxylate (Reg. No. 6065040), expressed as dimpropyridaz	No EU peer review and no MRL review	Not applicable
	Animal products	Sum of dimpropyridaz and 1-(3-hydroxy-3-methylbutan-2-yl)-5-methyl-N-(pyridazin-4-yl)-1H-pyrazole-4-carboxamide (M550I015), expressed as dimpropyridaz The residue is not fat soluble	No EU peer review and no MRL review	Not applicable

TABLE 181 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD RA	Plant products	Not concluded	No EU peer review and no MRL review	Not applicable
	Animal products	Sum of dimpropyridaz, 1-(3-hydroxy-3-methylbutan-2-yl)-5-methyl-N-(pyridazin-4-yl)-1H-pyrazole-4-carboxamide (M550I015), 5-methyl-1- (3-methylbutan-2-yl)-N-(pyridazin-4-yl)-1H-pyrazole-4-carboxamide (M550I002) and N-ethyl-1-(3-hydroxy-3-methylbutan-2-yl)-5-methyl-N-(pyridazin-4-yl)-1H-pyrazole-4-carboxamide (M550I004) expressed as dimpropyridaz	No EU peer review and no MRL review	Not applicable
Conclusion, comments	Dimpropyridaz was never notified or assessed at EU level. JMPR assessed plant metabolism studies **in primary crops** in tomato, lettuce (foliar and drench) and soybean, using dimpropyridaz radiolabelled in the 4 carbon of the pyrazole ring (14C-pyrazolyl-labelled dimpropyridaz or [13C]-dimpropyridaz (Pyrazolyl Label)) or in the 4 and 5 carbons of the pyridazine ring (14C-pyridazinyl-labelled dimpropyridaz). Metabolic pathways were qualitatively similar across crops and mainly involved amide N-dealkylation and hydroxylation of the isopentyl side chain, with minor pyridazine ring hydroxylation, amide-bond cleavage and conjugation. TRR in edible matrices were low to moderate (tomato fruits 0.080–0.097 mg eq/kg, lettuce leaves 5.1–5.6 mg eq/kg, soybean seeds 0.35–0.83 mg eq/kg), with 84%–99% of the TRR identified or characterised. Parent dimpropyridaz was predominant, except in soybean seed and lettuce after drench application. Metabolites identified in all or some primary crops were M550I004, M550I002, M550I006, M550I015, M550I042, M550I045 and M550I048. In plant metabolism studies, dimpropyridaz was applied as a racemate (R and S enantiomers) using radiolabelled and unlabelled test items. Selected extracts (tomato leaves; soybean seeds, straw and hulls; lettuce leaves; immature spinach; wheat forage) were fractionated, metabolites confirmed by HPLC–MS/MS and purified fractions analysed by chiral HPLC. The parent remained racemic (~50:50 R:S). Metabolite ratios were matrix-specific: M550I004 in tomato leaves, 56:44 (R:S); M550I006 in soybean seeds, 32:68; M550I002 in soybean straw, 37:63, and hulls, 44:56; M550I002 and M550I006 in lettuce leaves, 48:52 and 56:44; M550I014 in immature spinach, 71:29; M550I005 in wheat forage, 57:43. Overall, the data do not indicate a consistent preferential formation or degradation of one enantiomer across crops. **Rotational crops:** Confined and field rotational crop studies indicated low transfer to succeeding crops. In the confined study, residues in edible parts were low and parent dimpropyridaz was not detected; M550I014 predominated in spinach, M550I005 and M550I049 in radish leaves and M550I005 and M550I009 in wheat fodder. In field trials, dimpropyridaz was found only in wheat straw, M550I005 in wheat fodder and M550I014 and Reg. No. 6123135 in spinach. **Livestock:** JMPR received livestock metabolism studies conducted with radiolabelled dimpropyridaz and its metabolite M550I006 in lactating goats and laying hens. Following administration of dimpropyridaz, excretion was rapid and residue transfer to edible commodities was low. In goats, parent dimpropyridaz was identified in all matrices, particularly in liver, together with several metabolites, of which M550I015, M550I004 and M550I002 were the most significant residue components. In hens, parent dimpropyridaz was not detected and residues were dominated by metabolites M550I015 and, to a lesser extent, M550I002. Following administration of M550I006, excretion was also rapid and tissue retention was very limited. In both goats and hens, M550I006 remained the predominant residue component. Metabolism was limited and mainly involved hydroxylation to M550I051 and, in goats, further conjugation to the glucuronide metabolite M550I052. Compared with the parent compound, M550I006 showed a simpler metabolic pattern. **Storage stability:** Frozen storage studies (≤–18°C) were provided for dimpropyridaz and metabolites M550I002, M550I004, M550I005, M550I006 and M550I014 in plant and animal commodities. In plants, dimpropyridaz/Reg. No. 6065040, M550I002/Reg. No. 6065040, M550I004/Reg. No. 6123135, M550I005 and M550I006/Reg. No. 6065040 were stable for at least 36 months in high-water commodities (except onion) and high-oil commodities, 33 months in high-acid commodities, 25 months in high-protein commodities and 24 months in high-starch commodities. In animal commodities, residues were stable for at least 10 months for dimpropyridaz, M550I002 and M550I006 in muscle, liver, kidney, fat and eggs; 8 months for M550I004 in muscle, liver, kidney, fat and milk; 10 months for M550I014 and M550I028 in milk and up to 2 months in muscle, liver, kidney and fat; 10 months for M550I015 in muscle, liver, kidney and eggs and up to 4 months in fat; and 16 months for M550I005 in liver, kidney and fat.		

5.33.4 | Codex MRL proposals – Dimpropyridaz

No CXL proposals were derived by JMPR because the residue definition for dietary risk assessment of plant commodities was not concluded.

5.33.5 | Consumer risk assessment – Dimpropyridaz

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

5.33.6 | Conclusions – Dimpropyridaz

TABLE 182 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU, approval process ongoing (DAR submitted, EFSA peer review has not started yet).
Toxicological assessment	No EU HBGV available.
Residue definitions	No EU residue definitions are established; JMPR proposed residue definitions, except for the residue definition for risk assessment in plants.
Codex MRL proposals	No Codex MRL proposal derived, since no risk assessment residue definition for plants was derived.
Dietary risk assessment	No dietary risk assessment performed.
Final conclusion	–

5.34 | Ipflufenoquin (345) R/T

5.34.1 | Background information – Ipflufenoquin

TABLE 183 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	NL	
Approval status in the EU	Approval process ongoing	Draft Assessment Report (DAR) submitted, EFSA peer review has not started yet
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	–	

5.34.2 | Health-Based Guidance Values – Ipflufenoquin

TABLE 184 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	Comments	Value	Comments	HBGV comparable
ADI	0.07 mg/kg bw per day	JMPR, 2025	–	No EU assessment	Not applicable
ARfD	1 mg/kg bw	JMPR, 2025	–	No EU assessment	Not applicable
Conclusion/ comments on a.s.	JMPR established an ADI of 0–0.07 mg/kg bw per day, based on the NOAEL of 6.8 mg/kg bw per day from the long-term rat study, with bone globules in females as the critical effect and applying a safety factor of 100. An ARfD of 1 mg/kg bw was established based on the NOAEL of 125 mg/kg bw from the acute neurotoxicity study in rats, with a safety factor of 100. The ADI and ARfD established for the parent also apply to metabolites QP-1-10, QP-2, M16, M47, M48 and M51.				
Comments on metabolites	The ADI and ARfD established for the parent also apply to metabolites QP-1-10, QP-2, M16, M47, M48 and M51.				

5.34.3 | Residue definitions – Ipflufenoquin

TABLE 185 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Ipflufenoquin	No EU peer review and no MRL review	Not applicable
	Animal products	Not concluded The residue is fat soluble	No EU peer review and no MRL review	Not applicable
RD RA	Plant products	Ipflufenoquin	No EU peer review and no MRL review	Not applicable
	Animal products	Not concluded	No EU peer review and no MRL review	Not applicable
Conclusion, comments	Ipflufenoquin was never assessed at EU level; therefore, no EU residue definitions are applicable. JMPR received metabolism studies with radiolabelled ipflufenoquin in **primary crops** following foliar application, covering fruits (apple, grape), fruiting vegetables (cucumber), pulses and oilseeds (kidney bean, oilseed rape), cereals (rice) and tree nuts (almond). The metabolic pattern was qualitatively similar across crop groups. Parent ipflufenoquin was generally the predominant residue in edible commodities, accounting for up to 42% TRR in apple, 39% TRR in grape, 90% TRR in cucumber and 54% TRR in rice; in almond nutmeat, residues were negligible and parent was not detected. QP-2 was the main metabolite identified at low levels (up to 11% TRR in immature apples), while QP-1-3 was detected only in cucumber at very low proportions (up to 1.7% TRR). Other metabolites were individually present at low levels and no major crop-specific metabolites were identified. Overall, metabolism was limited, with parent remaining the main residue component, and the pathway was considered sufficiently elucidated and comparable among the crop categories investigated. As regards **rotational crops**, no information concerning residues in confined or field rotational crops were submitted to JMPR. **Livestock metabolism studies** of ipflufenoquin were available in lactating goats and laying hens. The metabolic pattern was similar in both species. Parent ipflufenoquin was the major residue in fat, while more extensive metabolism occurred in liver, kidney and muscle, resulting in the formation of several hydroxylated and conjugated metabolites, notably QP-1-10 and QP-1-11. The available studies were considered sufficient to elucidate the nature of residues in livestock. **Storage stability** was investigated in plant and animal commodities under frozen conditions (≤ –18°C). In plants, ipflufenoquin, QP-2 and QP-1-2 (expressed as QP-1-1) were stable for 1 month in mandarin pulp, 3 months in apples and pears, 4 months in dried tea leaves and up to 12 months in almond nutmeat; in almond hulls, ipflufenoquin and QP-1-2 (expressed as QP-1-1) were stable for at least 12 months, while QP-2 was stable for up to 75 days. JMPR concluded that residues were stable for the maximum storage intervals of the supervised residue trial samples. In animal commodities, ipflufenoquin and metabolites QP-1-8, QP-1-9, QP-1-10, QP-1-11, QP-1-12, QP-1-13, QP-1-14, QP-1-15, QP-1-16 and QP-1-18 were stable in milk, muscle, liver and eggs for at least 133 days under frozen conditions (≤ –18°C).		

5.34.4 | Codex MRL proposals – Ipflufenoquin

No CXL proposals derived by JMPR since the definition of residue for estimation of dietary intake for animal commodities was not concluded; animal dietary burden could not be calculated, and consequently, a complete dietary risk assessment could not be conducted.

5.34.5 | Consumer risk assessment – Ipflufenoquin

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

5.34.6 | Conclusions – Ipflufenoquin

TABLE 186 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, approval process ongoing (DAR submitted, EFSA peer review has not started yet).
Toxicological assessment	No EU HBGV available.
Residue definitions	No EU residue definitions have been derived; JMPR 2025 proposed residue definitions for plants only.
Codex MRL proposals	No Codex MRL proposal derived.
Dietary risk assessment	Not applicable as no CXL proposals were derived.
Final conclusion	–

5.35 | Metarylpicoxamid (346) R/T

5.35.1 | Background information – Metarylpicoxamid

TABLE 187 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status in the EU	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	–	

5.35.2 | Health-Based Guidance Values – Metarylpicoxamid

TABLE 188 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.2 mg/kg bw per day	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
ARfD	Unnecessary	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
Conclusion/comments on a.s.	There is no toxicological assessment at the EU level. The JMPR established an ADI of 0.2 mg/kg bw day from the mouse 18-month carcinogenicity study, applying a standard uncertainty factor of 100. No ARfD was allocated.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 2S,3S)-3-(2-methylphenyl)butan-2-yl N- {[3-hydroxy)-4-methoxypyridin-2-yl}-L-alaninate (X12644507) The JMPR considered this metabolite toxicity covered by the parent (major rat metabolite). Metabolites included in EU RD for RA: –				

5.35.3 | Residue definitions – Metarylpicoxamid

TABLE 189 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Metarylpicoxamid	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
	Animal products	Metarylpicoxamid The residue is not fat soluble	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
RD RA	Plant products	Sum of metarylpicoxamid and (2S,3S)-3-(2-methylphenyl)butan-2-yl N- {[3-hydroxy)-4-methoxypyridin-2-yl}-L-alaninate (X12644507), expressed as metarylpicoxamid	No EU peer review and no MRL review	Not applicable
	Animal products	Metarylpicoxamid	No EU peer review and no MRL review	Not applicable

TABLE 189 (Continued)

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
Conclusion, comments	This a.s. was never notified and authorised in the EU – for non-approved a.s. usually the default residue definition for MRL enforcement is applied (i.e. parent metarylpicoxamid); no RDs for risk assessment established at EU level. JMPR assessed a metabolism study on soya bean. In crop fractions for human consumption (soya bean seeds); metarylpicoxamid, X12644507 (free and hydroxylated) and X12777891 were identified at > 10% TRR. In animal feed commodities, metarylpicoxamid was the predominant compound. Metabolite X12644507 (free and hydroxylated), X12648727 (free and conjugated) were identified at > 10% TRR. The residue definitions derived by JMPR cover only pulses and oilseed since only metabolism studies in soya bean were available. In the confined rotational crop study, metarylpicoxamid was not found in any matrix at > 0.01 mg/kg, and no metabolite was identified or characterised at > 0.007 mg eq/kg. In the metabolism study with lactating goats, the TRRs were below 0.01 mg eq/kg in milk samples, fat and muscle; thus, no identification or characterization work was conducted on these matrices. In liver, parent compound was found in minor amounts, while two metabolites were found > 10%TRR: X12745065 (free and conjugated) and X12485473. In kidney, parent was not detected, while two metabolites were observed at > 10% TRR: X12745065 (conjugated only) and X12771593. In the metabolism study with laying hens, parent compound was only identified in poultry fat, but at very low levels. In eggs, metabolite X12771309 was found above 10% TRR. In the liver, identification was low, and no metabolite was found at relevant levels. In muscle, X12771309 was the only metabolite found above 10% TRR. In fat, metabolites X12644507, X12771309 and X12851221 were found above 10% TRR. In ruminant and poultry, at the maximum DB, no residues above 0.01 mg/kg were expected in any matrix based on the metabolism studies ruminants and poultry (overdosed by a factor of 430 and 1070, respectively). Moreover, from the lactating cow feeding study, no residues were identified at the 1.13 or 2.24 ppm feeding levels. On this basis, the JMPR conclude that all residues are expected to be below 0.01 mg/kg in livestock matrices. Although parent metarylpicoxamid was detected only at low levels in goat liver (2% TRR; 0.001 mg eq/kg) and hen fat (0.7% TRR; 0.001 mg eq/kg), JMPR considered it the only relevant compound for livestock residue definitions.			

5.35.4 | Codex MRL proposals – Metarylpicoxamid

TABLE 190 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of avians, edible offal	0.01*	0.01* default MRL Art.18(1)(b)	Max dietary burden (EU poultry broiler/USA/Canada poultry layer): 0.132/0.0099 ppm. Max. residues in poultry tissues and eggs: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable Follow-up action: None
Group of avian fats	0.01*	0.01* default MRL Art.18(1)(b)	See group of avians, edible offal.
Group of avian muscle	0.01*	0.01* default MRL Art.18(1)(b)	See group of avians, edible offal.
Group of edible offal (mammalian)	0.01*	0.01* default MRL Art.18(1)(b)	Max dietary burden (Japan beef cattle/Japan dairy cattle): 0.218/0.0153 ppm. Max. residues in ruminant tissues and milk: < 0.01 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable since it is at the LOQ level. Follow-up action: None.
Group of eggs	0.01*	0.01* default MRL Art.18(1)(b)	See group of avians, edible offal.
Group of mammalian fats (except milk fats)	0.01*	0.01* default MRL Art.18(1)(b)	See group of edible offal (mammalian).
Group of milks	0.01*	0.01* default MRL Art.18(1)(b)	See group of edible offal (mammalian).
Group of muscle (from mammals other than marine mammals)	0.01*	0.01* default MRL Art.18(1)(b)	See group of edible offal (mammalian).

(Continues)

TABLE 190 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Soya bean (dry)	0.01*	0.01* default MRL Art.18(1)(b)	cGAP: Paraguay, 3 × 48 g a.s./ha, 14-day RTI, 21-day PHI Number of trials: 18 Sufficiently supported by data: Yes Specific comments: The RTI between the 1st and 2nd application was 12–21 days; the RTI between the 2nd and 3rd application ranged between 6 and 75 days. The JMPR considered that residues were consistent regardless of the RTI between the 2nd and 3rd application. The JMPR noted that, in 10 decline trials, residues of metarylpicoxamid and X12644507 declined rapidly in soya bean seeds by 14 days. In two at-harvest trials, residues of X12644507 were > LOQ. Nevertheless, the JMPR concluded that the final application is likely to be driving the residue and that the trials are considered to reflect the GAP for soya bean seeds. **Conclusion:** The proposed Codex MRL is supported by data. See outcome of consumer risk assessment. Follow-up action: None
General comments	Storage stability at –18°C was assessed for metarylpicoxamid, X12644507, X12774135 and X12777891 in lettuce, soya bean seeds, navy bean seeds, carrot roots, oranges and wheat grain, and was demonstrated for at least 12 months, except for X12644507 in lettuce, stable for up to 3 months. In animal commodities, metarylpicoxamid, X12644507, X12485473, X12771593, X12745065 and X12797595 were stable for at least 6 months in muscle, fat, milk and cream; in liver and kidney, metabolites were stable for up to 4 months and the parent for up to 2 months.		

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.35.5 | Consumer risk assessment – Metarylpicoxamid

TABLE 191 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: No ARfD was allocated.	**RA assumptions:** The risk assessment was performed with the JMPR ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1, including the proposed CXLs. The risk assessment is indicative, since the substance was never assessed in the EU, and therefore, no definitive EU residue definitions and HBGVs are available. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 0.3% of the ADI. The main contributor was milk (cattle) accounting for up to 0.3% of the ADI.	**Results:** Long-term exposure: Max 0% of the JMPR ADI. Short-term exposure: Not relevant. GECDE mean: Max. 4% (children and adolescents) GECDE max: Max. 10% (children and adolescents; infants and toddlers)

5.35.6 | Conclusions – Metarylpicoxamid

TABLE 192 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU; no EU assessment available.
Toxicological assessment	No EU HBGVs available.
Residue definitions	No EU RDs available. The residue definitions derived by JMPR cover only pulses and oilseed since only metabolism studies in soya bean were available.

TABLE 192 (Continued)

Subsection of the assessment	Findings relevant for discussion of EU position
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers.

5.36 | Proquinazid (347) R/T

5.36.1 | Background information – Proquinazid

TABLE 193 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	SE	
Approval status in the EU	Approved, process of renewal of the approval ongoing	Commission Directive 2010/25/EU[75] EFSA conclusion published in March 2026. Discussion at risk management level ongoing
EFSA conclusion available	Yes, see comments	EFSA (2009d) EFSA (2026)
MRL review performed	Yes, see comments	EFSA (2020b)
EU MRL applications or other EU assessments	Yes, see comments	EFSA (2021f) (blueberries and cranberries)
Classification of a.s. (cut-off criteria)	No, see comments	No classification ATP05[76] ECHA (2023b)
Endocrine effects of a.s.	Yes, see comments	EFSA (2026a): ED criteria for the T-modality are met.
Other relevant information	–	

5.36.2 | Health-Based Guidance Values – Proquinazid

TABLE 194 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.01 mg/kg bw per day	JMPR, 2025	0.012 mg/kg bw per day (new) 0.01 mg/kg (current)	EFSA, 2026 EFSA, 2009	Yes See comments on a.s.
ARfD	0.3 mg/kg bw	JMPR, 2025	0.06 mg/kg bw (new) 0.2 mg/kg (current)	EFSA, 2026 EFSA, 2009	No See comments on a.s.
Conclusion/comments on a.s.	EFSA (2026a): ADI based on NOAEL from 2-year rat study, applying a standard uncertainty factor of 100. ARfD based on LOAEL from 90-day dog study, applying a standard uncertainty factor of 100 and an additional uncertainty factor of 3, given that the reference point is a LOAEL and not a NOAEL. JMPR 2025 (FAO and WHO, 2026): ADI based on NOAEL from 2-year rat study supported by NOAEL from reproductive toxicity study in rats, applying a standard uncertainty factor of 100. ARfD based on NOAEL from developmental toxicity study in rats, applying a standard uncertainty factor of 100. The reference points for ADI setting are the same in the EU and JMPR assessment, but a different rounding approach was used. The 90-day dog study that was used in the EU assessment to set the ARfD has also been reported in the JMPR assessment. The LOAEL that was used as reference point for ARfD setting in the EU assessment was considered a NOAEL in the JMPR assessment and not used for ARfD setting by JMPR.				

(Continues)

[75]Commission Directive 2010/25/EU of 18 March 2010 amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spirodiclofen as active substances. OJ L 69, 19.3.2010, pp. 11–15.

[76]Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 262, 3.10.2013, p. 5–22.

TABLE 194 (Continued)

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
Comments on metabolites	Metabolites included in JMPR RD for RA: • 2-(2-hydroxypropoxy)-6-iodo-3-propyl-quinazolin-4-one (IN-MW977 major isomer) • 2-(2-hydroxy-1-methyl-ethoxy)-6-iodo-3-propyl-quinazolin-4-one (IN-MW977 (minor isomer) • 3-[(6-iodo-4-oxo-3-propyl-3,4-dihydroquinazolin-2-yl)oxy]propanoic acid (IN-MU210) EFSA (2026a): IN-MW977 isomers (major and minor isomers) and IN-MU210 are considered unlikely to be genotoxic. Insufficient information is available to evaluate their general toxicity. Therefore, it cannot be concluded whether HBGVs of parent apply to these metabolites. JMPR 2025 (FAO and WHO, 2026): Metabolites IN-MW977 (both isomers) and IN-MU210 are covered by the parent, and therefore, the HBGVs of parent apply to these metabolites. Metabolites included in EU RD for RA: • 3-[(6-iodo-4-oxo-3-propyl-3,4-dihydroquinazolin-2-yl)oxy]propanoic acid (IN-MU210) • 2-(2-hydroxypropoxy)-6-iodo-3-propylquinazolin-4(3H)-one (IN-MW977)				

5.36.3 | Residue definitions – Proquinazid

TABLE 195 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Proquinazid	Reg. 396/2005 (implementing MRL review): Proquinazid Peer review (EFSA, 2026a): Cereals and fruit crops: Proquinazid	Yes
	Animal products	Sum of proquinazid and 3-(6-iodo-4-oxo-3-propyl-quinazolin-2-yl) oxypropanoic acid (IN-MU210), expressed as proquinazid The residue is fat soluble	Reg. 396/2005 (implementing MRL review): Sum of proquinazid and metabolite 3-[(6-iodo-4-oxo-3-propyl-3,4-dihydroquinazolin-2-yl)oxy] propanoic acid (IN-MU210) expressed as proquinazid Peer review (EFSA, 2026a): Sum of proquinazid and metabolite IN-MU210, expressed as proquinazid The residue is fat soluble	Yes
RD RA	Plant products	Sum of proquinazid and 2-(2-hydroxypropoxy)-6-iodo-3-propyl-quinazolin-4-one and 2-(2-hydroxy-1-methyl-ethoxy)-6-iodo-3-propyl- quinazolin-4-one(IN-MW977 (isomers)), expressed as proquinazid	Peer review (EFSA, 2026a): Cereals and fruit crops: Proquinazid and metabolite IN-MW977 (provisional) Rotational crops: inconclusive Processed commodities: proquinazid MRL review (EFSA, 2020b): Cereals and fruit crops: proquinazid and metabolite IN-MW977, expressed as proquinazid	Yes
	Animal products	Sum of proquinazid and 3-(6-iodo-4-oxo-3-propyl-quinazolin-2-yl) oxypropanoic acid (IN-MU210), expressed as proquinazid	Peer review (EFSA, 2026a): Sum of proquinazid and metabolites IN-MU210 and IN-MW977, expressed as proquinazid (tentative) MRL review (EFSA, 2020b): Sum of proquinazid and metabolites IN-MU210 and IN-MW977, expressed as proquinazid	No
Conclusion, comments	JMPR assessed metabolism studies in primary crops on apple, grape, and wheat. In addition, two confined rotational crops metabolism studies conducted on roots, pulses and oilseeds, leafy crops and cereals and covering all PBIs were also available. For enforcement in plants, JMPR included proquinazid as it was the major compound in all crops assessed. For RD-RA, JMPR considered the occurrence and toxicological relevance of the main metabolites found in the investigated crops. IN-MW977 (isomers) was the only major metabolite in plants; JMPR considered that IM-MW977 is covered by the HBGV of proquinazid and included in the residue definition for dietary intake. At EU level, the same metabolism studies were assessed during the peer review and similar conclusions were reached for the residue definition for enforcement and for the inclusion of IN-MW977 in the RD-RA for plants. The different outcome relates to the toxicological assessment of IN-MW977, which was not considered covered by the toxicity of the parent compound at EU level. Therefore, **a data gap** for general **toxicity data** was identified and **IN-MW977** was provisionally included in the EU RD-RA for plants.			

TABLE 195 (Continued)

Commodity group	JMPR evaluation	EU evaluation	RDs comparable
In livestock, JMPR assessed metabolism studies on poultry and ruminants, and a ruminant feeding study. Based on the studies **for enforcement, proquinazid and metabolite IM-MU210** (the only compound found in ruminant feeding study) were included in the RD. Although IN-MW977 was found in feed items, JMPR did not include it in the enforcement residue definition, as IM-MU210 was considered the higher contributor. For the RD-RA in animal commodities JMPR considered again the occurrence and toxicological relevance of metabolites. Metabolite IN-MU210 was found in high levels in milk and ruminant tissues while IN-MW977 was observed only in goat fat. In poultry, several metabolites were observed (e.g. IN-MW977, IN-MW398, IN-NA250, sulfate conjugates of hydroxylated proquinazid, IN-MY788), however their levels are expected to be low considering the level used in the metabolism study (30N); therefore, their inclusion in the RD-RA was not deemed necessary. Based on these results, **JMPR included proquinazid and IM-MU210 in the RD-RA for animal commodities**. At the EU level, the same livestock metabolism and feeding studies were assessed and a residue definition for enforcement comparable to that derived by JMPR was proposed. The EU RD-RA for livestock is broader as it includes both IN-MU210 and IN-MW977. In the EU, the residue definitions are provisional, pending the toxicity data for metabolites IN-MU210 and IN-MW977 (see above toxicological information on the HBGVs table). For metabolite CRC-Soy-01 which was identified at low levels in rotational crops, JMPR concluded that the threshold of toxicological concern (TTC) Cramer class III approach for chronic exposure (1.5 µg/kg bw per day) and for acute exposure (5 µg/kg bw) should be considered. For the current assessment and considering the low levels of CRC-Soy-01, JMPR decided that a dietary intake estimation was not necessary. However, JMPR noted, that this decision should be revisited in case future uses result in higher maximum seasonal application rates. In the EU, a data gap was set regarding the genotoxic potential and general toxicity for metabolite CRC-Soy-01.			

5.36.4 | Codex MRL proposals – Proquinazid

TABLE 196 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Apple	**0.3**	0.08	cGAP: Australia, foliar, 3 × 125 g a.s./ha, 14-day RTI, 28-day PHI Number of trials: 8 Sufficiently supported by data: Yes Specific comments: Eight trials were performed at 3 × 40–75 g a.s./ha with 9–11 days interval and 28 days PHI. Residue values were scaled using scaling factors of 1.7 to 3.1. Editorial: In table 5.30.10 (page 468) of the 2025 JMPR report, the STMR for apples and pears is reported as 0.795 mg/kg, instead of 0.0795 mg/kg, however in the assessment the correct value (0.0795 mg/kg) was considered. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Apple, juice	–	–	JMPR derived a processing factor of < 0.18. Currently no EU MRLs are established for processed products.
Apple pomace, dried	5	–	JMPR derived a processing factor of 12. Currently no EU MRLs are established for processed products.
Barley	0.03	0.04	cGAP: United Kingdom, foliar, 2 × 50 g a.s/ha, 28-day RTI, before BBCH 49 Number of trials: 15 Sufficiently supported by data: Yes Specific comments: For barley grain JMPR assessed 15 residue trials performed at 2 × 48–53 g a.s./ha with RTI 7–28 days, applied at BBCH 30–33 and BBCH 49–51. Although some trials were conducted with shorter intervals compared to the cGAP, residues were generally unquantified except for two trials with the residues close to the LOQ. JMPR therefore decided that the RTI was not a critical parameter in selection of field trials to support the cGAP on barley. JMPR stated that a more cGAP from Germany, consisting of 2 × 50 g a.s./ha up to BBCH 61, was not supported by residue trials. The current EU MRL is based on a SEU GAP (FR, 1 × 50 g a.s./ha, up to BBCH 39), tentatively supported by trials on barley grains performed with two applications (EFSA, 2020b). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Barley, hay and/or straw	0.3 (dm)	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.

(Continues)

TABLE 196 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Grapes	0.4	0.5	cGAP: Malta, foliar, 3 × 75 g a.s./ha, 10-day RTI, 28-day PHI Number of trials: 15 Sufficiently supported by data: Yes Specific comments: The current (higher) EU MRL is from a NEU GAP (CH, 3 × 80 g a.s./ha, 10-day RTI, up to BBCH 81, 28-day PHI) supported by 9 residue trials (EFSA, 2020b). The GAP from Malta assessed by JMPR matches the SEU GAP reported by Italy and assessed in the Art 12 MRL review. However, the Italian GAP was supported by 9 trials leading to an MRL of 0.15 mg/kg. In 2025, JMPR assessed 15 trials, to support the cGAP from Malta, resulting in a CXL proposal of 0.4 mg/kg (lower than the current EU MRL). **Conclusion:** The proposed Codex MRL is sufficiently supported by data. Follow-up action: None.
Grape, dried (raisin)	1.5	–	JMPR derived a processing factor of 2.8. Currently, no EU MRLs are established for processed products.
Grape, juice	–	–	JMPR derived a processing factor of 0.33. Currently no EU MRLs are established for processed products.
Grape pomace, dried	8	–	JMPR derived a processing factor of 17. Currently no EU MRLs are established for processed products.
Group of edible offal (mammalian)	**0.4**	0.02*	Max. dietary burden (AUS dairy cattle): 6.667 ppm. Max. residues in kidney: 0.312 mg/kg Sufficiently supported by data: Yes Specific comments: Estimated residues in mammalian commodities for proquinazid + IN-MU210. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Group of mammalian fats (except milk fats)	**0.07**	0.02*	Max. dietary burden (AUS dairy cattle): 6.667 ppm. Max. residues in fat: 0.065 mg/kg Sufficiently supported by data: Yes Specific comments: Estimated residues in mammalian commodities for proquinazid + IN-MU210. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Group of milks	**0.03**	0.02*	Max. dietary burden (AUS dairy cattle): 6.667 ppm. Max. residues in kidney: 0.028 mg/kg Sufficiently supported by data: Yes Specific comments: Estimated residues in mammalian commodities for proquinazid + IN-MU210. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Group of muscle (from mammals other than marine mammals)	**0.03**	0.02*	Max. dietary burden (AUS dairy cattle): 6.667 ppm. Max residues in muscle: 0.023 mg/kg Sufficiently supported by data: Yes Specific comments: Estimated residues in mammalian commodities for proquinazid + IN-MU210. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None
Must (wine by-product)	–	–	JMPR derived a processing factor of < 0.25. Currently, no EU MRLs are established for processed products.
Oats	0.03	0.04	See Barley.
Oat, hay and/or straw	0.3 (dm)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose.
Pear	**0.3**	0.08	See Apple.
Rye	0.01*	0.02	See Wheat.
Rye, hay and/or straw	0.15 (dm)	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Triticale	0.01*	0.02	See wheat.
Triticale, hay and/or straw	0.9 (dm)	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.

TABLE 196 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Wheat	0.01*	0.02	cGAP: United Kingdom, foliar, 2 × 50 g a.s/ha, 28-day RTI, before BBCH 65 Number of trials: 22 Sufficiently supported by data: Yes Specific comments: Out of 22 residue trials, 17 trials were analysed for metabolite IN-MW977. The current EU MRL is based on a SEU GAP (FR, 1 × 50 g a.s./ha, up to BBCH 39), supported by overdosed trials performed with 2 or 3 applications, that were deemed acceptable since residues were always below the LOQ (EFSA, 2020b). During the peer review, a comparable GAP to that assessed by JMPR was supported by 25 NEU and SEU trials resulting in an MRL of 0.01* mg/kg (EFSA, 2026a), in line with the proposed CXL. **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Wheat, hay and/or straw	0.9 (dm)	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Wine	–	–	JMPR derived a processing factor of 0.33 (data set from red, white, and sparkling white wine). Currently, no EU MRLs are established for processed products.
General comments	For the calculation of total proquinazid residues in plants (i.e. sum of proquinazid and IN-MW977), the JMPR estimated as < 0.02 mg/kg when both components were below 0.01 mg/kg, and as 0.02 mg/kg where proquinazid was 0.01 and IN-MW9777 < 0.01 mg/kg or when both were at 0.01 mg/kg.		

Abbreviation: dm, dry matter.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

5.36.5 | Consumer risk assessment – Proquinazid

TABLE 197 Summary of the consumer risk assessment.

Acute exposure assessment	Chronic exposure assessment	Comments on JMPR exposure assessment
RA assumptions: The risk assessment was performed with the current EU ARfD. The short-term dietary risk assessment (PRIMo rev. 3.1) was performed for the commodities, for which the Codex MRL proposal is higher than the existing EU MRL (i.e. apples, pears, milk and mammalian tissues). The calculations are indicative, because the residue definitions for RA derived by JMPR is different to the EU RD. Therefore, the calculations are affected by additional, non-standard uncertainties.	**RA assumptions:** The risk assessment was performed with the current EU ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1 (refined calculation mode). The input values of the most recent long-term risk assessment (EFSA, 2021f) were updated, including the STMR values derived by JMPR for the commodities for which the proposed Codex MRL is higher than the EU MRL (i.e. apples, pears, milk and mammalian tissues). The calculations are indicative, because the residue definitions for RA derived by JMPR is different to the EU RD. Therefore, the calculations are affected by additional, non-standard uncertainties.	**Specific comments:** –
Results: No short-term consumer health risk was identified for the crops under assessment. Pears: 12% of the current ARfD Pears: 39% of the new ARfD	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 26% of the ADI. Among the commodities under consideration, cattle milk (14% ADI) and was the main contributor. By using the new EU ADI of 0.012 mg/kg bw/day there is no change in the chronic exposure results.	**Results:** Long-term exposure: Max 5% of the JMPR ADI. Short-term exposure: Highest result for grapes: 8% of ARfD GECDE mean: Max. 20% (e.g. infants and toddler) GECDE max: Max. 40% (e.g. infants and toddler)

5.36.6 | Conclusions – Proquinazid

TABLE 198 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. approved in the EU, renewal process ongoing (peer review finalised by EFSA, discussion at risk management level ongoing).
Toxicological assessment	EU HBGV available.
Residue definitions	EU and Codex RDs for enforcement are identical; EU RD-RA livestock is more comprehensive.
Codex MRL proposals	The proposed Codex MRLs are sufficiently supported by data.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers.

5.37 | Spidoxamat (348) R/T

5.37.1 | Background information – Spidoxamat

TABLE 199 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	NL volunteered to act as RMS for this a.s.
Approval status in the EU	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	No assessment performed by ECHA RAC. Industry classifications available do not include classification cut-off criteria
Endocrine effects of a.s.	Not assessed	
Other relevant information	–	

5.37.2 | Health-Based Guidance Values – Spidoxamat

TABLE 200 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	Comments	Value	Comments	HBGV comparable
ADI	0.7 mg/kg bw per day	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
ARfD	Unnecessary	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
Conclusion/ comments on a.s.	No EU assessment has been performed, so no HBGVs have been derived. JMPR 2025 (FAO and WHO, 2026): ADI based on NOAEL from 13-week study in dogs, applying an uncertainty factor of 13. Given that the mode of action (MoA) for the urinary tract effects involves the precipitation of spidoxamat and its major metabolite BCS-AH92431 in the glomerular filtrate, the toxicodynamic subfactors for the inter- and intra-species differences were reduced to 1. The toxicokinetic subfactors for inter- and intra-species differences were retained. Thus, the total uncertainty factor applied was 13 (4.0 (interspecies differences due to toxicokinetics) × 3.16 (interindividual differences due to toxicokinetic factors)). ARfD not allocated.				
Comments on metabolites	Metabolites included in JMPR RD for RA: – Not relevant; the JMPR did not conclude on the residue definitions for estimation of dietary risk assessment for plant and animal commodities. Metabolites included in EU RD for RA: –				

5.37.3 | Residue definitions – Spidoxamat

TABLE 201 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Spidoxamat	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
	Animal products	Spidoxamat The residue is not fat soluble	Never notified and authorised in the EU No EU peer review and no MRL review	Not applicable
RD RA	Plant products	Not concluded	No EU peer review and no MRL review	Not applicable
	Animal products	Not concluded	No EU peer review and no MRL review	Not applicable
Conclusion, comments	This a.s. was never assessed in the EU, there are no RDs established at the EU level. The residue definition for enforcement for plants and livestock derived by the JMPR is parent only. The JMPR did not have sufficient time to conclude on the RD for RA (plants and livestock).			

5.37.4 | Codex MRL proposals – Spidoxamat

No CXL proposals derived by JMPR.

5.37.5 | Consumer risk assessment – Spidoxamat

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

5.37.6 | Conclusions – Spidoxamat

TABLE 202 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. not approved in the EU; no EU assessment available.
Toxicological assessment	No EU HBGV available.
Residue definitions	Not relevant, no Codex MRL proposals derived by JMPR.
Codex MRL proposals	Not relevant, no Codex MRL proposals derived by JMPR.
Dietary risk assessment	Not relevant, no Codex MRL proposals derived by JMPR.
Final conclusion	Not relevant, no Codex MRL proposals derived by JMPR.

5.38 | Tiafenacil (349) R/T

5.38.1 | Background information – Tiafenacil

TABLE 203 Background information.

		Comments, references
JMPR assessment	JMPR meeting 2025	
Type of JMPR evaluation	New compound evaluation	
RMS	No RMS assigned	
Approval status in the EU	Not approved	Never notified and authorised in the EU
EFSA conclusion available	No	
MRL review performed	No	
EU MRL applications or other EU assessments	No	
Classification of a.s. (cut-off criteria)	Not assessed	
Endocrine effects of a.s.	Not assessed	
Other relevant information	A.s. belongs to the class of PFAS chemicals.	

5.38.2 | Health-Based Guidance Values – Tiafenacil

TABLE 204 Comparison of health-based guidance values (HBGVs) derived by JMPR and at EU level.

	JMPR evaluation		EU evaluation		
	Value	**Comments**	**Value**	**Comments**	**HBGV comparable**
ADI	0.004 mg/kg bw per day	JMPR, 2025	–	No EU assessment	Not applicable See comments on a.s.
ARfD	Unnecessary	JMPR, 2025	–	No EU assessment	Not applicable
Conclusion/comments on a.s.	There is no toxicological assessment at the EU level. The JMPR derived an ADI of 0.004 mg/kg bw based on the NOAEL from the 18-month mouse study, applying a standard uncertainty factor of 100. No ARfD was allocated.				
Comments on metabolites	Metabolites included in JMPR RD for RA: • 3-(2-((2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydropyrimidin-1(2H)-yl)phenyl)thio) propanamido)propanoic acid (M-01) The JMPR considered that the ADI of the parent also applies also to metabolites M-01 and M-52, as these were major metabolites in the rat ADME study. Metabolites included in EU RD for RA: – It is noted that trifluoroacetic acid (TFA) is a metabolite of tiafenacil. TFA was recently classified by ECHA RAC as Repr. 1B (ECHA, 2026). Currently, HBGVs are being established in the EU for TFA.[77]				

5.38.3 | Residue definitions – Tiafenacil

TABLE 205 Comparison of the residue definitions derived by JMPR and at EU level.

	Commodity group	JMPR evaluation	EU evaluation	RDs comparable
RD enf	Plant products	Tiafenacil	Never notified and authorised in the EU No EU peer review and no MRL review	No applicable
	Animal products	Sum of tiafenacil, 3-(2-((2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydropyrimidin-1(2H)-yl)phenyl)thio) propanamido)propanoic acid (M-01) and 3-(4-chloro-2-fluoro-5-(methylsulfonyl)phenyl)-1-methyl-6-(trifluoromethyl)pyrimidine-2,4(1H,3H)-dione (M-88), expressed as tiafenacil The residue is fat soluble	Never notified and authorised in the EU No EU peer review and no MRL review	No applicable
RD RA	Plant products	Sum of tiafenacil and 3-(2-((2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydropyrimidin-1(2H)-yl)phenyl)thio) propanamido)propanoic acid (M-01), expressed as tiafenacil	No EU peer review and no MRL review	No applicable
	Animal products	Sum of tiafenacil and 3-(2-((2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydropyrimidin-1(2H)-yl)phenyl)thio) propanamido)propanoic acid (M-01), expressed as tiafenacil	No EU peer review and no MRL review	No applicable
Conclusion, comments	Tiafenacil was never assessed in the EU, the RD for enforcement set as parent compound only (by default). No RD for risk assessment at the EU level. The JMPR assessed plant metabolism studies on mandarin (soil-directed), soya bean (desiccation), maize (pre-plant), potato (pre-plant and desiccation) and cotton (desiccation). In mandarins, metabolite M-32 (trifluroacetic acid, TFA) represented the major residue, accounting for up to 91% TRR. In soya bean, tiafenacil was the predominant residue (88%–93% TRR), all other metabolites < 0.01 mg/kg. In maize and potatoes, the TRRs found in grain and tubers were low and not further characterised. In maize and potato foliage, in addition to TFA found at 58% TRR, other metabolites observed at > 10% TRR were M-36, M-52, M-56; metabolite M-01 despite was observed at the level < 10% TRR is still relevant since occurred at 0.331 mg eq/kg. For the desiccation treatments in potato, cotton and soybeans, tiafenacil was the major component observed at 43% to 93% TRR (up to 1.7 mg/kg in potato foliage). Tiafenacil was also the major component in soybean seed after desiccation treatment.			

[77] https://open.efsa.europa.eu/question/EFSA-Q-2024-00502.

TABLE 205 (Continued)

Commodity group	JMPR evaluation	EU evaluation	RDs comparable
	In the confined rotational crop metabolism study, TFA was the most prominent metabolite, followed by the metabolites M-36, M-52, M-53 and M-72 (radish roots and foliage). Despite TFA was found at high proportion in the confined metabolism studies, this metabolite was not investigated in the field rotational trials. In the field rotational crop study with wheat, residues of TFA were not reported. In wheat forage, residues of tiafenacil and all metabolites were ≤ 0.01 mg/kg. Residues of tiafenacil and metabolites in wheat hay samples were all < 0.01 mg/kg, except for M-36 and M-63 (from < 0.01 to 0.0133 mg/kg and from < 0.01 to 0.0171 mg/kg, respectively), becoming < 0.01 mg/kg at the 120-day PBI. In wheat grain samples (30-day PBI only), residues of all analytes were < 0.01 mg/kg. Residues of tiafenacil, M-01, M-10, M-52, M-56 and M-72 were < 0.01 mg/kg for all wheat straw samples. Tiafenacil metabolism was assessed in lactating goats and laying hens. Tiafenacil was not observed in goat muscle and fat or any of the poultry matrices, while in goat milk, liver and kidney, was present at very low levels (≤ 5% TRR; ≤ 0.007 mg/kg). Three predominant metabolites were observed in both animals: M-01 (goat/hen: liver and muscle, goat: kidney), M-36 (goat: kidney and muscle and poultry: egg whites) and M-88 (goat: muscle and fat, poultry: all matrices). Metabolites M-12 and/or M-13 were observed as major metabolites in poultry liver and kidney only. Lastly, the remaining major species-specific metabolites observed were TFA (goat: milk, kidney, muscle), M-34 (goat: liver and muscle) and M-87 (poultry: egg whites, egg yolks and skin with fat). Although TFA was predominant in primary and rotational crops, its transfer to animal commodities was not investigated; therefore, its contribution to dietary intake from animal products remains uncertain. In the feeding study done with ruminants, at the closed dose level of 5.15 ppm (140 × DB), there were no residues of tiafenacil, M-01 and M-88 in milk and muscle. In kidney and liver, the total residues of tiafenacil, M-01 and M-88 were 0.186 and 0.254 mg/kg. The a.s. contains one C-CF3 moiety in its chemical structure. TFA was found at measurable levels in all plant matrices in the metabolism studies. The 2024 JMPR established HBGVs for TFA (ADI of 0.04 mg/kg bw/d and an ARfD of 0.5 mg/kg bw for women of child-bearing aged). However, the 2025 JMPR concluded that, since this metabolite can arise from other sources, it should be assessed separately, and therefore, it was not included in the residue definition for dietary intake from the use of tiafenacil. Although TFA is a common metabolite to other pesticides, since this metabolite is of interest for the consumer risk assessment, sufficient data on magnitude of residues in primary and rotational crops should be made available to finalise the consumer risk assessment following the application of tiafenacil.		

5.38.4 | Codex MRL proposals – Tiafenacil

TABLE 206 Comparison of Codex MRL proposals derived by JMPR with EU MRLs.

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Coffee bean	0.01*	0.01* default MRL Art.18(1)(b)	cGAP: Brazil, direct spray application to weeds, 1 × 140 g a.s./ha, 7-day PHI. Number of trials: 8 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Group of avian, edible offal of	**0.03***	0.01* default MRL Art.18(1)(b)	Max. dietary burden (poultry layers): Europe 0.036 ppm. Max. residues in all poultry matrices: < 0.0001 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of avian fat	**0.03***	0.01* default MRL Art.18(1)(b)	See group of avian edible offal.
Group of avian muscle	**0.03***	0.01* default MRL Art.18(1)(b)	See group of avian edible offal.
Group of eggs	**0.03***	0.01* default MRL Art.18(1)(b)	See group of avian edible offal.
Group of edible offal, mammalian	**0.03***	0.01* default MRL Art.18(1)(b)	Max. dietary burden (beef cattle/dairy cattle): Australia 0.08/0.075 ppm. Max. residues in milk and tissues: < 0.0005 mg/kg Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is acceptable. Follow-up action: None
Group of mammalian fats (except milk fats)	**0.03***	0.01* default MRL Art.18(1)(b)	See group of edible offal (mammalian)

(Continues)

TABLE 206 (Continued)

Commodity[a]	Codex MRL proposal	EU MRL[b]	Comment
Group of milks	**0.03***	0.01* default MRL Art.18(1)(b)	See group of edible offal (mammalian)
Group of milk fats[c]	0.01*	–	In the EU, specific MRLs are not set for milk fats.
Group of muscle (from mammals other than marine mammals)	**0.03***	0.01* default MRL Art.18(1)(b)	See group of edible offal (mammalian)
Maize	0.01*	0.01* (default MRL)	cGAP: United States, 2 pre-plant applications of 75 g a.s./ha, 14-day RTI, PHI not specified Number of trials: 19 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Maize stover	0.01* (ar)	–	Not relevant; currently, no EU MRLs are established for products exclusively used for feed purpose.
Soya bean (dry)	0.01*	0.01* default MRL Art.18(1)(b)	cGAP: United States, 2 pre-plant applications at 75 g a.s./ha, 14-day RTI, PHI not specified Number of trials: 9 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Soya bean hay	0.01*	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Wheat	0.01*	0.01* default MRL Art.18(1)(b)	cGAP: 2 pre-plant and/or pre-emergence applications of 75 g a.s./ha, 14-day RTI, PHI not specified. Number of trials: 33 Sufficiently supported by data: Yes Specific comments: – **Conclusion:** The proposed Codex MRL is sufficiently supported by data. See outcome of consumer risk assessment. Follow-up action: None.
Wheat hay	0.01*	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
Wheat straw	0.01*	–	Not relevant; currently no EU MRLs are established for products exclusively used for feed purpose.
General comments			

Abbreviation: ar, as received.

*Indicates that the input value is proposed at the limit of quantification.

[a]Commodity description according to Codex food classification.

[b]EU MRLs for corresponding commodities in EU food classification. See also supporting document Codex_MRL_proposals_existing EU_MRLs.xlsx.

[c]For monitoring and regulatory purposes, whole milk is to be analysed, and the result compared to the MRL for whole milk.

5.38.5 | Consumer risk assessment – Tiafenacil

TABLE 207 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 risk assessment was performed with the JMPR ADI. A long-term dietary risk assessment was performed using PRIMo rev. 3.1, including the STMR values derived by JMPR for coffee bean, soya bean, maize, wheat and livestock commodities. The risk assessment is indicative, since the substance was never assessed in the EU, and therefore, no definitive EU residue definitions and HBGVs are available. Therefore, the calculations are affected by additional, non-standard uncertainties. Moreover, residue data for TFA on magnitude of residues in primary and rotational crops should be made available to finalise the consumer risk assessment following the application of tiafenacil.	**Specific comments:** The JMPR concluded that metabolites M-10, M-12, M-13, M-34, M-36, M-53, M-56, M-63, M-87 and M-88 could be assessed using the TTC approach for chronic exposure (Cramer class III threshold of 1.5 μg/kg bw per day), and metabolites M-10, M-12, M-13, M-34, M-56, M-63, M-87 and M-88 could each be assessed using the TTC Cramer class III for acute exposure (5 μg/kg bw per day). The 2025 JMPR estimated a maximum dietary exposure of 5.8 μg/person or 0.10 μg/kg bw for each of the metabolite: M-10 (highest exposure among the metabolites M-10, M-12, M-13, M-34, M-63, M-87, M-88, addressing each of the individual chronic exposures) and M-36 (highest exposure among the metabolites M-36, M-53 and M-56, addressing each of the individual chronic exposures), which was below the TTC of 1.5 μg/kg bw per day. The JMPR concluded that the estimated long-term dietary exposures to residues of M-10, M-12, M-13, M-34, M-36, M-53, M-56, M-63, M-87 and M-88 from uses considered by the current JMPR were below the TTC for Cramer class III compounds. The 2025 JMPR estimated a maximum dietary exposure of 0.34 μg/kg bw per day for the metabolite M-10 (highest exposure among the metabolites M-10, M-12, M-13, M-34, M-56, M-63, M-87 and M-88, addressing each of the individual acute exposures), which was below the TTC of 5 μg/kg bwper day.
Results: Not relevant	**Results:** No long-term consumer health risk was identified. The overall chronic exposure accounted for 7% of the ADI. Among the crops under consideration, maize/corn was identified as the main contributor, accounting for up to 4% of the ADI.	**Results:** Long-term exposure: Max 5% of the JMPR ADI. Short-term exposure: Not relevant (JMPR did not derive an ARfD). GECDE mean: Max. 6% (children and adolescents) GECDE max: Max. 10% (children and adolescents; infants and toddler)

5.38.6 | Conclusions – Tiafenacil

TABLE 208 Summary of the assessment.

Subsection of the assessment	Findings relevant for discussion of EU position
Background information	A.s. never approved in the EU; no EU assessment available.
Toxicological assessment	No EU HBGV available.
Residue definitions	No RD at EU level.
Codex MRL proposals	The proposed Codex MRLs are supported by data. Although the CXL proposals are at the LOQ, since the contribution of TFA to the overall exposure was not performed, a conclusion on the acceptability of the CXLs should consider the potential contribution of TFA to the consumer exposure.
Dietary risk assessment	No acute and no chronic intake concern identified.
Final conclusion	The final EU position should be discussed/decided by risk managers since tiafenacil was never approved or assessed in the EU.

6 | LIST OF MRL PROPOSALS MAINTAINED AT STEPS 4 OR 7 (APPENDIX VI OF CCPR REPORT 2025)

In the following table, EFSA provides 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 209 Detailed information on the MRL proposals maintained at steps 4 or 7.

Active substance	Commodity	CXL proposal/ existing CXL	Step	Existing EU MRL/new EU MRL[a]	Note from CCPR report 2025	Discussions in previous JMPR and CCPR meetings, conclusion
Dimethoate (027)	AB 0004 Orange, dried pulp	5	4	n.r.	Dimethoate(027)/Omethoate(055)	Codex MRL proposal refers to a processed product and is therefore not relevant for the EU. It is however linked to the MRL proposal for oranges, sweet (see below).
	FC 0004 Oranges, sweet, sour (including orange-like hybrids) (subgroup)	2	4	0.01*	Dimethoate(027)/Omethoate(055)	**Overview on Codex activities:** The Codex MRL proposals were derived by JMPR 2022 in the context of the periodic review of dimethoate (N.B. The periodic review started in the 2019 JMPR meeting, but since data were missing, the review could not be completed. In 2022, JMPR received the additional data that allowed to finalise the evaluation). In CCPR54 (2023), the existing CXL of for citrus fruits (group) (excluding kumquat) of 5 mg/kg was revoked and the new proposed MRL for oranges, sweet, sour (including orange-like hybrids) (subgroup) and orange pulp, dried, was retained at step 4, awaiting further consideration by JMPR, noting that the new MRL proposal may present a public health concern due to the exceedance of the acute reference dose. During CCPR54, the WHO agreed to evaluate new dimethoate toxicology data to support oranges. The CCPR56 agreed to retain the proposed MRLs for orange, dried pulp; and oranges, sweet, sour, at Step 4, pending data submission from the sponsor and the outcome of the 2026 JMPR review. The assessment was scheduled for the 2025 JMPR meeting. A summary report on physiologically based pharmacokinetic (PBPK) modelling to support the use of chemical-specific adjustment factors for dimethoate was submitted by the sponsor for assessment by the JMPR, but the proposed chemical-specific adjustment factors were not accepted (WHO, 2025). **Overview on EU activities**: In the EU peer review for dimethoate, a genotoxic potential in vivo was identified for the metabolite omethoate. Hence, the previously established toxicological reference values for dimethoate and omethoate were withdrawn. **Conclusion**: In CCPR57, it is not expected that a decision will be taken on the advancement/revocation of the MRL proposal for dimethoate/ omethoate in oranges, as the JMPR assessment of the new toxicology data (PBPK modelling done by the sponsor) was not considered acceptable by the 2025 JMPR meeting and therefore the toxicological assessment is still pending.

TABLE 209 (Continued)

Active substance	Commodity	CXL proposal/ existing CXL	Step	Existing EU MRL/new EU MRL[a]	Note from CCPR report 2025	Discussions in previous JMPR and CCPR meetings, conclusion
Methyl Bromide (052)	CP 0179 Bread and other cooked cereal	0.01 (*)	4	n.r.	To apply to commodity at point of products retail sale or when offered for consumption	**Overview on Codex activities:** **The Codex Secretariat further stated that these 'guideline levels'** In CCPR55 (2024), the Codex secretariat noted that the guideline levels for methyl bromide were never submitted to CAC for formal adoption as CXLs and were essentially retained at Step 4 without full adoption. In addition, there was no adopted definition in the Procedural Manual for GLs for pesticides. However, in the Codex database, they were presented as Guideline levels (GLs) giving the impression they are Codex recommendations. It was therefore agreed by CCPR55 to revise the Codex database, highlighting that the MRLs listed in column 3 are MRL proposals retained at Step 4 (instead of reporting them as GLs). In addition, methyl bromide was added to Priority List Table 2A (list of substances scheduled for periodic review for 2026), but so far no Member State, Member Organization, or Observer submitted an appropriate data package for the periodic review of this compound by JMPR. Consequently, EFSA supports the revocation of all CXLs for methyl bromide at CCPR 57. **Overview on EU activities:** In the EU, MRLs for methyl bromide are not established. Hence, the default MRL would be applicable. An EU assessment of bromide has been recently published (Scientific opinion on the risks for human health related to the presence of bromide ion in food and risks on animal health and transfer from feed to food of animal origin related to the presence of bromide ion in feed, in particular in algae and seaweed and derived products (EFSA Scientific Committee, 2025); a follow-up mandate that will deal with the review of the existing EU MRLs set in Regulation (EC) No 396/2005 was sent to EFSA (EFSA-Q-2026-00132); this assessment is ongoing, and expected to be finalised by 2027. **Conclusions/recommendations:** The decision to modify the Codex database, clarifying that the MRL proposals are at step 4, does not have an impact on the EU, since the previous GL are not implemented in the EU legislation. Revocation of the MRL proposals at step 4 should be decided in CCPR 57.
	SB 0715 Cacao beans	5 Po	4	default MRL	To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before	
	GC 0080 Cereal grains (group)	5 Po	4	default MRL	To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before	
	AO6 Cocoa products	0.01 (*) Po	4	n.r.	To apply to commodity at point of retail sale or when offered for consumption	
	DF 0167 Dried fruits	2 Po	4	n.r.	To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24h after fumigation and before	
	DF 0167 Dried fruits	0.01 (*) Po	4	n.r.	To apply to commodity at point of retail sale or when offered for consumption	
	AO4 Milled cereals products	0.01 (*) Po	4	n.r.	To apply to commodity at point of retail sale or when offered for consumption	
	AO4 Milled cereals products	1 Po	4	n.r.	To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before	
	SO 0697 Peanut	0.01 (*) Po	4	default MRL	To apply to commodity at point of retail sale or when offered for consumption	
	SO 0697 Peanut	10 Po	4	default MRL	To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before	
	TN 0085 Tree nuts (group)	0.01 (*) Po	4	default MRL	To apply to commodity at point of retail sale or when offered for consumption	
	TN 0085 Tree nuts (group)	10 Po	4	default MRL	To apply at point of entry into a country and, in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before	

(Continues)

TABLE 209 (Continued)

Active substance	Commodity	CXL proposal/ existing CXL	Step	Existing EU MRL/new EU MRL[a]	Note from CCPR report 2025	Discussions in previous JMPR and CCPR meetings, conclusion
Omethoate (055)	AB 0004 Orange, dried pulp	0.04	4	n.r.		Codex MRL proposal refers to a processed product and is therefore not relevant for the EU. It is however linked to the MRL proposal for oranges, sweet (see below).
	FC 0004 Oranges, sweet, sour (including orange-like hybrids) (subgroufipro p)	0.02	4	0.01*		**Overview on Codex activities:** Because omethoate results from an application of dimethoate, the same conclusions as derived for dimethoate was derived: • to revoke the CXL for omethoate for citrus pulp, dried, and • to retain the proposed MRLs for oranges, sweet, sour (including orange-like hybrids) (subgroup) and orange pulp, dried, at Step 4, awaiting further evaluation by JMPR (scheduled for JMPR meeting of 2025). **Conclusion**: See above on Dimethoate
Guazatine (114)	GC 0080 Cereal grains (group)	0.05 (*)	4	0.05*		**Overview on Codex activities:** In CCPR55 (2024), the Codex secretariat noted that the guideline levels for guazatine were never formally adopted as CXLs by CAC and were retained at step 4. The secretariat also highlighted that a definition for guideline levels has not been established. It was therefore agreed to revise the Codex database, highlighting that the MRLs listed in column 3 are MRLs retained at Step 4 (instead of reporting them as GLs). Guazatine was also included in the priority list for periodic review by JMPR in 2025. **Overview on EU activities:** Since 2015, the EU MRLs for guazatine are all set at the LOQ and the a.s. is listed in Annex V. The Codex guideline levels are not implemented in the current EU legislation. **Conclusions/recommendations:** The EU decision to flag the MRLs as GL does not have an impact on the EU.
	FC 0001 Citrus fruits (group)	5 Po	4	0.05*		
Metalaxyl (138)	OR 0004 Orange oil, edible	7	4	n.r.		Codex MRL proposal refers to a processed product and is therefore not relevant for the EU. It is however linked to the MRL proposal for oranges, sweet (see below).

TABLE 209 (Continued)

Active substance	Commodity	CXL proposal/ existing CXL	Step	Existing EU MRL/new EU MRL[a]	Note from CCPR report 2025	Discussions in previous JMPR and CCPR meetings, conclusion
	FC 0004 Oranges, sweet, sour (including Orange-like hybrids) (subgroup)	0.7	4	0.7	Residue data that was the basis for the Codex MRL proposal of 0.7 mg/kg: Metalaxyl (M))	**Overview on Codex activities for oranges**: In 2021 JMPR report, the withdrawal of this citrus fruit CXL was recommended, because the post-harvest GAP is no longer supported. The CCPR53 (2022) agreed to advance the proposed MRLs for orange oil, edible and oranges, sweet, sour (including orange-like hybrids) (subgroup) to Step 4, awaiting the conclusion on the citrus fruit CXL of 5 mg/kg (based on a post-harvest use of metalaxyl-M, derived in 2004). In Metalaxyl/metalaxyl-M in oranges is scheduled for new use evaluation by JMPR in 2026 (including the uses in oranges). **Overview on EU activities:** The existing EU MRL of 0.7 mg/kg for oranges was established in 2017 following an application for a Spanish GAP (same GAP as the one assessed by JMPR in 2021). **Conclusion/EFSA recommendation**: It is likely that the decision on the revocation of the existing Codex MRL of 5 mg/kg for citrus fruits (group) is further postponed at the CCPR 57, since the substance is scheduled for the assessment of new uses in JMPR 2026.
Metalaxyl (138)	VO 0445 Peppers, sweet (including pimento or pimiento)	0.5	7	0.4		**Overview on Codex activities for peppers:** The Codex MRL proposal of 0.5 mg/kg for sweet peppers was derived by JMPR in 2004; it reflects an Italian GAP for metalaxyl-M (3 soil applications of 1 kg a.s./ha with PHI 15 days). In the 2022 CCPR meeting, the MRL proposal of 0.5 mg/kg was retained at step 7, awaiting the submission of new data and the existing CXL of 1 for pepper (subgroup) was retained under the 4 years rule. Metalaxyl/metalaxyl-M is scheduled for assessment of new uses (including peppers subgroup) for 2026 JMPR. **Overview on EU activities:** The Italian GAP for metalaxyl-M assessed by JMPR in 2004 seems to be no longer approved (EFSA, 2015c). The existing EU MRL for peppers was derived in the framework of the evaluation of confirmatory data following the Article 12 MRL review for metalaxyl/metalaxyl-M (EFSA, 2021i). It reflects the critical indoor GAP for metalaxyl-M (3 × 240 g a.s./ha (foliar spray), PHI 14 days). **Conclusion/EFSA recommendation**: For CCPR 2027, a new Codex MRL proposal is expected for metalaxyl/peppers, if the assessment will take place as scheduled (JMPR 2026). In addition, Italy should be consulted, whether the cGAP for metalaxyl-M for peppers, which was assessed by JMPR in 2004, is still authorised.

(Continues)

TABLE 209 (Continued)

Active substance	Commodity	CXL proposal/ existing CXL	Step	Existing EU MRL/new EU MRL[a]	Note from CCPR report 2025	Discussions in previous JMPR and CCPR meetings, conclusion
Flutriafol (248)	GC 0649 Rice	4	4	n.r.		**Overview on Codex activities:** The Codex MRL proposals were derived by the JMPR meeting of 2022 for an Italian GAP. However, as the previously authorised GAP is no longer in place (flutriafol is no longer approved in the EU), the EU made a reservation. The CCPR55 (2024) agreed to retain the proposed MRLs for all rice commodities at Step 4, awaiting additional data from the sponsor and the outcome of the JMPR re-evaluation which has been scheduled for 2026 (assessment of new uses; among other crops, data for rice will be provided by the sponsor (rice as rotational crop)). **Conclusion**: A discussion in CCPR57 is not expected on flutriafol/rice.
	AS 0649 Rice, hay and/ or straw	6 (dw)	4	n.r.		
	AS 3570 Rice, hulls	20 (dw)	4	n.r.		
	CM 0649 Rice, husked	1	4	0.01*	(husks)	
	CM 1205 Rice, polished	1.5	4	n.r.		

Note: n.r., not relevant since currently no EU MRLs are established for processed products and products exclusively used for feed purpose.

*Indicates that the input value is proposed at the limit of quantification.

[a]Existing EU MRL (Status February 2026). New EU MRL: MRL proposal derived in an EFSA output, voted, but not yet applicable.

ABBREVIATIONS

AChE	acetylcholinesterase
ADI	acceptable daily intake
AhR	aryl hydrocarbon receptor
ARfD	acute reference dose
a.s.	active substance
AUC	area under the concentration–time curve
bw	body weight
CCPR	Codex Committee on Pesticide Residues
cGAP	critical Good Agricultural Practice
CXL	Codex maximum residue limit (Codex MRL)
DAR	Draft Assessment Report
dw	dry weight
ED	endocrine disruptor
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GECDE	global estimate of chronic dietary exposure
GLC-EC	gas–liquid chromatography with electron-capture detection
GLP	Good Laboratory Practice
ha	hectare
HBGV	Health-Based Guidance Values
hL	hectolitre
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IATA	integrated approaches to testing and assessment
IEDI	international estimated daily intake
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
n.a.	not applicable
NAM	new approach methodologies
NEU	Northern European Union
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PFAS	perfluoroalkyl substances
PHI	pre-harvest interval
Po	post-harvest
ppm	parts per million (10-6)
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	Committee for Risk Assessment
RACs	input values of raw agricultural commodities
RAR	Renewal Assessment Report
RD enf	residue definition for enforcement practice
RD	residue definition
RD-RA	residue definition for risk assessment
RMS	rapporteur Member State
RTI	Re-treatment interval
SEU	Southern European Union
STMR	supervised trials median residue
TDM	triazole derivative metabolite
ToR	Terms of Reference
TRR	total radioactive residues
TTC	threshold of toxicological concern
UF	Uncertainty factor
WHO	World Health Organization

REQUESTOR

European Commission

QUESTION NUMBER

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APPENDIX A

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

EFSA PRIMo revision 3.1; 2021/01/06

Cyfluthrin (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2020	Year of evaluation:	2020

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)
	24%	NL toddler	2.42	12%	Milk: Cattle	2%	Apples	2%	Wheat	3%	4%
	13%	DE child	1.33	4%	Milk: Cattle	2%	Apples	2%	Wheat	1%	4%
	13%	NL child	1.32	5%	Milk: Cattle	2%	Wheat	1%	Table grapes	2%	3%
	12%	UK infant	1.18	8%	Milk: Cattle	1%	Wheat	0.3%	Potatoes	1%	1%
	11%	FR child 3 15 yr	1.14	5%	Milk: Cattle	2%	Wheat	0.6%	Tomatoes	2%	3%
	11%	GEMS/Food G06	1.11	4%	Wheat	3%	Tomatoes	1%	Table grapes	2%	5%
	11%	FR toddler 2 3 yr	1.08	6%	Milk: Cattle	2%	Wheat	0.6%	Apples	1%	2%
	11%	RO general	1.08	3%	Wheat	2%	Milk: Cattle	2%	Wine grapes	0.8%	5%
	10%	GEMS/Food G07	0.98	2%	Wheat	2%	Wine grapes	1%	Milk: Cattle	1%	4%
	10%	GEMS/Food G15	0.97	2%	Wheat	1%	Milk: Cattle	1%	Wine grapes	1%	4%
	9%	GEMS/Food G11	0.94	2%	Wheat	2%	Milk: Cattle	1%	Wine grapes	1%	4%
	9%	GEMS/Food G08	0.94	2%	Wheat	1%	Wine grapes	1%	Milk: Cattle	1%	4%
	9%	UK toddler	0.91	4%	Milk: Cattle	2%	Wheat	0.4%	Tomatoes	1%	2%
	8%	DK child	0.85	3%	Milk: Cattle	2%	Wheat	0.6%	Rye	1%	2%
	8%	GEMS/Food G10	0.82	2%	Wheat	1%	Milk: Cattle	1.0%	Tomatoes	1%	3%
	8%	DE women 14-50 yr	0.80	2%	Milk: Cattle	1%	Wheat	1%	Wine grapes	1%	2%
	8%	ES child	0.79	2%	Milk: Cattle	2%	Wheat	0.7%	Tomatoes	1%	2%
	8%	DE general	0.78	2%	Milk: Cattle	1.0%	Wine grapes	0.9%	Wheat	1%	2%
	7%	PT general	0.74	3%	Wine grapes	2%	Wheat	0.6%	Tomatoes	0.5%	5%
	7%	SE general	0.74	2%	Milk: Cattle	2%	Wheat	1.0%	Bovine: Muscle/meat	0.9%	2%
	7%	IE adult	0.72	2%	Wine grapes	1%	Wheat	0.9%	Milk: Cattle	2%	3%
	7%	FR adult	0.69	3%	Wine grapes	1%	Wheat	0.9%	Milk: Cattle	0.8%	4%
	6%	NL general	0.63	2%	Milk: Cattle	1.0%	Wheat	0.7%	Wine grapes	1%	2%
	5%	IT toddler	0.54	3%	Wheat	1.0%	Tomatoes	0.2%	Apples	0.5%	3%
	5%	FR infant	0.53	3%	Milk: Cattle	0.4%	Wheat	0.3%	Apples	0.6%	0.4%
	5%	ES adult	0.50	1%	Wheat	1.0%	Milk: Cattle	0.5%	Tomatoes	0.6%	2%
	5%	DK adult	0.47	1%	Wine grapes	1%	Milk: Cattle	0.6%	Wheat	0.4%	2%
	4%	FI adult	0.44	3%	Coffee beans	0.4%	Tomatoes	0.4%	Wine grapes	3%	0.6%
	4%	UK vegetarian	0.40	1%	Wheat	1.0%	Wine grapes	0.7%	Milk: Cattle	0.5%	2%
	4%	UK adult	0.40	1%	Wine grapes	0.8%	Wheat	0.6%	Milk: Cattle	0.4%	2%
	4%	IT adult	0.38	2%	Wheat	0.8%	Tomatoes	0.2%	Apples	0.4%	2%
	3%	LT adult	0.33	0.8%	Milk: Cattle	0.5%	Wheat	0.4%	Tomatoes	0.3%	0.5%
	3%	FI 3 yr	0.30	0.6%	Wheat	0.5%	Potatoes	0.4%	Tomatoes	0.9%	0.9%
	2%	FI 6 yr	0.24	0.5%	Wheat	0.4%	Potatoes	0.3%	Tomatoes	0.7%	0.7%
	2%	PL general	0.21	0.6%	Tomatoes	0.4%	Apples	0.4%	Table grapes	0.2%	0.4%
	2%	IE child	0.19	0.7%	Milk: Cattle	0.6%	Wheat	0.1%	Swine: Fat tissue	0.2%	0.7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Cyfluthrin (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
163%	Table grapes	0.4 / 0.22	16
21%	Wine grapes	0.4 / 0.22	2.1
7%	Wheat	0.05 / 0.05	0.72

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
76%	Table grapes	0.4 / 0.22	7.6
53%	Wine grapes	0.4 / 0.22	5.3
4%	Wheat	0.05 / 0.05	0.42

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
52%	Wine grapes / juice	0.4 / 0.12	5.2
6%	Wheat / milling (flour)	0.05 / 0.05	0.60
3%	Wheat / milling (wholemeal)-baking	0.05 / 0.05	0.28

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
25%	Wine grapes / juice	0.4 / 0.12	2.5
21%	Wine grapes / wine	0.4 / 0.22	2.1
10%	Table grapes / raisins	0.4 / 0.83	1.0
2%	Wheat / bread/pizza	0.05 / 0.05	0.22
2%	Wheat / pasta	0.05 / 0.05	0.19
2%	Wheat / bread (wholemeal)	0.05 / 0.05	0.17

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.

EFSA PRIMo revision 3.1; 2021/01/06

Bifenthrin (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.015	ARfD (mg/kg bw):	0.03
Source of ADI:	EC	Source of ARfD:	EC
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: **The EU TRVs established are not compliant with the current scientific standard. As it is recommended to withdraw them, EFSA emphasises that the risk assessment presented under this review cannot be concluded and is indicative only.**
Scenario 1a: RA considering the EU TRVs. All commodities for which the existing MRL is sufficiently substantiated (and MRLs still to be discussed by risk managers) are included in the calculation; MRLs that are not substantiated are lowered to the appropriate LOQ. All Commodities for which no GAP was reported are lowered to the appropriate LOQ.

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)
39%	NL toddler	5.80	21%	Milk: Cattle	7%	Wheat	2%	Maize/corn	2%	37%
23%	UK infant	3.41	14%	Milk: Cattle	4%	Wheat	1%	Potatoes	0.6%	22%
22%	NL child	3.33	9%	Milk: Cattle	7%	Wheat	1%	Potatoes	2%	21%
22%	FR child 3 15 yr	3.27	8%	Milk: Cattle	8%	Wheat	0.9%	Oranges	1.0%	21%
20%	DE child	3.07	7%	Wheat	7%	Milk: Cattle	1%	Oranges	2%	19%
20%	FR toddler 2 3 yr	3.00	10%	Milk: Cattle	5%	Wheat	0.6%	Potatoes	0.9%	19%
19%	GEMS/Food G06	2.90	12%	Wheat	1%	Tomatoes	0.9%	Milk: Cattle	0.9%	18%
19%	UK toddler	2.78	7%	Milk: Cattle	7%	Wheat	1%	Potatoes	0.7%	18%
18%	RO general	2.67	8%	Wheat	4%	Milk: Cattle	1%	Potatoes	0.6%	17%
18%	GEMS/Food G15	2.66	8%	Wheat	2%	Milk: Cattle	1%	Potatoes	0.8%	17%
17%	GEMS/Food G11	2.54	6%	Wheat	3%	Milk: Cattle	1%	Potatoes	0.9%	16%
17%	ES child	2.49	7%	Wheat	4%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.7%	16%
16%	GEMS/Food G07	2.47	7%	Wheat	2%	Milk: Cattle	1%	Potatoes	0.8%	16%
16%	DK child	2.47	7%	Wheat	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	16%
16%	GEMS/Food G08	2.44	7%	Wheat	2%	Milk: Cattle	1%	Potatoes	0.9%	15%
15%	SE general	2.32	5%	Wheat	4%	Milk: Cattle	2%	Bovine: Muscle/meat	0.5%	15%
15%	GEMS/Food G10	2.31	7%	Wheat	2%	Milk: Cattle	1%	Soyabeans	0.8%	15%
13%	IE adult	1.94	4%	Wheat	2%	Milk: Cattle	1%	Sweet potatoes	0.8%	12%
13%	IT toddler	1.92	11%	Wheat	0.6%	Tomatoes	0.3%	Potatoes	0.4%	12%
12%	DE women 14-50 yr	1.83	4%	Milk: Cattle	4%	Wheat	0.5%	Oranges	1.0%	11%
12%	DE general	1.76	4%	Milk: Cattle	3%	Wheat	0.5%	Swine: Muscle/meat	0.9%	11%
11%	PT general	1.66	7%	Wheat	2%	Potatoes	1.0%	Wine grapes	0.3%	11%
10%	NL general	1.53	3%	Wheat	3%	Milk: Cattle	0.8%	Potatoes	0.7%	10%
10%	FR infant	1.44	6%	Milk: Cattle	1%	Wheat	0.6%	Potatoes	0.4%	9%
9%	ES adult	1.34	4%	Wheat	2%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.5%	9%
9%	FR adult	1.34	4%	Wheat	2%	Milk: Cattle	0.9%	Wine grapes	0.6%	8%
8%	IT adult	1.25	7%	Wheat	0.5%	Tomatoes	0.2%	Potatoes	0.3%	8%
7%	DK adult	1.09	2%	Wheat	2%	Milk: Cattle	0.8%	Swine: Fat tissue	0.3%	7%
7%	UK vegetarian	0.99	3%	Wheat	1%	Milk: Cattle	0.5%	Potatoes	0.3%	6%
6%	LT adult	0.92	2%	Wheat	1%	Milk: Cattle	1%	Potatoes	0.4%	6%
6%	UK adult	0.91	3%	Wheat	1%	Milk: Cattle	0.5%	Potatoes	0.3%	6%
6%	FI 3 yr	0.83	2%	Wheat	2%	Potatoes	0.4%	Raspberries (red and yellow)	0.5%	5%
4%	FI 6 yr	0.67	2%	Wheat	1%	Potatoes	0.3%	Raspberries (red and yellow)	0.4%	4%
4%	IE child	0.65	2%	Wheat	1%	Milk: Cattle	0.5%	Swine: Fat tissue	0.1%	4%
4%	FI adult	0.58	2%	Coffee beans	0.5%	Wheat	0.4%	Potatoes	2%	2%
2%	PL general	0.34	1%	Potatoes	0.4%	Tomatoes	0.1%	Apples	0.3%	2%

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
61%	Sweet peppers/bell peppers	0.5 / 0.31	18
49%	Oranges	0.15 / 0.11	15
46%	Bovine: Edible offals (other	3 / 1.9	14
34%	Table grapes	0.3 / 0.14	10
32%	Blueberries	3 / 1.6	9.5
29%	Tomatoes	0.3 / 0.15	8.7
26%	Potatoes	0.05 / 0.05	7.7
22%	Milk: Cattle	0.2 / 0.05	6.6
19%	Wheat	0.5 / 0.4	5.8
19%	Swine: Edible offals (other	3 / 1.9	5.7
18%	Blackberries	1 / 0.51	5.5
16%	Raspberries (red and	1 / 0.51	4.7
14%	Peas (with pods)	0.9 / 0.5	4.1
13%	Bovine: Fat tissue	3 / 1.9	4.0
13%	Grapefruits	0.05 / 0.05	3.9

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
49%	Blueberries	3 / 1.6	15
21%	Bovine: Edible offals (other	3 / 1.9	6.3
17%	Sweet peppers/bell peppers	0.5 / 0.31	5.1
17%	Swine: Edible offals (other	3 / 1.9	5.0
16%	Table grapes	0.3 / 0.14	4.7
14%	Blackberries	1 / 0.51	4.2
13%	Swine: Fat tissue	3 / 1.9	3.9
11%	Oranges	0.15 / 0.11	3.4
11%	Wheat	0.5 / 0.4	3.4
11%	Wine grapes	0.3 / 0.14	3.3
9%	Raspberries (red and	1 / 0.51	2.8
9%	Aubergines/egg plants	0.3 / 0.1	2.7
9%	Other farmed animals:	0.2 / 0.46	2.6
8%	Tomatoes	0.3 / 0.15	2.4
7%	Milk: Cattle	0.2 / 0.05	2.0

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Wheat / milling (flour)	0.5 / 0.4	4.8
16%	Potatoes / fried	0.05 / 0.05	4.7
11%	Raspberries / juice	1 / 0.29	3.4
11%	Cranberries / juice	1.5 / 0.56	3.2
10%	Potatoes / dried (flakes)	0.05 / 0.23	3.0
9%	Wine grapes / juice	0.3 / 0.06	2.6
8%	Turnips / boiled	0.05 / 0.05	2.5
8%	Parsnips / boiled	0.05 / 0.05	2.5
8%	Sweet potatoes / boiled	0.05 / 0.05	2.5
7%	Wheat / milling (wholemeal)	0.5 / 0.4	2.2
7%	Beetroots / boiled	0.05 / 0.05	2.2
7%	Oranges / juice	0.15 / 0.04	2.1
6%	Carrots / juice	0.05 / 0.05	1.8
4%	Salsifies / boiled	0.05 / 0.05	1.3
4%	Jerusalem artichokes / boile	0.05 / 0.05	1.3

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)
6%	Beetroots / boiled	0.05 / 0.05	1.9
6%	Wheat / bread/pizza	0.5 / 0.4	1.8
6%	Peas (with pods) / boiled	0.9 / 0.5	1.7
5%	Wheat / pasta	0.5 / 0.4	1.5
5%	Wheat / bread (wholemeal)	0.5 / 0.4	1.4
4%	Wine grapes / wine	0.3 / 0.14	1.3
4%	Wine grapes / juice	0.3 / 0.06	1.2
4%	Parsnips / boiled	0.05 / 0.05	1.1
3%	Turnips / boiled	0.05 / 0.05	0.95
3%	Cassava roots / boiled	0.05 / 0.05	0.95
3%	Celeriacs / boiled	0.05 / 0.05	0.91
3%	Table grapes / raisins	0.3 / 0.66	0.81
3%	Sweet potatoes / boiled	0.05 / 0.05	0.77
2%	Maize / oil	0.05 / 1.25	0.63
2%	Oranges / juice	0.15 / 0.04	0.60

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

EFSA PRIMo revision 3.1; 2021/01/06

Pyriproxyfen (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2019	Year of evaluation:	2019

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	12%	NL toddler	5.77	8%	Bananas	1%	Milk: Cattle	0.4%	Table grapes	0.5%	4%
	5%	NL child	2.57	3%	Bananas	0.5%	Milk: Cattle	0.3%	Table grapes	0.4%	2%
	5%	DE child	2.54	2%	Bananas	0.4%	Tomatoes	0.4%	Table grapes	0.3%	3%
	4%	UK infant	2.04	2%	Bananas	0.8%	Milk: Cattle	0.5%	Tea (dried leaves of Camellia sinens	0.2%	2%
	4%	GEMS/Food G06	1.91	2%	Tomatoes	0.4%	Bananas	0.4%	Tea (dried leaves of Camellia sinens	0.3%	3%
	4%	SE general	1.89	3%	Bananas	0.3%	Tomatoes	0.2%	Milk: Cattle	0.1%	1%
	4%	IE adult	1.86	1%	Bananas	1%	Tea (dried leaves of Camellia sinensis)	0.4%	Wine grapes	0.2%	2%
	3%	UK toddler	1.56	2%	Bananas	0.4%	Milk: Cattle	0.2%	Tomatoes	0.2%	1%
	3%	FR child 3 15 yr	1.49	1.0%	Bananas	0.5%	Milk: Cattle	0.4%	Tomatoes	0.3%	2%
	3%	GEMS/Food G07	1.44	0.6%	Bananas	0.5%	Tomatoes	0.4%	Wine grapes	0.3%	2%
	3%	DK child	1.41	2%	Bananas	0.3%	Milk: Cattle	0.2%	Tomatoes	0.3%	1.0%
	3%	FI 3 yr	1.39	2%	Bananas	0.2%	Tomatoes	0.1%	Strawberries	0.1%	0.8%
	3%	ES child	1.38	1%	Bananas	0.4%	Tomatoes	0.2%	Milk: Cattle	0.3%	1%
	3%	FR adult	1.37	1%	Tea (dried leaves of Camellia sinensis)	0.7%	Wine grapes	0.2%	Bananas	0.2%	2%
	3%	GEMS/Food G15	1.37	0.6%	Bananas	0.5%	Tomatoes	0.3%	Wine grapes	0.3%	2%
	3%	RO general	1.37	0.8%	Tomatoes	0.5%	Wine grapes	0.3%	Bananas	0.2%	2%
	3%	GEMS/Food G08	1.36	0.5%	Bananas	0.5%	Tomatoes	0.3%	Wine grapes	0.3%	2%
	3%	GEMS/Food G10	1.27	0.6%	Tomatoes	0.5%	Bananas	0.3%	Tea (dried leaves of Camellia sinens	0.3%	2%
	3%	GEMS/Food G11	1.27	0.4%	Bananas	0.4%	Tomatoes	0.3%	Tea (dried leaves of Camellia sinens	0.3%	2%
	2%	DE women 14-50 yr	1.16	0.4%	Bananas	0.3%	Tomatoes	0.2%	Milk: Cattle	0.3%	2%
	2%	FR toddler 2 3 yr	1.14	0.8%	Bananas	0.6%	Milk: Cattle	0.2%	Tomatoes	0.2%	1%
	2%	DE general	1.10	0.4%	Bananas	0.3%	Tomatoes	0.2%	Milk: Cattle	0.2%	2%
	2%	PT general	1.10	0.7%	Wine grapes	0.5%	Bananas	0.4%	Tomatoes	0.1%	2%
	2%	IT toddler	0.97	0.8%	Bananas	0.6%	Tomatoes	0.1%	Wheat	0.2%	1%
	2%	NL general	0.91	0.4%	Bananas	0.3%	Tea (dried leaves of Camellia sinensis)	0.2%	Tomatoes	0.2%	1%
	2%	UK vegetarian	0.90	0.5%	Bananas	0.4%	Tea (dried leaves of Camellia sinensis)	0.3%	Tomatoes	0.1%	1%
	2%	FI 6 yr	0.88	1%	Bananas	0.2%	Tomatoes	0.1%	Strawberries	0.1%	0.6%
	2%	UK adult	0.87	0.5%	Bananas	0.4%	Tea (dried leaves of Camellia sinensis)	0.3%	Wine grapes	0.1%	1%
	2%	DK adult	0.81	0.6%	Bananas	0.3%	Wine grapes	0.2%	Tomatoes	0.1%	0.9%
	2%	ES adult	0.78	0.5%	Bananas	0.3%	Tomatoes	0.1%	Wine grapes	0.1%	0.9%
	2%	FI adult	0.77	0.6%	Coffee beans	0.4%	Bananas	0.2%	Tomatoes	0.6%	0.5%
	1%	IT adult	0.64	0.5%	Tomatoes	0.3%	Bananas	0.1%	Peaches	0.1%	0.9%
	1%	PL general	0.52	0.4%	Tomatoes	0.3%	Bananas	0.1%	Table grapes	0.0%	0.8%
	1%	FR infant	0.51	0.3%	Milk: Cattle	0.3%	Bananas	0.0%	Strawberries	0.1%	0.7%
	0.7%	LT adult	0.36	0.3%	Tomatoes	0.1%	Bananas	0.1%	Milk: Cattle	0.1%	0.6%
	0.5%	IE child	0.27	0.3%	Bananas	0.1%	Milk: Cattle	0.0%	Currants (red, black and white)	0.0%	0.2%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Pyriproxyfen (F) is unlikely to present a public health concern.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Table grapes	3 / 1.9	139
7%	Bananas	0.7 / 0.7	68
2%	Peaches	0.5 / 0.24	23
2%	Tomatoes	0.7 / 0.38	22
2%	Wine grapes	3 / 1.9	18
2%	Sweet peppers/bell peppers	0.6 / 0.28	17
1%	Head cabbages	0.6 / 0.33	15
1%	Tea (dried leaves of Camellia sinensis)	15 / 9.24	14
0.8%	Plums	0.3 / 0.2	8.4
0.8%	Cauliflowers	0.3 / 0.14	8.1
0.8%	Cherries (sweet)	1.5 / 0.62	7.6
0.7%	Aubergines/egg plants	0.6 / 0.28	7.0
0.7%	Apricots	0.5 / 0.2	7.0
0.7%	Strawberries	0.7 / 0.41	6.7
0.6%	Papayas	0.3 / 0.15	6.4

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Table grapes	3 / 1.9	64
5%	Wine grapes	3 / 1.9	45
1%	Bananas	0.7 / 0.7	15
1%	Head cabbages	0.6 / 0.33	14
0.8%	Red mustards	4 / 1.6	8.5
0.8%	Aubergines/egg plants	0.6 / 0.28	7.6
0.6%	Cherries (sweet)	1.5 / 0.62	6.2
0.6%	Tomatoes	0.7 / 0.38	6.0
0.6%	Blueberries	1.5 / 0.62	5.7
0.5%	Tea (dried leaves of Camellia sinensis)	15 / 9.24	4.6
0.5%	Sweet peppers/bell peppers	0.6 / 0.28	4.6
0.4%	Peaches	0.5 / 0.24	4.5
0.4%	Currants (red, black and white)	1.5 / 0.62	4.1
0.4%	Strawberries	0.7 / 0.41	3.8
0.4%	Plums	0.3 / 0.2	3.6

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Currants (red, black and white) / juice	1.5 / 0.37	10
1%	Oranges / juice	0.7 / 0.19	10
1.0%	Cauliflowers / boiled	0.3 / 0.14	9.7
0.6%	Wine grapes / juice	3 / 0.15	6.3
0.6%	Peaches / canned	1 / 0.24	6.2
0.4%	Tomatoes / juice	0.7 / 0.21	4.0
0.3%	Peaches / juice	0.5 / 0.16	2.7
0.2%	Tomatoes / sauce/puree	0.7 / 0.21	2.0
0.2%	Beans (with pods) / boiled	0.1 / 0.13	1.6
0.1%	Tea (dried leaves of Camellia sinensis) / infusion	15 / 0.04	1.4
0.1%	Rose hips / jam	1.5 / 0.37	1.1
0.1%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.1%	Potatoes / fried	0.01 / 0.01	0.93
0.1%	Pumpkins / boiled	0.01 / 0.01	0.89
0.1%	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): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wine grapes / wine	3 / 1.9	18
1%	Table grapes / raisins	3 / 8.93	11
0.6%	Cauliflowers / boiled	0.3 / 0.14	5.8
0.5%	Currants (red, black and white) / juice	1.5 / 0.37	4.7
0.3%	Wine grapes / juice	3 / 0.15	3.0
0.3%	Oranges / juice	0.7 / 0.19	2.9
0.2%	Grapefruits / juice	0.7 / 0.19	2.1
0.2%	Peaches / canned	0.5 / 0.24	1.9
0.2%	Tomatoes / sauce/puree	0.7 / 0.21	1.7
0.08%	Tea (dried leaves of Camellia sinensis) / infusion	15 / 0.04	0.82
0.06%	Pumpkins / boiled	0.01 / 0.01	0.55
0.05%	Courgettes / boiled	0.04 / 0.02	0.46
0.05%	Rose hips / jam	1.5 / 0.37	0.46
0.04%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.04%	Lemons / juice	0.7 / 0.19	0.36

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

EFSA PRIMo revision 3.1; 2021/01/06

Cyprodinil (F)

LOQs (mg/kg) range from:	0.02	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	2
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2025	Year of evaluation:	2025

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
56%	NL toddler	16.83	17%	Apples	7%	Spinaches	7%	Pears	0.0%	56%
43%	DE child	12.85	20%	Apples	3%	Table grapes	2%	Spinaches	0.0%	43%
29%	GEMS/Food G11	8.61	8%	Celeries	2%	Apples	2%	Wine grapes	0.0%	29%
28%	NL child	8.52	9%	Apples	3%	Spinaches	2%	Table grapes	0.0%	28%
24%	GEMS/Food G07	7.30	4%	Celeries	3%	Wine grapes	2%	Lettuces	0.0%	24%
23%	GEMS/Food G08	6.80	2%	Wine grapes	2%	Barley	2%	Lettuces	0.0%	23%
20%	IE adult	6.15	4%	Celeries	3%	Wine grapes	1%	Spinaches	0.0%	20%
20%	GEMS/Food G10	6.14	3%	Lettuces	2%	Wheat	2%	Celeries	0.0%	20%
20%	GEMS/Food G15	5.98	2%	Celeries	2%	Wine grapes	2%	Wheat	0.0%	20%
20%	GEMS/Food G06	5.86	3%	Wheat	2%	Table grapes	2%	Tomatoes	0.0%	20%
18%	DK child	5.41	4%	Apples	2%	Rye	2%	Carrots	0.0%	18%
17%	FR child 3 15 yr	5.23	3%	Apples	2%	Wheat	2%	Milk: Cattle	0.0%	17%
17%	FR toddler 2 3 yr	5.12	5%	Apples	2%	Milk: Cattle	2%	Spinaches	0.0%	17%
17%	IT adult	5.00	4%	Lettuces	2%	Wheat	2%	Other lettuce and other salad plants	0.0%	17%
16%	IT toddler	4.84	3%	Lettuces	3%	Wheat	1%	Apples	0.0%	16%
16%	ES adult	4.76	6%	Lettuces	1%	Apples	1%	Barley	0.0%	16%
16%	SE general	4.71	4%	Lettuces	2%	Apples	1%	Wheat	0.0%	16%
15%	DE women 14-50 yr	4.63	4%	Apples	2%	Wine grapes	1%	Lettuces	0.0%	15%
15%	DE general	4.55	4%	Apples	2%	Wine grapes	1%	Barley	0.0%	15%
15%	ES child	4.54	4%	Lettuces	2%	Wheat	2%	Apples	0.0%	15%
15%	PT general	4.50	6%	Wine grapes	2%	Wheat	2%	Apples	0.0%	15%
14%	RO general	4.34	4%	Wine grapes	2%	Apples	2%	Wheat	0.0%	14%
14%	FR adult	4.27	5%	Wine grapes	2%	Other lettuce and other salad plants	1%	Apples	0.0%	14%
14%	NL general	4.13	2%	Apples	2%	Spinaches	1%	Wine grapes	0.0%	14%
13%	UK infant	3.99	3%	Milk: Cattle	3%	Apples	2%	Carrots	0.0%	13%
13%	FR infant	3.98	3%	Spinaches	3%	Apples	2%	Carrots	0.0%	13%
12%	UK toddler	3.73	3%	Apples	2%	Wheat	1%	Milk: Cattle	0.0%	12%
11%	FI 3 yr	3.41	2%	Apples	1%	Oat	1%	Carrots	0.0%	11%
9%	UK vegetarian	2.81	2%	Wine grapes	1%	Lettuces	1.0%	Celeries	0.0%	9%
9%	DK adult	2.75	2%	Wine grapes	2%	Apples	0.9%	Lettuces	0.0%	9%
9%	FI 6 yr	2.63	0.9%	Strawberries	0.9%	Apples	0.9%	Carrots	0.0%	9%
8%	PL general	2.34	3%	Apples	0.7%	Table grapes	0.5%	Tomatoes	0.0%	8%
8%	UK adult	2.32	2%	Wine grapes	1%	Lettuces	0.7%	Wheat	0.0%	8%
7%	LT adult	2.17	3%	Apples	0.7%	Lettuces	0.5%	Rye		7%
7%	FI adult	1.96	1%	Lettuces	0.9%	Apples	0.7%	Wine grapes	0.0%	7%
3%	IE child	0.78	0.5%	Apples	0.5%	Wheat	0.3%	Carrots	0.0%	3%

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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Uni

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Celeries	30 / 16	599
18%	Escaroles/broad-leaved	15 / 8.9	358
17%	Lettuces	15 / 8.9	339
10%	Spinaches	15 / 8.9	201
9%	Granate	5 / 3.4	187
9%	Pears	2 / 1.3	180
8%	Table grapes	3 / 2.3	168
8%	Peaches	2 / 1.7	162
7%	Apples	2 / 1.3	140
7%	Chards/beet leaves	15 / 8.9	139
4%	Plums	2 / 1.7	72
3%	Carrots	1.5 / 1.04	66
3%	Cauliflowers	2 / 1.1	64
3%	Strawberries	5 / 3.74	61
3%	Kaki/Japanese persimmons	2 / 1.3	61

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
13%	Celeries	30 / 16	256
9%	Escaroles/broad-leaved	15 / 8.9	179
8%	Chards/beet leaves	15 / 8.9	168
5%	Lettuces	15 / 8.9	108
4%	Table grapes	3 / 2.3	78
3%	Granate	5 / 3.4	60
3%	Wine grapes	3 / 2.3	55
2%	Red mustards	15 / 8.9	47
2%	Pears	2 / 1.3	40
2%	Blueberries	8 / 4.1	37
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

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Escaroles/broad-leaved endi	15 / 8.9	590
14%	Chards/beet leaves / boiled	15 / 8.9	277
6%	Spinaches / frozen; boiled	15 / 8.9	124
4%	Broccoli / boiled	2 / 1.1	87
4%	Florence fennels / boiled	4 / 1.71	78
4%	Cauliflowers / boiled	2 / 1.1	77
3%	Parsnips / boiled	1.5 / 1.04	53
2%	Beetroots / boiled	1.5 / 1.04	46
2%	Peaches / canned	2 / 1.7	44
2%	Pumpkins / boiled	0.6 / 0.36	32
1%	Rhubarbs / sauce/puree	2 / 0.79	29
1%	Wine grapes / juice	3 / 0.67	29
1%	Currants (red, black and whit	8 / 1.02	29
1%	Salsifies / boiled	1.5 / 1.04	27
1%	Apples / juice	2 / 0.48	26

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)
27%	Celeries / boiled	30 / 16	540
9%	Escaroles/broad-leaved	15 / 8.9	182
6%	Chards/beet leaves / boiled	15 / 8.9	111
4%	Spinaches / frozen; boiled	15 / 8.9	74
2%	Cauliflowers / boiled	2 / 1.1	46
2%	Beetroots / boiled	1.5 / 1.04	40
2%	Purslanes / boiled	15 / 8.9	37
2%	Florence fennels / boiled	4 / 1.71	33
1%	Broccoli / boiled	2 / 1.1	26
1%	Parsnips / boiled	1.5 / 1.04	22
1%	Wine grapes / wine	3 / 2.3	22
1.0%	Pumpkins / boiled	0.6 / 0.36	20
0.8%	Apples / juice	2 / 0.48	16
0.7%	Wine grapes / juice	3 / 0.67	14
0.7%	Peaches / canned	2 / 1.7	14

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.

EFSA PRIMo revision 3.1; 2021/01/06

Pyraclostrobin (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2004	Year of evaluation:	2004

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)	22%	NL toddler	6.55	5%	Apples	4%	Milk: Cattle	2%	Pears	0.1%	22%
	16%	DE child	4.75	6%	Apples	1%	Table grapes	1%	Milk: Cattle	0.3%	16%
	13%	NL child	3.77	3%	Apples	2%	Milk: Cattle	1%	Sugar beet roots	0.2%	13%
	9%	GEMS/Food G11	2.76	2%	Wine grapes	0.9%	Barley	0.7%	Apples	0.2%	9%
	9%	GEMS/Food G07	2.76	2%	Wine grapes	0.7%	Barley	0.5%	Apples	0.2%	9%
	9%	FR child 3 15 yr	2.74	1%	Milk: Cattle	0.9%	Other lettuce and other salad plants	0.9%	Oranges	0.3%	9%
	9%	GEMS/Food G08	2.71	2%	Wine grapes	1%	Barley	0.6%	Apples	0.2%	9%
	9%	GEMS/Food G15	2.56	2%	Wine grapes	0.9%	Barley	0.5%	Apples	0.2%	9%
	8%	IE adult	2.48	2%	Wine grapes	0.4%	Other other small fruit & berries	0.3%	Blackberries	0.1%	8%
	8%	FR adult	2.39	4%	Wine grapes	1%	Other lettuce and other salad plants	0.4%	Apples	0.1%	8%
	8%	DE women 14-50 yr	2.38	1%	Wine grapes	1%	Apples	0.8%	Milk: Cattle	0.1%	8%
	8%	FR toddler 2 3 yr	2.38	2%	Milk: Cattle	1%	Apples	0.4%	Sugar beet roots	0.2%	8%
	8%	GEMS/Food G06	2.37	1%	Tomatoes	1%	Table grapes	0.5%	Wheat	0.1%	8%
	8%	DE general	2.37	1%	Wine grapes	1%	Apples	0.8%	Milk: Cattle	0.1%	8%
	8%	RO general	2.36	3%	Wine grapes	0.7%	Milk: Cattle	0.7%	Apples	0.2%	8%
	8%	GEMS/Food G10	2.31	0.7%	Barley	0.7%	Wine grapes	0.5%	Cress and other sprouts and shoots	0.2%	8%
	7%	PT general	2.16	4%	Wine grapes	0.5%	Apples	0.4%	Potatoes		7%
	7%	UK infant	2.10	2%	Milk: Cattle	0.7%	Apples	0.5%	Carrots	0.3%	7%
	7%	DK child	2.01	1%	Apples	0.8%	Cucumbers	0.8%	Milk: Cattle	0.2%	7%
	6%	UK toddler	1.94	1%	Milk: Cattle	0.8%	Apples	0.5%	Oranges	0.2%	6%
	6%	NL general	1.75	0.9%	Wine grapes	0.7%	Apples	0.5%	Milk: Cattle	0.1%	6%
	6%	SE general	1.71	0.8%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Apples	0.1%	6%
	5%	ES child	1.58	0.8%	Milk: Cattle	0.5%	Oranges	0.5%	Apples	0.3%	5%
	5%	FI 3 yr	1.46	0.7%	Oat	0.5%	Raspberries (red and yellow)	0.5%	Cucumbers		5%
	5%	ES adult	1.46	0.7%	Wine grapes	0.6%	Barley	0.5%	Lettuces	0.2%	5%
	4%	FR infant	1.32	1%	Milk: Cattle	0.8%	Apples	0.4%	Carrots	0.1%	4%
	4%	DK adult	1.32	2%	Wine grapes	0.4%	Apples	0.3%	Milk: Cattle	0.1%	4%
	4%	IT adult	1.29	1%	Other lettuce and other salad plants	0.4%	Tomatoes	0.4%	Apples		4%
	4%	IT toddler	1.26	0.9%	Other lettuce and other salad plants	0.5%	Tomatoes	0.4%	Wheat		4%
	4%	UK vegetarian	1.13	1%	Wine grapes	0.3%	Apples	0.2%	Oranges	0.1%	4%
	4%	UK adult	1.13	2%	Wine grapes	0.2%	Apples	0.2%	Milk: Cattle	0.1%	4%
	3%	FI 6 yr	1.03	0.4%	Raspberries (red and yellow)	0.4%	Oat	0.4%	Cucumbers		3%
	3%	LT adult	0.89	0.9%	Apples	0.3%	Milk: Cattle	0.2%	Potatoes	0.1%	3%
	3%	FI adult	0.88	0.5%	Wine grapes	0.5%	Coffee beans	0.3%	Apples		3%
	3%	PL general	0.84	1.0%	Apples	0.3%	Table grapes	0.3%	Tomatoes		3%
	1%	IE child	0.36	0.2%	Milk: Cattle	0.2%	Apples	0.1%	Swine: Fat tissue	0.1%	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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European U

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
103%	Lettuces	2 / 0.81	31
92%	Mangoes	0.6 / 0.35	28
90%	Cucumbers	0.5 / 0.41	27
89%	Kales	1.5 / 0.61	27
84%	Globe artichokes	3 / 1.44	25
80%	Oranges	2 / 0.18	24
76%	Celeries	1.5 / 0.61	23
75%	Chinese cabbages/pe-tsai	1.5 / 0.7	22
73%	Apricots	1 / 0.63	22
73%	Melons	0.5 / 0.15	22
73%	Table grapes	0.3 / 0.3	22
64%	Cherries (sweet)	3 / 1.57	19
60%	Sweet peppers/bell peppers	0.5 / 0.3	18
59%	Watermelons	0.5 / 0.15	18
57%	Pears	0.5 / 0.29	17

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
100%	Wine grapes	2 / 1.27	30
74%	Red mustards	10 / 4.16	22
63%	Blueberries	4 / 2.08	19
62%	Globe artichokes	3 / 1.44	19
59%	Chinese cabbages/pe-tsai	1.5 / 0.7	18
52%	Cherries (sweet)	3 / 1.57	16
51%	Chards/beet leaves	1.5 / 0.81	15
46%	Currants (red, black and	3 / 2.1	14
39%	Kales	1.5 / 0.61	12
38%	Cucumbers	0.5 / 0.41	11
38%	Florence fennels	1.5 / 0.61	11
36%	Blackberries	3 / 1.32	11
34%	Table grapes	0.3 / 0.3	10
33%	Lettuces	2 / 0.81	9.8
33%	Celeries	1.5 / 0.61	9.8

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
95%	Oranges / juice	2 / 0.54	28
92%	Florence fennels / boiled	1.5 / 0.61	28
90%	Currants (red, black and wh	3 / 0.94	27
86%	Pumpkins / boiled	0.5 / 0.29	26
84%	Chards/beet leaves / boiled	1.5 / 0.81	25
62%	Escaroles/broad-leaved end	0.4 / 0.28	19
56%	Kales / boiled	1.5 / 0.61	17
55%	Leeks / boiled	0.8 / 0.29	17
50%	Elderberries / juice	3 / 0.94	15
50%	Broccoli / boiled	0.5 / 0.19	15
44%	Cauliflowers / boiled	0.5 / 0.19	13
34%	Raspberries / juice	3 / 0.87	10
32%	Courgettes / boiled	0.5 / 0.27	9.6
30%	Parsnips / boiled	0.5 / 0.18	9.1
26%	Pineapples / canned	0.3 / 0.19	7.8

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)
69%	Celeries / boiled	1.5 / 0.61	21
53%	Pumpkins / boiled	0.5 / 0.29	16
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
27%	Oranges / juice	2 / 0.54	8.2
26%	Cauliflowers / boiled	0.5 / 0.19	7.9
21%	Courgettes / boiled	0.5 / 0.27	6.2
20%	Grapefruits / juice	2 / 0.54	5.9
19%	Onions / boiled	1.5 / 0.62	5.8
19%	Escaroles/broad-leaved	0.4 / 0.28	5.7
17%	Leeks / boiled	0.8 / 0.29	5.1
16%	Apples / juice	0.5 / 0.14	4.7
15%	Broccoli / boiled	0.5 / 0.19	4.6

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.

EFSA PRIMo revision 3.1; 2021/01/06

Fludioxonil (F)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.37	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2024	Year of evaluation:	2024

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)	21%	NL toddler	78.62	6%	Apples	3%	Oranges	2%	Pears	0.0%	21%
	18%	DE child	67.92	7%	Apples	6%	Oranges	1%	Potatoes	0.0%	18%
	14%	NL child	50.19	3%	Apples	3%	Sugar beet roots	2%	Oranges	0.0%	14%
	11%	IE adult	39.75	4%	Sweet potatoes	1%	Oranges	1.0%	Grapefruits	0.0%	11%
	10%	FR child 3 15 yr	35.33	5%	Oranges	1%	Sugar beet roots	1.0%	Apples	0.0%	10%
	8%	FR toddler 2 3 yr	31.18	2%	Oranges	2%	Apples	1%	Mandarins	0.0%	8%
	8%	DE women 14-50 yr	29.53	3%	Oranges	1%	Apples	1%	Sugar beet roots	0.0%	8%
	8%	UK toddler	28.27	3%	Oranges	1%	Potatoes	1.0%	Apples	0.0%	8%
	7%	DE general	26.46	2%	Oranges	1%	Apples	1%	Sugar beet roots	0.0%	7%
	7%	GEMS/Food G11	26.06	2%	Potatoes	1%	Oranges	0.9%	Apples	0.0%	7%
	7%	ES child	26.02	3%	Oranges	0.9%	Lettuces	0.7%	Potatoes	0.0%	7%
	7%	GEMS/Food G07	25.53	2%	Oranges	2%	Potatoes	0.6%	Apples	0.0%	7%
	7%	SE general	25.42	2%	Potatoes	1%	Oranges	0.9%	Lettuces	0.0%	7%
	6%	GEMS/Food G10	23.56	2%	Oranges	1%	Potatoes	0.7%	Lettuces	0.0%	6%
	6%	GEMS/Food G06	23.12	1%	Oranges	0.8%	Potatoes	0.6%	Tomatoes	0.0%	6%
	6%	GEMS/Food G08	21.66	2%	Potatoes	0.7%	Apples	0.7%	Oranges	0.0%	6%
	6%	NL general	21.61	1%	Oranges	1.0%	Potatoes	0.9%	Sugar beet roots	0.0%	6%
	6%	UK infant	21.18	2%	Oranges	1%	Potatoes	0.9%	Apples	0.0%	6%
	5%	ES adult	20.04	2%	Oranges	1%	Lettuces	0.4%	Apples	0.0%	5%
	5%	PT general	20.03	2%	Potatoes	0.9%	Oranges	0.6%	Apples	0.0%	5%
	5%	GEMS/Food G15	19.04	1%	Potatoes	1.0%	Oranges	0.6%	Apples	0.0%	5%
	5%	DK child	16.90	1%	Apples	1.0%	Potatoes	0.4%	Carrots	0.0%	5%
	5%	FI 3 yr	16.88	2%	Potatoes	0.6%	Mandarins	0.5%	Apples	0.0%	5%
	5%	RO general	16.83	2%	Potatoes	0.8%	Apples	0.4%	Oranges	0.0%	5%
	4%	IT toddler	15.55	0.7%	Oranges	0.7%	Lettuces	0.5%	Apples	0.0%	4%
	4%	IT adult	15.05	0.8%	Lettuces	0.5%	Oranges	0.5%	Apples	0.0%	4%
	4%	FR infant	14.88	1.0%	Apples	0.8%	Potatoes	0.4%	Spinaches	0.0%	4%
	4%	FI 6 yr	14.05	2%	Potatoes	0.5%	Mandarins	0.3%	Apples	0.0%	4%
	4%	PL general	13.10	1%	Potatoes	1%	Apples	0.2%	Pears	0.0%	4%
	3%	UK vegetarian	12.87	1%	Oranges	0.6%	Potatoes	0.3%	Apples	0.0%	3%
	3%	FR adult	12.03	0.8%	Oranges	0.4%	Apples	0.3%	Potatoes	0.0%	3%
	3%	LT adult	11.20	1%	Potatoes	1%	Apples	0.1%	Lettuces	0.0%	3%
	3%	UK adult	10.06	0.8%	Oranges	0.6%	Potatoes	0.3%	Lettuces	0.0%	3%
	2%	FI adult	9.22	0.6%	Oranges	0.5%	Potatoes	0.3%	Apples	0.1%	2%
	2%	DK adult	9.22	0.5%	Apples	0.5%	Potatoes	0.2%	Oranges	0.0%	2%
	0.8%	IE child	2.89	0.2%	Potatoes	0.2%	Apples	0.1%	Oranges	0.0%	0.8%

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
103%	Oranges	10 / 7.8	1034
84%	Lettuces	40 / 22	838
61%	Grapefruits	10 / 7.8	612
59%	Kiwi fruits (green, red,	15 / 9.5	591
52%	Peaches	10 / 5.5	523
46%	Mandarins	10 / 7.8	462
46%	Escaroles/broad-leaved	20 / 11.42	459
45%	Potatoes	5 / 2.9	446
39%	Pears	5 / 2.8	388
36%	Spinaches	30 / 16	362
32%	Chinese cabbages/pe-tsai	10 / 10	321
30%	Apples	5 / 2.8	302
29%	Pineapples	7 / 2.84	287
27%	Table grapes	5 / 3.73	272
27%	Lemons	10 / 7.8	267

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
27%	Lettuces	40 / 22	267
25%	Chinese cabbages/pe-tsai	10 / 10	253
24%	Oranges	10 / 7.8	239
23%	Escaroles/broad-leaved	20 / 11.42	230
22%	Chards/beet leaves	20 / 11.42	216
16%	Yams	10 / 5.7	162
14%	Mandarins	10 / 7.8	140
14%	Grapefruits	10 / 7.8	139
13%	Kiwi fruits (green, red,	15 / 9.5	132
13%	Table grapes	5 / 3.73	126
12%	Sweet potatoes	10 / 5.7	118
10%	Peaches	10 / 5.5	103
9%	Potatoes	5 / 2.9	87
9%	Pears	5 / 2.8	86
8%	Pineapples	7 / 2.84	84

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
76%	Escaroles/broad-leaved end	20 / 11.42	757
36%	Chards/beet leaves / boiled	20 / 11.42	355
29%	Sweet potatoes / boiled	10 / 5.7	287
28%	Oranges / juice	10 / 5.3	280
27%	Potatoes / fried	5 / 2.9	271
22%	Spinaches / frozen; boiled	30 / 16	223
14%	Peaches / canned	10 / 5.5	143
13%	Kiwi fruits / juice	15 / 7.3	131
12%	Sugar beets (root) / sugar	4 / 13.32	122
12%	Pineapples / canned	7 / 2.84	116
11%	Apples / juice	5 / 2.1	114
9%	Potatoes / dried (flakes)	5 / 6.9	89
8%	Parsnips / boiled	1 / 1.51	77
7%	Pears / juice	5 / 2.1	68
7%	Beetroots / boiled	1 / 1.51	67

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)
23%	Escaroles/broad-leaved	20 / 11.42	233
14%	Chards/beet leaves / boiled	20 / 11.42	143
13%	Spinaches / frozen; boiled	30 / 16	132
9%	Sweet potatoes / boiled	10 / 5.7	88
8%	Oranges / juice	10 / 5.3	80
7%	Apples / juice	5 / 2.1	70
6%	Beetroots / boiled	1 / 1.51	59
6%	Grapefruits / juice	10 / 5.3	58
5%	Sugar beets (root) / sugar	4 / 13.32	49
5%	Purslanes / boiled	20 / 11.42	47
4%	Peaches / canned	10 / 5.5	45
4%	Pineapples / canned	7 / 2.84	37
3%	Parsnips / boiled	1 / 1.51	32
3%	Wine grapes / wine	4 / 2.65	25
2%	Table grapes / raisins	4 / 17.53	21

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.

EFSA PRIMo revision 3.1; 2021/01/06

Trifloxystrobin (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	0.5
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: With input values on escarole derived from the indoor use leading to MRL propoal of 30 mg/kg

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)	12%	NL toddler	11.80	5%	Spinaches	1%	Milk: Cattle	1%	Apples		12%
	7%	DE child	6.94	2%	Spinaches	1%	Apples	0.5%	Oranges		7%
	6%	NL child	5.70	2%	Spinaches	0.6%	Apples	0.5%	Milk: Cattle		6%
	4%	FR child 3 15 yr	3.74	0.8%	Spinaches	0.5%	Milk: Cattle	0.4%	Oranges		4%
	4%	GEMS/Food G10	3.70	0.9%	Lettuces	0.4%	Spinaches	0.2%	Parsley		4%
	4%	FR toddler 2 3 yr	3.67	1%	Spinaches	0.6%	Milk: Cattle	0.3%	Apples		4%
	4%	ES child	3.55	1%	Lettuces	0.6%	Spinaches	0.2%	Milk: Cattle		4%
	3%	SE general	3.47	1%	Lettuces	0.5%	Spinaches	0.2%	Milk: Cattle		3%
	3%	GEMS/Food G06	3.43	0.4%	Spinaches	0.3%	Wheat	0.3%	Lettuces		3%
	3%	GEMS/Food G11	3.38	0.7%	Spinaches	0.2%	Lamb's lettuce/corn salads	0.2%	Lettuces		3%
	3%	IE adult	3.38	1.0%	Spinaches	0.2%	Lettuces	0.2%	Wine grapes		3%
	3%	IT adult	3.33	1%	Lettuces	0.7%	Spinaches	0.4%	Other lettuce and other salad plants		3%
	3%	GEMS/Food G07	3.31	0.7%	Lettuces	0.3%	Spinaches	0.2%	Wine grapes		3%
	3%	FR infant	3.28	2%	Spinaches	0.3%	Milk: Cattle	0.2%	Apples		3%
	3%	ES adult	3.26	2%	Lettuces	0.6%	Spinaches	0.1%	Oranges		3%
	3%	GEMS/Food G08	3.22	0.6%	Lettuces	0.2%	Spinaches	0.2%	Lamb's lettuce/corn salads		3%
	3%	NL general	3.15	1%	Spinaches	0.3%	Escaroles/broad-leaved endives	0.3%	Lettuces		3%
	3%	DE women 14-50 yr	2.96	0.4%	Spinaches	0.3%	Lettuces	0.3%	Apples		3%
	3%	IT toddler	2.78	0.8%	Lettuces	0.4%	Spinaches	0.3%	Other lettuce and other salad plants		3%
	3%	DE general	2.76	0.3%	Spinaches	0.3%	Lettuces	0.3%	Apples		3%
	3%	GEMS/Food G15	2.67	0.3%	Lettuces	0.2%	Wheat	0.2%	Wine grapes		3%
	2%	DK child	2.26	0.4%	Lettuces	0.3%	Apples	0.3%	Milk: Cattle		2%
	2%	UK toddler	2.23	0.4%	Milk: Cattle	0.2%	Oranges	0.2%	Spinaches		2%
	2%	FR adult	2.21	0.4%	Other lettuce and other salad plants	0.4%	Spinaches	0.3%	Wine grapes		2%
	2%	UK infant	2.19	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Oranges		2%
	2%	RO general	2.03	0.3%	Wine grapes	0.2%	Head cabbages	0.2%	Milk: Cattle		2%
	2%	PT general	1.85	0.4%	Wine grapes	0.3%	Lettuces	0.2%	Wheat		2%
	2%	FI 3 yr	1.77	0.5%	Spinaches	0.1%	Strawberries	0.1%	Raspberries (red and yellow)		2%
	2%	UK vegetarian	1.60	0.4%	Lettuces	0.3%	Spinaches	0.1%	Wine grapes		2%
	2%	FI 6 yr	1.53	0.4%	Spinaches	0.2%	Lettuces	0.1%	Strawberries		2%
	1%	UK adult	1.33	0.3%	Lettuces	0.2%	Wine grapes	0.1%	Spinaches		1%
	1%	DK adult	1.24	0.3%	Lettuces	0.1%	Wine grapes	0.1%	Milk: Cattle		1%
	1%	FI adult	1.05	0.4%	Lettuces	0.1%	Spinaches	0.1%	Apples		1%
	1.0%	LT adult	0.99	0.2%	Apples	0.2%	Lettuces	0.1%	Milk: Cattle		1.0%
	0.9%	PL general	0.89	0.2%	Apples	0.1%	Tomatoes	0.1%	Potatoes		0.9%
	0.4%	IE child	0.40	0.1%	Milk: Cattle	0.0%	Rice	0.0%	Wheat		0.4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Trifloxystrobin (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
80%	Escaroles/broad-leaved endives	15 / 10	402
76%	Lettuces	15 / 10	381
45%	Spinaches	20 / 10	226
39%	Celeries	15 / 5.2	195
38%	Peaches	3 / 2	190
32%	Table grapes	3 / 2.2	160
17%	Plums	3 / 2	84
14%	Apricots	3 / 2	70
12%	Pears	0.7 / 0.44	61
9%	Apples	0.7 / 0.44	47
9%	Kales	2 / 1.05	46
9%	Leeks	0.9 / 0.73	43
7%	Melons	0.3 / 0.24	36
7%	Sweet peppers/bell peppers	0.9 / 0.55	33
6%	Watermelons	0.3 / 0.24	29

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)
40%	Escaroles/broad-leaved endives	15 / 10	202
24%	Lettuces	15 / 10	121
17%	Celeries	15 / 5.2	83
15%	Table grapes	3 / 2.2	75
11%	Red mustards	15 / 10	53
10%	Wine grapes	3 / 2.2	52
8%	Spinaches	20 / 10	40
7%	Peaches	3 / 2	37
7%	Plums	3 / 2	36
4%	Apricots	3 / 2	22
4%	Parsley	30 / 18.09	22
4%	Kales	2 / 1.05	20
4%	Cherries (sweet)	3 / 2	20
4%	Blueberries	3 / 2.11	19
4%	Purslanes	15 / 10	19

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)
48%	Escaroles/broad-leaved endives / boiled	15 / 3.64	241
28%	Spinaches / frozen; boiled	20 / 10	139
10%	Peaches / canned	3 / 2	52
8%	Leeks / boiled	0.9 / 0.73	42
7%	Broccoli / boiled	0.6 / 0.43	34
6%	Kales / boiled	2 / 1.05	29
5%	Cauliflowers / boiled	0.5 / 0.39	27
4%	Pumpkins / boiled	0.3 / 0.24	21
2%	Currants (red, black and white) / juice	3 / 0.33	9.4
2%	Courgettes / boiled	0.3 / 0.24	8.5
1%	Raspberries / juice	3 / 0.62	7.3
1%	Wine grapes / juice	3 / 0.15	6.5
1%	Beans (with pods) / boiled	0.8 / 0.51	6.4
1%	Peaches / juice	3 / 0.38	6.3
1%	Oranges / juice	0.4 / 0.11	6.0

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)
35%	Celeries / boiled	15 / 5.2	176
17%	Spinaches / frozen; boiled	20 / 10	83
15%	Escaroles/broad-leaved endives / boiled	15 / 3.64	74
8%	Purslanes / boiled	15 / 10	41
4%	Wine grapes / wine	3 / 2.2	21
3%	Peaches / canned	3 / 2	16
3%	Cauliflowers / boiled	0.5 / 0.39	16
3%	Pumpkins / boiled	0.3 / 0.24	13
3%	Leeks / boiled	0.9 / 0.73	13
3%	Table grapes / raisins	3 / 10.34	13
2%	Broccoli / boiled	0.6 / 0.43	10
1%	Courgettes / boiled	0.3 / 0.24	5.5
0.8%	Currants (red, black and white) / juice	3 / 0.33	4.2
0.7%	Apples / juice	0.7 / 0.11	3.7
0.6%	Wine grapes / juice	3 / 0.15	3.1

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

EFSA PRIMo revision 3.1; 2021/01/06

Indoxacarb (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.005	ARfD (mg/kg bw):	0.005
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
98%	NL toddler	4.90	84%	Milk: Cattle	2%	Apples	1%	Maize/corn	12%	86%
60%	UK infant	3.00	54%	Milk: Cattle	0.7%	Potatoes	0.6%	Bovine: Muscle/meat	4%	56%
48%	FR toddler 2 3 yr	2.42	41%	Milk: Cattle	0.6%	Apples	0.6%	Bovine: Muscle/meat	5%	44%
45%	NL child	2.24	34%	Milk: Cattle	2%	Sugar beet roots	1%	Apples	8%	37%
42%	FR child 3 15 yr	2.11	32%	Milk: Cattle	1%	Swine: Fat tissue	0.9%	Other farmed animals: Muscle/mea	5%	37%
37%	DE child	1.86	28%	Milk: Cattle	2%	Apples	0.8%	Wheat	8%	29%
36%	UK toddler	1.80	29%	Milk: Cattle	2%	Bovine: Fat tissue	0.8%	Wheat	4%	32%
27%	FR infant	1.35	24%	Milk: Cattle	0.4%	Other farmed animals: Muscle/meat	0.4%	Potatoes	2%	25%
26%	ES child	1.30	17%	Milk: Cattle	1%	Swine: Fat tissue	1%	Other farmed animals: Muscle/mea	4%	22%
25%	DK child	1.23	18%	Milk: Cattle	1%	Swine: Muscle/meat	1%	Rye	5%	20%
24%	DE general	1.22	17%	Milk: Cattle	1%	Swine: Fat tissue	0.8%	Sugar beet roots	4%	20%
24%	DE women 14-50 yr	1.22	17%	Milk: Cattle	1.0%	Swine: Fat tissue	0.9%	Sugar beet roots	5%	20%
24%	SE general	1.19	17%	Milk: Cattle	2%	Bovine: Muscle/meat	0.8%	Potatoes	4%	20%
23%	GEMS/Food G11	1.14	11%	Milk: Cattle	3%	Swine: Fat tissue	1%	Bovine: Fat tissue	6%	17%
22%	RO general	1.12	16%	Milk: Cattle	1%	Wheat	0.7%	Potatoes	5%	18%
21%	GEMS/Food G15	1.07	10%	Milk: Cattle	4%	Swine: Fat tissue	0.9%	Wheat	5%	16%
19%	GEMS/Food G08	0.95	8%	Milk: Cattle	3%	Swine: Fat tissue	1%	Swine: Muscle/meat	6%	13%
18%	GEMS/Food G07	0.92	9%	Milk: Cattle	0.9%	Swine: Fat tissue	0.8%	Wheat	6%	13%
18%	NL general	0.88	12%	Milk: Cattle	0.6%	Sugar beet roots	0.5%	Swine: Muscle/meat	4%	14%
17%	GEMS/Food G10	0.86	8%	Milk: Cattle	0.9%	Bovine: Fat tissue	0.9%	Swine: Fat tissue	6%	12%
17%	IE adult	0.84	6%	Milk: Cattle	3%	Other farmed animals: Muscle/meat	1%	Tea (dried leaves of Camellia sinens	5%	12%
14%	DK adult	0.69	7%	Milk: Cattle	3%	Swine: Fat tissue	0.9%	Bovine: Fat tissue	2%	12%
13%	FR adult	0.63	6%	Milk: Cattle	1%	Tea (dried leaves of Camellia sinensis)	0.7%	Other farmed animals: Muscle/mea	3%	10%
12%	ES adult	0.62	7%	Milk: Cattle	0.9%	Other farmed animals: Muscle/meat	0.7%	Swine: Fat tissue	3%	10%
12%	GEMS/Food G06	0.60	3%	Milk: Cattle	1%	Wheat	0.7%	Tomatoes	7%	5%
10%	LT adult	0.51	6%	Milk: Cattle	2%	Swine: Fat tissue	0.6%	Potatoes	2%	8%
8%	IE child	0.40	5%	Milk: Cattle	2%	Swine: Fat tissue	0.2%	Wheat	0.7%	7%
7%	UK vegetarian	0.37	5%	Milk: Cattle	0.4%	Wheat	0.4%	Tea (dried leaves of Camellia sinens	2%	5%
7%	UK adult	0.37	4%	Milk: Cattle	0.4%	Tea (dried leaves of Camellia sinensis)	0.4%	Bovine: Fat tissue	2%	6%
7%	FI adult	0.35	6%	Coffee beans	0.2%	Potatoes	0.1%	Rye	7%	
4%	PT general	0.21	1%	Potatoes	0.8%	Wheat	0.5%	Wine grapes	4%	
4%	FI 3 yr	0.18	0.9%	Potatoes	0.3%	Bananas	0.2%	Wheat	4%	
3%	IT toddler	0.16	1%	Wheat	0.3%	Other cereals	0.3%	Tomatoes	3%	
3%	FI 6 yr	0.14	0.8%	Potatoes	0.2%	Cocoa beans	0.2%	Wheat	3%	
2%	IT adult	0.12	0.8%	Wheat	0.2%	Tomatoes	0.2%	Apples	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 Indoxacarb (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European U

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 7

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
339%	Poultry: Muscle/meat	0.1 / 1	17
242%	Swine: Muscle/meat	0.1 / 1	12
174%	Milk: Cattle	0.2 / 0.07	8.7
144%	Bovine: Muscle/meat	0.1 / 1	7.2
138%	Other farmed animals:	0.1 / 1	6.9
120%	Equine: Muscle/meat	0.1 / 1	6.0
109%	Sheep: Muscle/meat	0.1 / 1	5.4
79%	Bovine: Fat tissue	2 / 1.9	4.0
65%	Swine: Fat tissue	2 / 1.9	3.2
62%	Cranberries	1 / 0.69	3.1
34%	Milk: Goat	0.2 / 0.07	1.7
31%	Potatoes	0.01 / 0.01	1.5
30%	Melons	0.01 / 0.01	1.5
28%	Pears	0.01 / 0.01	1.4
27%	Oranges	0.01 / 0.01	1.3

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
235%	Poultry: Muscle	0.1 / 1	12
114%	Bovine: Muscle	0.1 / 1	5.7
112%	Other farmed animals:	0.1 / 1	5.6
97%	Swine: Muscle/meat	0.1 / 1	4.8
96%	Equine: Muscle/meat	0.1 / 1	4.8
95%	Sheep: Muscle/meat	0.1 / 1	4.7
77%	Swine: Fat tissue	2 / 1.9	3.9
54%	Milk: Cattle	0.2 / 0.07	2.7
37%	Bovine: Fat tissue	2 / 1.9	1.8
31%	Goat: Muscle	0.1 / 1	1.6
26%	Milk: Goat	0.2 / 0.07	1.3
21%	Milk: Sheep	0.2 / 0.07	1.1
16%	Cranberries	1 / 0.69	0.78
8%	Head cabbages	0.01 / 0.01	0.42
8%	Watermelons	0.01 / 0.01	0.41

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)
22%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
19%	Potatoes / fried	0.01 / 0.01	0.93
18%	Pumpkins / boiled	0.01 / 0.01	0.89
18%	Witloofs / boiled	0.01 / 0.01	0.89
17%	Cranberries / juice	1 / 0.15	0.87
16%	Broccoli / boiled	0.01 / 0.01	0.79
14%	Cauliflowers / boiled	0.01 / 0.01	0.70
13%	Escaroles/broad-leaved	0.01 / 0.01	0.66
12%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
11%	Leeks / boiled	0.01 / 0.01	0.57
11%	Apples / juice	0.01 / 0.01	0.54
11%	Oranges / juice	0.01 / 0.01	0.53
10%	Turnips / boiled	0.01 / 0.01	0.51
10%	Parsnips / boiled	0.01 / 0.01	0.51
10%	Sweet potatoes / boiled	0.01 / 0.01	0.50

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)
11%	Pumpkins / boiled	0.01 / 0.01	0.55
9%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
8%	Cauliflowers / boiled	0.01 / 0.01	0.42
8%	Beetroots / boiled	0.01 / 0.01	0.39
7%	Celeries / boiled	0.01 / 0.01	0.34
7%	Apples / juice	0.01 / 0.01	0.33
5%	Broccoli / boiled	0.01 / 0.01	0.24
5%	Coffee beans / extraction	0.05 / 0.01	0.24
5%	Courgettes / boiled	0.01 / 0.01	0.23
4%	Parsnips / boiled	0.01 / 0.01	0.21
4%	Kohlrabies / boiled	0.01 / 0.01	0.21
4%	Wine grapes / juice	0.01 / 0.01	0.21
4%	Escaroles/broad-leaved	0.01 / 0.01	0.20
4%	Florence fennels / boiled	0.01 / 0.01	0.19
4%	Turnips / boiled	0.01 / 0.01	0.19

Conclusion:
#N/A

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

EFSA PRIMo revision 3.1; 2021/01/06

Boscalid (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2026	Year of evaluation:	2026

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 2

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
159%	NL toddler	31.83	23%	Apples	20%	Spinaches	15%	Milk: Cattle		159%
103%	DE child	20.52	26%	Apples	10%	Table grapes	6%	Spinaches		103%
83%	NL child	16.60	12%	Apples	7%	Table grapes	7%	Spinaches		83%
72%	GEMS/Food G08	14.46	7%	Wine grapes	6%	Potatoes	6%	Onions		72%
70%	IE adult	14.08	9%	Wine grapes	5%	Sweet potatoes	4%	Spinaches		70%
70%	GEMS/Food G06	13.90	8%	Onions	7%	Table grapes	7%	Tomatoes		70%
70%	GEMS/Food G10	13.90	9%	Lettuces	6%	Onions	5%	Potatoes		70%
68%	GEMS/Food G07	13.68	11%	Wine grapes	7%	Lettuces	6%	Potatoes		68%
67%	GEMS/Food G15	13.37	7%	Wine grapes	6%	Onions	5%	Potatoes		67%
66%	GEMS/Food G11	13.25	7%	Wine grapes	6%	Potatoes	4%	Barley		66%
62%	SE general	12.36	11%	Lettuces	6%	Potatoes	5%	Onions		62%
60%	RO general	12.07	12%	Wine grapes	8%	Onions	8%	Head cabbages		60%
57%	FR child 3 15 yr	11.32	6%	Milk: Cattle	4%	Wheat	4%	Apples		57%
54%	PT general	10.71	18%	Wine grapes	8%	Potatoes	4%	Onions		54%
53%	FR toddler 2 3 yr	10.55	7%	Milk: Cattle	7%	Apples	4%	Spinaches		53%
52%	NL general	10.45	6%	Witloofs/Belgian endives	4%	Spinaches	4%	Wine grapes		52%
48%	DK child	9.66	6%	Cucumbers	5%	Apples	5%	Rye		48%
47%	FR adult	9.48	16%	Wine grapes	4%	Other lettuce and other salad plants	3%	Witloofs/Belgian endives		47%
46%	DE women 14-50 yr	9.27	6%	Wine grapes	5%	Apples	3%	Lettuces		46%
46%	DE general	9.27	6%	Wine grapes	5%	Apples	3%	Milk: Cattle		46%
43%	FI 3 yr	8.64	7%	Potatoes	4%	Onions	4%	Cucumbers		43%
43%	ES adult	8.61	15%	Lettuces	3%	Wine grapes	3%	Barley		43%
42%	IT adult	8.46	11%	Lettuces	4%	Other lettuce and other salad plants	4%	Wheat		42%
42%	ES child	8.42	12%	Lettuces	4%	Wheat	3%	Milk: Cattle		42%
41%	UK infant	8.20	9%	Milk: Cattle	5%	Potatoes	3%	Apples		41%
40%	IT toddler	8.08	8%	Lettuces	6%	Wheat	3%	Other lettuce and other salad plants		40%
40%	UK toddler	7.99	5%	Potatoes	5%	Milk: Cattle	4%	Apples		40%
39%	FR infant	7.75	7%	Spinaches	4%	Milk: Cattle	4%	Apples		39%
34%	FI 6 yr	6.71	6%	Potatoes	3%	Onions	3%	Strawberries		34%
30%	UK vegetarian	6.06	6%	Wine grapes	4%	Lettuces	2%	Onions		30%
28%	PL general	5.57	5%	Potatoes	4%	Apples	4%	Onions		28%
28%	DK adult	5.55	7%	Wine grapes	3%	Lettuces	2%	Apples		28%
27%	UK adult	5.30	8%	Wine grapes	3%	Lettuces	2%	Potatoes		27%
23%	FI adult	4.64	4%	Lettuces	2%	Wine grapes	2%	Potatoes		23%
22%	LT adult	4.44	5%	Potatoes	4%	Apples	2%	Head cabbages		22%
8%	IE child	1.69	1.0%	Wheat	0.9%	Potatoes	0.9%	Milk: Cattle		8%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 159.1 % of the ADI.
For 2 diet(s) the ADI is exceeded.

EFSA PRIMo revision 3.1; 2021/01/06

Difenoconazole (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.16
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: **Scenario CX, considering existing CXLs**
UF 1.3 applied to accommodate the potential shift in the isomers ratio of parent difenoconazole in plants.
Indicative UF 2 applied to accommodate the potential shift in the isomers ratio of metabolite CGA205375 in livestock.

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)
85%	NL toddler	8.52	15%	Apples	13%	Milk: Cattle	10%	Table grapes		85%
61%	GEMS/Food G06	6.11	18%	Rice	12%	Tomatoes	7%	Table grapes	0.0%	61%
61%	DE child	6.10	18%	Apples	9%	Table grapes	4%	Milk: Cattle	0.0%	61%
52%	GEMS/Food G10	5.18	14%	Rice	4%	Tomatoes	3%	Wine grapes	0.1%	52%
49%	GEMS/Food G07	4.89	10%	Wine grapes	4%	Rice	4%	Tomatoes	0.1%	49%
48%	IE adult	4.82	8%	Wine grapes	8%	Tea (dried leaves of Camellia sinensis)	3%	Sheep: Liver	0.0%	48%
48%	GEMS/Food G08	4.76	7%	Wine grapes	5%	Olives for oil production	4%	Tomatoes	0.1%	48%
47%	NL child	4.74	8%	Apples	7%	Table grapes	5%	Milk: Cattle	0.0%	47%
47%	GEMS/Food G11	4.68	7%	Wine grapes	3%	Rice	3%	Tomatoes	0.2%	47%
42%	PT general	4.20	17%	Wine grapes	9%	Rice	3%	Tomatoes		42%
42%	GEMS/Food G15	4.15	7%	Wine grapes	4%	Tomatoes	4%	Rice	0.1%	42%
40%	FR adult	3.97	16%	Wine grapes	9%	Tea (dried leaves of Camellia sinensis)	2%	Rice	0.2%	40%
39%	FR child 3 15 yr	3.88	5%	Rice	5%	Milk: Cattle	3%	Tomatoes	0.0%	39%
37%	RO general	3.68	11%	Wine grapes	6%	Tomatoes	3%	Rice		37%
35%	FR toddler 2 3 yr	3.53	7%	Rice	6%	Milk: Cattle	5%	Apples	0.0%	35%
34%	ES child	3.40	5%	Rice	4%	Olives for oil production	3%	Tomatoes		34%
34%	UK infant	3.40	9%	Milk: Cattle	7%	Rice	4%	Tea (dried leaves of Camellia sinensis		34%
33%	SE general	3.32	6%	Bovine: Muscle/meat	5%	Rice	3%	Lettuces		33%
32%	DE women 14-50 yr	3.17	6%	Wine grapes	4%	Apples	3%	Milk: Cattle	0.2%	32%
32%	DK child	3.17	3%	Rice	3%	Apples	3%	Swine: Muscle/meat		32%
30%	DE general	3.05	6%	Wine grapes	3%	Apples	3%	Milk: Cattle	0.2%	30%
30%	UK toddler	2.96	7%	Rice	5%	Milk: Cattle	2%	Apples		30%
26%	NL general	2.63	4%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	2%	Apples	0.1%	26%
26%	ES adult	2.60	4%	Lettuces	3%	Wine grapes	3%	Rice		26%
23%	UK adult	2.33	7%	Wine grapes	4%	Rice	3%	Tea (dried leaves of Camellia sinensis		23%
23%	UK vegetarian	2.30	6%	Wine grapes	4%	Rice	3%	Tea (dried leaves of Camellia sinensis		23%
21%	DK adult	2.13	6%	Wine grapes	2%	Tomatoes	1%	Apples		21%
21%	IT toddler	2.05	5%	Tomatoes	3%	Wheat	2%	Rice		21%
20%	FI 3 yr	1.95	6%	Rice	2%	Strawberries	2%	Tomatoes	0.0%	20%
19%	IT adult	1.89	4%	Tomatoes	3%	Lettuces	2%	Wheat		19%
17%	FR infant	1.68	4%	Milk: Cattle	2%	Apples	1%	Carrots	0.0%	17%
15%	FI 6 yr	1.54	5%	Rice	2%	Strawberries	1%	Tomatoes	0.0%	15%
14%	LT adult	1.40	3%	Apples	2%	Rice	2%	Tomatoes		14%
14%	FI adult	1.36	3%	Coffee beans	2%	Wine grapes	2%	Tomatoes	3%	14%
12%	PL general	1.16	3%	Apples	3%	Tomatoes	2%	Table grapes		12%
8%	IE child	0.78	3%	Rice	0.8%	Milk: Cattle	0.6%	Wheat	0.0%	8%

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
89%	Table grapes	3 / 1.95	142
79%	Celeries	5 / 3.37	126
78%	Rhubarbs	5 / 3.37	125
78%	Lettuces	4 / 3.26	124
61%	Tomatoes	2 / 1.69	98
49%	Escaroles/broad-leaved endives	3 / 1.95	78
48%	Spring onions/green onions and Welsh onions	9 / 4.94	77
37%	Spinaches	4 / 2.6	59
34%	Florence fennels	5 / 3.37	55
32%	Pears	0.4 / 0.36	50
31%	Chinese cabbages/pe-tsai	3 / 1.52	49
25%	Apples	0.4 / 0.36	39
20%	Kales	1.5 / 0.74	33
20%	Peaches	0.5 / 0.34	32
20%	Sweet peppers/bell peppers	0.9 / 0.53	32

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
41%	Table grapes	3 / 1.95	66
39%	Florence fennels	5 / 3.37	63
34%	Celeries	5 / 3.37	54
30%	Blueberries	4 / 5.2	47
29%	Wine grapes	3 / 1.95	46
25%	Lettuces	4 / 3.26	40
25%	Escaroles/broad-leaved endives	3 / 1.95	39
24%	Chinese cabbages/pe-tsai	3 / 1.52	39
22%	Cardoons	5 / 3.37	35
20%	Chards/beet leaves	3 / 1.69	32
20%	Rhubarbs	5 / 3.37	31
17%	Tomatoes	2 / 1.69	27
15%	Red mustards	4 / 4.42	23
14%	Spring onions/green onions and Welsh onions	9 / 4.94	22
9%	Strawberries	2 / 1.56	15

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
95%	Florence fennels / boiled	5 / 3.37	153
81%	Escaroles/broad-leaved endives / boiled	3 / 1.95	129
78%	Rhubarbs / sauce/puree	5 / 3.37	126
33%	Chards/beet leaves / boiled	3 / 1.69	53
26%	Broccoli / boiled	0.7 / 0.53	42
23%	Spinaches / frozen; boiled	4 / 2.6	36
19%	Leeks / boiled	0.6 / 0.52	30
18%	Wine grapes / juice	3 / 0.68	30
13%	Kales / boiled	1.5 / 0.74	20
12%	Turnips / boiled	0.5 / 0.39	20
12%	Parsnips / boiled	0.5 / 0.39	20
11%	Beetroots / boiled	0.5 / 0.39	17
9%	Pumpkins / boiled	0.2 / 0.16	14
7%	Oranges / juice	0.6 / 0.21	11
6%	Salsifies / boiled	0.5 / 0.39	10

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)
71%	Celeries / boiled	5 / 3.37	114
41%	Florence fennels / boiled	5 / 3.37	65
31%	Rhubarbs / sauce/puree	5 / 3.37	49
26%	Cardoons / boiled	5 / 3.37	41
25%	Escaroles/broad-leaved endives / boiled	3 / 1.95	40
13%	Spinaches / frozen; boiled	4 / 2.6	22
13%	Chards/beet leaves / boiled	3 / 1.69	21
9%	Beetroots / boiled	0.5 / 0.39	15
9%	Wine grapes / juice	3 / 0.68	14
8%	Broccoli / boiled	0.7 / 0.53	13
7%	Table grapes / raisins	3 / 9.17	11
6%	Leeks / boiled	0.6 / 0.52	9.1
5%	Pumpkins / boiled	0.2 / 0.16	8.6
5%	Parsnips / boiled	0.5 / 0.39	8.3
5%	Turnips / boiled	0.5 / 0.39	7.4

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

Azoxystrobin – EU HBGVs

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin

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

Toxicological reference values

ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
15%	NL toddler	30.72	5%	Potatoes	4%	Sugar beet roots	1%	Spinaches	0.1%	
14%	NL child	27.17	6%	Sugar beet roots	4%	Potatoes	0.5%	Spinaches	0.0%	
9%	DE child	18.64	3%	Potatoes	1.0%	Oranges	0.5%	Table grapes	0.1%	
9%	PT general	18.34	6%	Potatoes	0.9%	Wine grapes	0.4%	Onions	0.0%	
9%	RO general	18.02	4%	Potatoes	0.9%	Sugar beet roots	0.9%	Head cabbages	0.0%	
9%	GEMS/Food G08	17.52	4%	Potatoes	0.6%	Onions	0.4%	Parsley	0.0%	
9%	SE general	17.32	5%	Potatoes	0.7%	Lettuces	0.5%	Onions	0.0%	
9%	UK toddler	17.05	4%	Potatoes	2%	Sugar beet roots	0.5%	Oranges	0.0%	
9%	GEMS/Food G07	17.05	4%	Potatoes	0.5%	Wine grapes	0.4%	Lettuces	0.0%	
8%	GEMS/Food G11	16.73	4%	Potatoes	0.4%	Wine grapes	0.3%	Leeks	0.0%	
8%	GEMS/Food G06	16.68	2%	Potatoes	1%	Sugar beet roots	0.8%	Onions	0.0%	
8%	GEMS/Food G15	16.51	4%	Potatoes	0.6%	Onions	0.5%	Head cabbages	0.0%	
8%	FR child 3 15 yr	16.38	2%	Sugar beet roots	2%	Potatoes	0.8%	Oranges	0.0%	
8%	GEMS/Food G10	16.24	3%	Potatoes	0.6%	Onions	0.6%	Lettuces	0.0%	
8%	IE adult	15.29	3%	Potatoes	0.5%	Wine grapes	0.4%	Sweet potatoes	0.0%	
8%	FI 3 yr	15.13	5%	Potatoes	0.4%	Onions	0.2%	Strawberries	0.0%	
7%	NL general	14.95	3%	Potatoes	2%	Sugar beet roots	0.3%	Spinaches	0.0%	
7%	FR toddler 2 3 yr	14.86	2%	Potatoes	2%	Sugar beet roots	0.4%	Beans (with pods)	0.0%	
7%	DE women 14-50 yr	14.46	3%	Sugar beet roots	1%	Potatoes	0.5%	Oranges	0.0%	
7%	UK infant	13.97	4%	Potatoes	1.0%	Sugar beet roots	0.3%	Oranges	0.0%	
7%	DE general	13.82	3%	Sugar beet roots	1%	Potatoes	0.4%	Oranges	0.0%	
6%	FI 6 yr	12.40	4%	Potatoes	0.3%	Onions	0.2%	Strawberries	0.0%	
5%	FR infant	10.97	2%	Potatoes	0.9%	Sugar beet roots	0.5%	Spinaches	0.0%	
5%	PL general	10.86	4%	Potatoes	0.4%	Onions	0.2%	Head cabbages	0.0%	
5%	ES child	10.49	2%	Potatoes	0.7%	Lettuces	0.5%	Oranges	0.0%	
5%	DK child	9.72	3%	Potatoes	0.3%	Onions	0.2%	Lettuces	0.0%	
4%	LT adult	8.98	4%	Potatoes	0.2%	Head cabbages	0.1%	Tomatoes	0.0%	
4%	FR adult	8.26	0.8%	Potatoes	0.8%	Wine grapes	0.5%	Sugar beet roots	0.0%	
4%	ES adult	8.15	1%	Potatoes	0.9%	Lettuces	0.3%	Oranges	0.0%	
4%	UK vegetarian	7.91	2%	Potatoes	0.4%	Sugar beet roots	0.3%	Wine grapes	0.0%	
4%	IT toddler	7.89	1%	Potatoes	0.5%	Lettuces	0.2%	Tomatoes	0.0%	
4%	IT adult	7.64	0.7%	Potatoes	0.6%	Lettuces	0.3%	Other lettuce and other salad plants	0.0%	
4%	UK adult	7.26	2%	Potatoes	0.4%	Wine grapes	0.4%	Sugar beet roots	0.0%	
3%	DK adult	5.88	1%	Potatoes	0.3%	Wine grapes	0.2%	Onions	0.0%	
3%	FI adult	5.33	1%	Potatoes	0.2%	Lettuces	0.2%	Onions	0.0%	
1%	IE child	2.40	0.7%	Potatoes	0.1%	Rice	0.1%	Onions	0.0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Azoxystrobin – JMPR HBGVs

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin

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

Toxicological reference values

ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	not necessary
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2024	Year of evaluation:	2024

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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

Calculated exposure (% of ADI)	MS Diet	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)
102%	NL toddler	30.72	33%	Potatoes	24%	Sugar beet roots	9%	Spinaches	0.6%	
91%	NL child	27.17	38%	Sugar beet roots	26%	Potatoes	3%	Spinaches	0.3%	
62%	DE child	18.64	20%	Potatoes	7%	Oranges	3%	Table grapes	0.5%	
61%	PT general	18.34	41%	Potatoes	6%	Wine grapes	3%	Onions	0.1%	
60%	RO general	18.02	29%	Potatoes	6%	Sugar beet roots	6%	Head cabbages	0.1%	
58%	GEMS/Food G08	17.52	30%	Potatoes	4%	Onions	3%	Parsley	0.1%	
58%	SE general	17.32	32%	Potatoes	5%	Lettuces	3%	Onions	0.1%	
57%	UK toddler	17.05	27%	Potatoes	14%	Sugar beet roots	3%	Oranges	0.1%	
57%	GEMS/Food G07	17.05	29%	Potatoes	4%	Wine grapes	3%	Lettuces	0.1%	
56%	GEMS/Food G11	16.73	30%	Potatoes	2%	Wine grapes	2%	Leeks	0.1%	
56%	GEMS/Food G06	16.68	15%	Potatoes	7%	Sugar beet roots	6%	Onions	0.1%	
55%	GEMS/Food G15	16.51	27%	Potatoes	4%	Onions	3%	Head cabbages	0.1%	
55%	FR child 3 15 yr	16.38	17%	Sugar beet roots	12%	Potatoes	6%	Oranges	0.2%	
54%	GEMS/Food G10	16.24	23%	Potatoes	4%	Onions	4%	Lettuces	0.1%	
51%	IE adult	15.29	18%	Potatoes	3%	Wine grapes	3%	Sweet potatoes	0.1%	
50%	FI 3 yr	15.13	36%	Potatoes	3%	Onions	2%	Strawberries	0.1%	
50%	NL general	14.95	19%	Potatoes	13%	Sugar beet roots	2%	Spinaches	0.1%	
50%	FR toddler 2 3 yr	14.86	14%	Potatoes	13%	Sugar beet roots	3%	Beans (with pods)	0.2%	
48%	DE women 14-50 yr	14.46	21%	Sugar beet roots	8%	Potatoes	3%	Oranges	0.1%	
47%	UK infant	13.97	25%	Potatoes	6%	Sugar beet roots	2%	Oranges	0.1%	
46%	DE general	13.82	19%	Sugar beet roots	9%	Potatoes	3%	Oranges	0.1%	
41%	FI 6 yr	12.40	30%	Potatoes	2%	Onions	1%	Strawberries	0.1%	
37%	FR infant	10.97	15%	Potatoes	6%	Sugar beet roots	3%	Spinaches	0.1%	
36%	PL general	10.86	26%	Potatoes	2%	Onions	1%	Head cabbages	0.1%	
35%	ES child	10.49	14%	Potatoes	5%	Lettuces	4%	Oranges	0.2%	
32%	DK child	9.72	19%	Potatoes	2%	Onions	2%	Lettuces	0.1%	
30%	LT adult	8.98	24%	Potatoes	2%	Head cabbages	0.7%	Tomatoes	0.1%	
28%	FR adult	8.26	6%	Potatoes	6%	Wine grapes	4%	Sugar beet roots	0.1%	
27%	ES adult	8.15	7%	Potatoes	6%	Lettuces	2%	Oranges	0.1%	
26%	UK vegetarian	7.91	11%	Potatoes	2%	Sugar beet roots	2%	Wine grapes	0.0%	
26%	IT toddler	7.89	7%	Potatoes	3%	Lettuces	2%	Tomatoes	0.1%	
25%	IT adult	7.64	5%	Potatoes	4%	Lettuces	2%	Other lettuce and other salad plants	0.1%	
24%	UK adult	7.26	11%	Potatoes	3%	Wine grapes	3%	Sugar beet roots	0.0%	
20%	DK adult	5.88	10%	Potatoes	2%	Wine grapes	1%	Onions	0.0%	
18%	FI adult	5.33	9%	Potatoes	2%	Lettuces	1%	Onions	0.0%	
8%	IE child	2.40	5%	Potatoes	0.5%	Rice	0.4%	Onions	0.0%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 102.4 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2021/01/06

Spinetoram (F)

LOQs (mg/kg) range from: 0.02 to: 1.00

Toxicological reference values

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

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)
19%	NL toddler	4.83	6%	Broccoli	2%	Apples	2%	Milk: Cattle	3%	16%
11%	DE child	2.64	3%	Apples	1%	Broccoli	0.8%	Milk: Cattle	1%	9%
9%	NL child	2.28	1%	Apples	1%	Broccoli	1.0%	Milk: Cattle	2%	7%
7%	IE adult	1.70	2%	Broccoli	0.4%	Potatoes	0.3%	Mandarins	1%	5%
7%	GEMS/Food G10	1.66	1%	Soyabeans	1%	Cress and other sprouts and shoots	0.5%	Potatoes	1%	3%
6%	GEMS/Food G11	1.62	1%	Soyabeans	0.7%	Broccoli	0.6%	Potatoes	1%	3%
6%	FR toddler 2 3 yr	1.60	1%	Broccoli	1%	Milk: Cattle	0.7%	Apples	1%	5%
6%	GEMS/Food G07	1.46	0.7%	Broccoli	0.6%	Potatoes	0.6%	Soyabeans	1%	3%
6%	GEMS/Food G06	1.45	0.6%	Wheat	0.5%	Rice	0.4%	Soyabeans	2%	3%
6%	GEMS/Food G08	1.42	0.6%	Soyabeans	0.6%	Potatoes	0.3%	Wheat	1%	3%
6%	FR child 3 15 yr	1.39	0.9%	Milk: Cattle	0.6%	Oranges	0.5%	Broccoli	1%	4%
5%	UK toddler	1.31	0.8%	Milk: Cattle	0.7%	Broccoli	0.6%	Potatoes	1%	3%
5%	GEMS/Food G15	1.29	0.6%	Potatoes	0.6%	Soyabeans	0.4%	Broccoli	1%	3%
5%	SE general	1.28	0.9%	Broccoli	0.7%	Potatoes	0.5%	Milk: Cattle	1%	3%
5%	DE women 14-50 yr	1.19	0.7%	Broccoli	0.6%	Apples	0.5%	Milk: Cattle	1%	3%
5%	FI 3 yr	1.16	0.9%	Broccoli	0.8%	Potatoes	0.7%	Raspberries (red and yellow)	0.8%	3%
4%	UK infant	1.12	2%	Milk: Cattle	0.5%	Potatoes	0.4%	Apples	1.0%	3%
4%	DK child	1.11	0.5%	Cucumbers	0.5%	Apples	0.5%	Milk: Cattle	1%	3%
4%	DE general	1.11	0.6%	Broccoli	0.5%	Apples	0.5%	Milk: Cattle	1%	3%
4%	FR infant	1.06	1%	Broccoli	0.7%	Milk: Cattle	0.4%	Apples	0.5%	3%
4%	NL general	0.99	0.6%	Broccoli	0.4%	Potatoes	0.3%	Milk: Cattle	0.9%	3%
4%	ES child	0.99	0.5%	Milk: Cattle	0.4%	Lettuces	0.4%	Oranges	1%	3%
4%	FI adult	0.99	2%	Coffee beans	0.2%	Broccoli	0.2%	Potatoes	3%	1%
4%	RO general	0.93	0.6%	Potatoes	0.5%	Milk: Cattle	0.4%	Wheat	0.9%	2%
3%	PT general	0.82	0.9%	Potatoes	0.5%	Wine grapes	0.3%	Wheat	0.6%	1%
3%	FI 6 yr	0.78	0.6%	Potatoes	0.5%	Raspberries (red and yellow)	0.2%	Cucumbers	0.7%	2%
3%	UK vegetarian	0.72	0.9%	Broccoli	0.2%	Potatoes	0.2%	Wine grapes	0.5%	2%
3%	ES adult	0.70	0.5%	Lettuces	0.2%	Oranges	0.2%	Milk: Cattle	0.6%	2%
3%	FR adult	0.69	0.5%	Wine grapes	0.2%	Broccoli	0.2%	Milk: Cattle	0.7%	2%
3%	IT toddler	0.69	0.5%	Wheat	0.3%	Lettuces	0.2%	Apples	0.9%	2%
3%	IT adult	0.65	0.4%	Lettuces	0.3%	Wheat	0.3%	Broccoli	0.6%	2%
3%	UK adult	0.63	0.8%	Broccoli	0.2%	Wine grapes	0.2%	Potatoes	0.4%	2%
2%	DK adult	0.56	0.4%	Broccoli	0.2%	Apples	0.2%	Milk: Cattle	0.4%	2%
2%	LT adult	0.50	0.5%	Potatoes	0.4%	Apples	0.2%	Milk: Cattle	0.3%	1%
2%	PL general	0.46	0.5%	Potatoes	0.5%	Apples	0.1%	Broccoli	0.1%	1%
1%	IE child	0.36	0.6%	Broccoli	0.1%	Milk: Cattle	0.1%	Potatoes	0.2%	1%

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
324%	Broccoli	10 / 7.8	324
45%	Lettuces	1.5 / 1.18	45
39%	Table grapes	0.4 / 0.53	39
28%	Pears	0.15 / 0.21	28
28%	Spring onions/green onions	0.8 / 1.76	28
26%	Spinaches	0.9 / 1.14	26
24%	Cherries (sweet)	2 / 1.99	24
23%	Sweet peppers/bell peppers	0.4 / 0.38	23
22%	Apples	0.15 / 0.21	22
20%	Chards/beet leaves	1.5 / 1.31	20
14%	Lamb's lettuce/corn salads	4 / 4.9	14
13%	Peaches	0.3 / 0.14	13
13%	Roman rocket/rucola	4 / 4.9	13
11%	Prickly pears/cactus fruits	0.5 / 0.5	11
9%	Aubergines/egg plants	0.4 / 0.38	9.4

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
186%	Broccoli	10 / 7.8	186
26%	Red mustards	4 / 4.9	26
25%	Chards/beet leaves	1.5 / 1.31	25
20%	Cherries (sweet)	2 / 1.99	20
18%	Table grapes	0.4 / 0.53	18
14%	Lettuces	1.5 / 1.18	14
14%	Wine grapes	0.4 / 0.57	14
10%	Aubergines/egg plants	0.4 / 0.38	10
9%	Lamb's lettuce/corn salads	4 / 4.9	9.2
8%	Spring onions/green onions	0.8 / 1.76	7.9
8%	Purslanes	4 / 4	7.6
6%	Pears	0.15 / 0.21	6.3
6%	Sweet peppers/bell peppers	0.4 / 0.38	6.2
6%	Parsley	4 / 4.9	5.9
6%	Roman rocket/rucola	4 / 4.9	5.8

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
614%	Broccoli / boiled	10 / 7.8	614
41%	Chards/beet leaves / boiled	1.5 / 1.31	41
14%	Currants (red, black and wh	0.5 / 0.5	14
12%	Raspberries / juice	1 / 1	12
10%	Spinaches / frozen; boiled	0.9 / 0.68	9.5
5%	Courgettes / boiled	0.06 / 0.14	5.0
4%	Potatoes / fried	0.02 / 0.04	3.7
4%	Peaches / canned	0.3 / 0.14	3.6
4%	Pumpkins / boiled	0.03 / 0.04	3.5
3%	Gherkins / pickled	0.06 / 0.14	3.2
3%	Apples / juice	0.15 / 0.06	3.0
3%	Leeks / boiled	0.05 / 0.05	2.9
3%	Cauliflowers / boiled	0.02 / 0.04	2.8
2%	Potatoes / dried (flakes)	0.02 / 0.18	2.4
2%	Wine grapes / juice	0.4 / 0.05	2.3

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)
188%	Broccoli / boiled	10 / 7.8	188
16%	Purslanes / boiled	4 / 4	16
16%	Chards/beet leaves / boiled	1.5 / 1.31	16
6%	Currants (red, black and	0.5 / 0.5	6.4
6%	Spinaches / frozen; boiled	0.9 / 0.68	5.7
5%	Wine grapes / wine	0.4 / 0.57	5.4
3%	Courgettes / boiled	0.06 / 0.14	3.2
3%	Table grapes / raisins	0.4 / 2.51	3.1
2%	Pumpkins / boiled	0.03 / 0.04	2.2
2%	Apples / juice	0.15 / 0.06	1.9
2%	Cauliflowers / boiled	0.02 / 0.04	1.7
1%	Elderberries / juice	0.4 / 0.13	1.2
1%	Peaches / canned	0.3 / 0.14	1.1
1%	Wine grapes / juice	0.4 / 0.05	1.1
0.9%	Sugar beets (root) / sugar	0.02 / 0.24	0.88

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.

EFSA PRIMo revision 3.1; 2021/01/06

Metaflumizone (F)

LOQs (mg/kg) range from:	0.02	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.13
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)	70%	DE child	7.03	34%	Apples	27%	Oranges	2%	Milk: Cattle		70%
	56%	NL toddler	5.65	30%	Apples	15%	Oranges	6%	Milk: Cattle		56%
	33%	FR child 3 15 yr	3.30	22%	Oranges	5%	Apples	2%	Milk: Cattle		33%
	33%	NL child	3.25	16%	Apples	9%	Oranges	2%	Milk: Cattle		33%
	27%	ES child	2.74	14%	Oranges	6%	Lettuces	3%	Apples		27%
	27%	DE women 14-50 yr	2.74	13%	Oranges	7%	Apples	2%	Lettuces		27%
	26%	GEMS/Food G10	2.64	7%	Oranges	4%	Lettuces	3%	Cress and other sprouts and shoots		26%
	24%	GEMS/Food G06	2.42	7%	Oranges	5%	Tomatoes	3%	Apples		24%
	24%	DE general	2.41	10%	Oranges	7%	Apples	1%	Lettuces		24%
	24%	GEMS/Food G11	2.39	5%	Oranges	4%	Lamb's lettuce/corn salads	4%	Apples		24%
	24%	FR toddler 2 3 yr	2.38	9%	Oranges	9%	Apples	3%	Milk: Cattle		24%
	23%	GEMS/Food G07	2.26	9%	Oranges	3%	Lettuces	3%	Apples		23%
	23%	UK toddler	2.26	13%	Oranges	5%	Apples	2%	Milk: Cattle		23%
	21%	SE general	2.11	5%	Lettuces	5%	Oranges	3%	Apples		21%
	21%	ES adult	2.08	9%	Oranges	7%	Lettuces	2%	Apples		21%
	20%	GEMS/Food G08	2.03	4%	Lamb's lettuce/corn salads	3%	Apples	3%	Oranges		20%
	19%	UK infant	1.93	9%	Oranges	4%	Apples	4%	Milk: Cattle		19%
	16%	GEMS/Food G15	1.64	4%	Oranges	3%	Apples	2%	Tomatoes		16%
	15%	NL general	1.53	7%	Oranges	4%	Apples	1%	Lettuces		15%
	15%	DK child	1.50	6%	Apples	2%	Lettuces	1%	Cucumbers		15%
	14%	IE adult	1.41	7%	Oranges	2%	Apples	1%	Lettuces		14%
	14%	RO general	1.36	4%	Apples	3%	Tomatoes	2%	Oranges		14%
	13%	IT toddler	1.26	4%	Lettuces	3%	Oranges	2%	Apples		13%
	12%	IT adult	1.24	5%	Lettuces	2%	Oranges	2%	Apples		12%
	12%	PT general	1.18	4%	Oranges	3%	Apples	1%	Lettuces		12%
	12%	UK vegetarian	1.16	6%	Oranges	2%	Lettuces	2%	Apples		12%
	9%	LT adult	0.94	5%	Apples	0.9%	Tomatoes	0.9%	Lettuces		9%
	9%	FR adult	0.93	4%	Oranges	2%	Apples	1.0%	Lamb's lettuce/corn salads		9%
	9%	FR infant	0.92	5%	Apples	2%	Milk: Cattle	2%	Oranges		9%
	9%	FI adult	0.90	3%	Oranges	2%	Lettuces	2%	Apples		9%
	9%	PL general	0.89	6%	Apples	1%	Tomatoes	0.7%	Potatoes		9%
	8%	UK adult	0.82	4%	Oranges	2%	Lettuces	1%	Apples		8%
	8%	DK adult	0.76	3%	Apples	1%	Lettuces	0.9%	Oranges		8%
	7%	FI 3 yr	0.72	3%	Apples	1.0%	Oranges	0.9%	Potatoes		7%
	6%	FI 6 yr	0.64	2%	Apples	1%	Lettuces	1%	Oranges		6%
	2%	IE child	0.24	0.9%	Apples	0.6%	Oranges	0.4%	Milk: Cattle		2%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Metaflumizone (F) is unlikely to present a public health concern.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
306%	Oranges	3 / 3	398
117%	Melons	1 / 1	152
92%	Lettuces	6 / 3.14	120
75%	Apples	0.9 / 0.9	97
71%	Chinese cabbages/pe-tsai	8 / 2.89	93
53%	Lemons	2 / 2	69
37%	Sweet peppers/bell peppers	1.5 / 0.81	48
31%	Limes	2 / 2	40
18%	Tomatoes	0.7 / 0.41	24
14%	Lamb's lettuce/corn salads	20 / 6.4	18
13%	Roman rocket/rucola	20 / 6.4	17
10%	Cucumbers	0.4 / 0.2	13
8%	Aubergines/egg plants	0.7 / 0.41	10
8%	Cauliflowers	0.5 / 0.17	9.8
7%	Courgettes	0.4 / 0.2	9.3

Expand/collapse list

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

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)
71%	Oranges	3 / 3	92
56%	Chinese cabbages/pe-tsai	8 / 2.89	73
30%	Melons	1 / 1	39
29%	Lettuces	6 / 3.14	38
26%	Red mustards	20 / 6.4	34
19%	Apples	0.9 / 0.9	25
14%	Lemons	2 / 2	18
11%	Limes	2 / 2	14
10%	Sweet peppers/bell peppers	1.5 / 0.81	13
9%	Lamb's lettuce/corn salads	20 / 6.4	12
9%	Aubergines/egg plants	0.7 / 0.41	11
6%	Roman rocket/rucola	20 / 6.4	7.6
5%	Tomatoes	0.7 / 0.41	6.5
4%	Cucumbers	0.4 / 0.2	5.6
4%	Courgettes	0.4 / 0.2	4.7

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)
27%	Oranges / juice	3 / 0.66	35
11%	Apples / juice	0.9 / 0.28	15
9%	Cauliflowers / boiled	0.5 / 0.17	12
5%	Courgettes / boiled	0.4 / 0.2	7.1
4%	Gherkins / pickled	0.4 / 0.2	4.6
3%	Brussels sprouts / boiled	1 / 0.39	4.0
1%	Potatoes / fried	0.02 / 0.02	1.9
1%	Lemons / jam	2 / 0.52	1.6
1%	Tomatoes / juice	0.7 / 0.08	1.4
1%	Kales / boiled	0.05 / 0.05	1.4
0.9%	Potatoes / dried (flakes)	0.02 / 0.09	1.2
0.8%	Tomatoes / sauce/puree	0.7 / 0.1	1.00
0.4%	Maize / oil	0.04 / 0.5	0.47
0.2%	Head cabbages / canned	0.15 / 0.04	0.20
0.1%	Soyabeans / soya drink	0.2 / 0.02	0.08

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Oranges / juice	3 / 0.66	10.0
7%	Apples / juice	0.9 / 0.28	9.2
5%	Cauliflowers / boiled	0.5 / 0.17	7.1
4%	Courgettes / boiled	0.4 / 0.2	4.6
0.8%	Lemons / juice	2 / 0.52	0.99
0.7%	Tomatoes / sauce/puree	0.7 / 0.1	0.86
0.3%	Head cabbages / canned	0.15 / 0.04	0.33
0.2%	Maize / oil	0.04 / 0.5	0.25
0.1%	Potatoes / chips	0.02 / 0.02	0.17
0.09%	Potatoes / dried (flakes)	0.02 / 0.09	0.12
0.07%	Coffee beans / extraction	0.15 / 0	0.10

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.

EFSA PRIMo revision 3.1; 2021/01/06

Clothianidin

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

Toxicological reference values

ADI (mg/kg bw/day):	0.097	ARfD (mg/kg bw):	0.1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2006	Year of evaluation:	2006

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)	3%	NL toddler	3.20	3%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn	0.7%	3%
	2%	UK infant	1.90	2%	Milk: Cattle	0.0%	Bovine: Edible offals (other than liver and	0.0%	Potatoes	0.2%	2%
	2%	FR toddler 2 3 yr	1.53	1%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.3%	1%
	2%	NL child	1.48	1%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	0.5%	1%
	1%	FR child 3 15 yr	1.32	1.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.4%	1.0%
	1%	DE child	1.26	0.8%	Milk: Cattle	0.1%	Apples	0.0%	Wheat	0.5%	0.8%
	1%	UK toddler	1.12	0.9%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.9%
	0.9%	DK child	0.87	0.5%	Milk: Cattle	0.1%	Rye	0.0%	Swine: Muscle/meat	0.3%	0.6%
	0.9%	FR infant	0.83	0.7%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.1%	0.7%
	0.8%	ES child	0.82	0.5%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.3%	0.6%
	0.8%	SE general	0.80	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes	0.3%	0.5%
	0.8%	DE women 14-50 yr	0.78	0.5%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.3%	0.5%
	0.8%	DE general	0.77	0.5%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.3%	0.5%
	0.8%	RO general	0.76	0.5%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.3%	0.5%
	0.7%	GEMS/Food G11	0.71	0.3%	Milk: Cattle	0.0%	Potatoes	0.0%	Soyabeans	0.4%	0.4%
	0.7%	GEMS/Food G15	0.68	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.4%
	0.7%	GEMS/Food G07	0.68	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.4%	0.3%
	0.6%	GEMS/Food G08	0.61	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat	0.4%	0.3%
	0.6%	GEMS/Food G10	0.60	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans	0.4%	0.3%
	0.6%	NL general	0.59	0.4%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.2%	0.4%
	0.6%	IE adult	0.57	0.2%	Milk: Cattle	0.1%	Sheep: Liver	0.0%	Sweet potatoes	0.3%	0.3%
	0.5%	GEMS/Food G06	0.50	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Tomatoes	0.4%	0.1%
	0.4%	FR adult	0.40	0.2%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.2%	0.2%
	0.4%	ES adult	0.39	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat	0.2%	0.2%
	0.4%	DK adult	0.36	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Potatoes	0.1%	0.2%
	0.4%	FI adult	0.35	0.3%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.4%	
	0.3%	LT adult	0.31	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Swine: Muscle/meat	0.1%	0.2%
	0.3%	UK vegetarian	0.25	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.1%
	0.3%	UK adult	0.25	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.1%
	0.2%	PT general	0.21	0.1%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.2%	
	0.2%	IE child	0.20	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.2%
	0.2%	FI 3 yr	0.17	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.2%	
	0.2%	IT toddler	0.16	0.1%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.2%	
	0.1%	FI 6 yr	0.14	0.0%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.1%	
	0.1%	IT adult	0.12	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.1%	
	0.1%	PL general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Clothianidin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European U

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Milk: Cattle	0.05 / 0.04	5.1
3%	Bovine: Liver	0.4 / 0.37	3.0
3%	Bovine: Edible offals (other	0.4 / 0.37	2.7
2%	Potatoes	0.01 / 0.01	1.5
2%	Melons	0.01 / 0.01	1.5
1%	Bovine: Kidney	0.4 / 0.37	1.4
1%	Pears	0.01 / 0.01	1.4
1%	Oranges	0.01 / 0.01	1.3
1%	Watermelons	0.01 / 0.01	1.2
1%	Swine: Edible offals (other	0.4 / 0.37	1.1
1%	Apples	0.01 / 0.01	1.1
1%	Pineapples	0.01 / 0.01	1.0
1.0%	Milk: Goat	0.05 / 0.04	0.99
1.0%	Bananas	0.01 / 0.01	0.97
1.0%	Peaches	0.01 / 0.01	0.95

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Poultry: Liver	0.4 / 0.37	1.7
2%	Milk: Cattle	0.05 / 0.04	1.6
1%	Bovine: Liver	0.4 / 0.37	1.5
1%	Bovine: Edible offals (other	0.4 / 0.37	1.2
1%	Sheep: Liver	0.4 / 0.37	1.0
1.0%	Swine: Edible offals (other	0.4 / 0.37	0.97
0.8%	Swine: Kidney	0.4 / 0.37	0.81
0.8%	Bovine: Kidney	0.4 / 0.37	0.78
0.8%	Milk: Goat	0.05 / 0.04	0.75
0.6%	Milk: Sheep	0.05 / 0.04	0.62
0.5%	Swine: Liver	0.4 / 0.37	0.52
0.5%	Poultry: Kidney	0.4 / 0.37	0.48
0.4%	Head cabbages	0.01 / 0.01	0.42
0.4%	Watermelons	0.01 / 0.01	0.41
0.4%	Melons	0.01 / 0.01	0.39

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.9%	Potatoes / fried	0.01 / 0.01	0.93
0.9%	Pumpkins / boiled	0.01 / 0.01	0.89
0.9%	Witloofs / boiled	0.01 / 0.01	0.89
0.8%	Broccoli / boiled	0.01 / 0.01	0.79
0.7%	Cauliflowers / boiled	0.01 / 0.01	0.70
0.7%	Escaroles/broad-leaved end	0.01 / 0.01	0.66
0.6%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
0.6%	Leeks / boiled	0.01 / 0.01	0.57
0.5%	Apples / juice	0.01 / 0.01	0.54
0.5%	Oranges / juice	0.01 / 0.01	0.53
0.5%	Turnips / boiled	0.01 / 0.01	0.51
0.5%	Parsnips / boiled	0.01 / 0.01	0.51
0.5%	Sweet potatoes / boiled	0.01 / 0.01	0.50
0.5%	Florence fennels / boiled	0.01 / 0.01	0.45

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)
0.6%	Pumpkins / boiled	0.01 / 0.01	0.55
0.4%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.4%	Cauliflowers / boiled	0.01 / 0.01	0.42
0.4%	Beetroots / boiled	0.01 / 0.01	0.39
0.3%	Celeries / boiled	0.01 / 0.01	0.34
0.3%	Apples / juice	0.01 / 0.01	0.33
0.2%	Broccoli / boiled	0.01 / 0.01	0.24
0.2%	Coffee beans / extraction	0.05 / 0.01	0.24
0.2%	Courgettes / boiled	0.01 / 0.01	0.23
0.2%	Parsnips / boiled	0.01 / 0.01	0.21
0.2%	Kohlrabies / boiled	0.01 / 0.01	0.21
0.2%	Wine grapes / juice	0.01 / 0.01	0.21
0.2%	Escaroles/broad-leaved	0.01 / 0.01	0.20
0.2%	Florence fennels / boiled	0.01 / 0.01	0.19
0.2%	Turnips / boiled	0.01 / 0.01	0.19

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

EFSA PRIMo revision 3.1; 2021/01/06

Etoxazole (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	not necessary
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)
3%	NL toddler	1.25	1%	Milk: Cattle	0.3%	Apples	0.2%	Maize/corn	3%	0.0%
2%	NL child	0.67	0.6%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	2%	0.0%
2%	DE child	0.64	0.5%	Milk: Cattle	0.3%	Apples	0.1%	Wheat	2%	0.0%
2%	UK infant	0.62	1.0%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	0.0%
1%	FR toddler 2 3 yr	0.57	0.7%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	1%	0.0%
1%	FR child 3 15 yr	0.57	0.6%	Milk: Cattle	0.1%	Wheat	0.1%	Sugar beet roots	1%	0.0%
1%	UK toddler	0.45	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1%	0.0%
1%	GEMS/Food G11	0.42	0.2%	Milk: Cattle	0.1%	Potatoes	0.1%	Soyabeans	1%	0.0%
1%	DK child	0.42	0.3%	Milk: Cattle	0.1%	Rye	0.1%	Wheat	1%	0.0%
1.0%	GEMS/Food G07	0.39	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1.0%	0.0%
1.0%	SE general	0.39	0.3%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.1%	Potatoes	1.0%	0.0%
1.0%	GEMS/Food G08	0.39	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1.0%	0.0%
1.0%	GEMS/Food G15	0.39	0.2%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1.0%	0.0%
1.0%	ES child	0.39	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Cocoa beans	1.0%	0.0%
1.0%	RO general	0.38	0.3%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	1.0%	0.0%
1.0%	GEMS/Food G06	0.38	0.2%	Wheat	0.1%	Tomatoes	0.1%	Milk: Cattle	1.0%	0.0%
0.9%	DE women 14-50 yr	0.38	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	0.9%	0.0%
0.9%	GEMS/Food G10	0.38	0.1%	Milk: Cattle	0.1%	Wheat	0.1%	Soyabeans	0.9%	0.0%
0.9%	DE general	0.37	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	0.9%	0.0%
0.9%	FI adult	0.35	0.7%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.9%	0.0%
0.9%	IE adult	0.34	0.1%	Milk: Cattle	0.1%	Sweet potatoes	0.1%	Wheat	0.8%	0.0%
0.8%	NL general	0.31	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Potatoes	0.8%	0.0%
0.7%	FR infant	0.30	0.4%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.7%	0.0%
0.6%	FR adult	0.23	0.1%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat	0.6%	0.0%
0.5%	ES adult	0.21	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Oranges	0.5%	0.0%
0.5%	PT general	0.21	0.1%	Potatoes	0.1%	Wheat	0.1%	Wine grapes	0.5%	
0.4%	FI 3 yr	0.18	0.1%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.4%	
0.4%	DK adult	0.17	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Swine: Muscle/meat	0.4%	0.0%
0.4%	LT adult	0.17	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	Apples	0.4%	0.0%
0.4%	IT toddler	0.16	0.2%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.4%	0.0%
0.4%	UK vegetarian	0.15	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.4%	0.0%
0.4%	FI 6 yr	0.14	0.1%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.4%	
0.4%	UK adult	0.14	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	0.0%
0.3%	IT adult	0.12	0.1%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.3%	0.0%
0.2%	PL general	0.10	0.1%	Potatoes	0.1%	Apples	0.0%	Tomatoes	0.2%	
0.2%	IE child	0.08	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	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 Etoxazole (F) is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2021/01/06

Flubendiamide (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.017	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
68%	NL toddler	11.56	29%	Milk: Cattle	16%	Apples	6%	Pears	2%	66%
43%	DE child	7.30	18%	Apples	10%	Milk: Cattle	3%	Table grapes	1%	41%
36%	IE adult	6.14	18%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	2%	Milk: Cattle	1%	35%
36%	UK infant	6.06	19%	Milk: Cattle	8%	Tea (dried leaves of Camellia sinensis)	2%	Apples	0.9%	35%
34%	NL child	5.86	12%	Milk: Cattle	9%	Apples	3%	Table grapes	2%	33%
34%	FR adult	5.77	19%	Tea (dried leaves of Camellia sinensis)	6%	Wine grapes	2%	Milk: Cattle	0.6%	33%
29%	FR child 3 15 yr	4.94	11%	Milk: Cattle	3%	Tea (dried leaves of Camellia sinensis)	2%	Apples	1%	27%
27%	FR toddler 2 3 yr	4.58	14%	Milk: Cattle	5%	Apples	2%	Beans (with pods)	1%	26%
27%	GEMS/Food G06	4.54	7%	Tomatoes	7%	Tea (dried leaves of Camellia sinensis)	3%	Table grapes	1%	26%
26%	GEMS/Food G11	4.36	5%	Tea (dried leaves of Camellia sinensis)	4%	Milk: Cattle	3%	Celeries	1%	24%
25%	GEMS/Food G07	4.29	7%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes	3%	Milk: Cattle	1%	24%
23%	UK toddler	3.95	10%	Milk: Cattle	4%	Tea (dried leaves of Camellia sinensis)	3%	Apples	1%	22%
22%	DE women 14-50 yr	3.79	6%	Milk: Cattle	4%	Tea (dried leaves of Camellia sinensis)	4%	Apples	1%	21%
22%	DE general	3.70	6%	Milk: Cattle	4%	Tea (dried leaves of Camellia sinensis)	4%	Apples	1.0%	21%
21%	GEMS/Food G15	3.55	3%	Milk: Cattle	2%	Wine grapes	2%	Tomatoes	1%	20%
21%	GEMS/Food G08	3.54	4%	Tea (dried leaves of Camellia sinensis)	3%	Milk: Cattle	3%	Wine grapes	1%	20%
21%	RO general	3.53	6%	Milk: Cattle	4%	Wine grapes	4%	Tomatoes	0.9%	20%
19%	GEMS/Food G10	3.22	4%	Tea (dried leaves of Camellia sinensis)	3%	Tomatoes	3%	Milk: Cattle	1%	18%
18%	NL general	3.05	5%	Tea (dried leaves of Camellia sinensis)	4%	Milk: Cattle	2%	Apples	0.9%	17%
16%	ES child	2.76	6%	Milk: Cattle	2%	Tomatoes	2%	Apples	1.0%	15%
16%	DK child	2.75	6%	Milk: Cattle	3%	Apples	1%	Tomatoes	1%	15%
15%	UK adult	2.57	7%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	1%	Milk: Cattle	0.4%	15%
15%	UK vegetarian	2.55	7%	Tea (dried leaves of Camellia sinensis)	2%	Wine grapes	2%	Milk: Cattle	0.4%	15%
15%	PT general	2.55	6%	Wine grapes	2%	Tomatoes	2%	Apples	0.8%	14%
14%	SE general	2.46	6%	Milk: Cattle	2%	Tomatoes	2%	Bovine: Muscle/meat	1.0%	13%
14%	FR infant	2.43	8%	Milk: Cattle	2%	Apples	1%	Beans (with pods)	0.5%	14%
13%	DK adult	2.13	3%	Milk: Cattle	2%	Wine grapes	1%	Apples	0.3%	12%
11%	ES adult	1.86	2%	Milk: Cattle	2%	Tomatoes	1%	Apples	0.6%	10%
10%	IT toddler	1.62	3%	Tomatoes	1%	Apples	1%	Peaches	0.7%	8%
9%	IT adult	1.46	2%	Tomatoes	1%	Peaches	1%	Apples	0.5%	8%
8%	LT adult	1.38	3%	Apples	2%	Milk: Cattle	1%	Tomatoes	0.4%	8%
8%	PL general	1.32	3%	Apples	2%	Tomatoes	0.8%	Table grapes	0.3%	7%
6%	FI 3 yr	0.99	1%	Apples	1%	Tomatoes	0.6%	Table grapes	0.8%	5%
5%	FI adult	0.93	2%	Coffee beans	1%	Tomatoes	0.9%	Apples	2%	4%
4%	FI 6 yr	0.75	0.9%	Tomatoes	0.9%	Apples	0.4%	Table grapes	0.6%	4%
4%	IE child	0.69	2%	Milk: Cattle	0.5%	Swine: Fat tissue	0.5%	Apples	0.2%	4%

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

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

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

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
98%	Celeries	6 / 2.62	98
95%	Peaches	2 / 1	95
82%	Pears	0.9 / 0.59	82
64%	Apples	0.9 / 0.59	64
59%	Table grapes	2 / 0.81	59
42%	Plums	2 / 1	42
37%	Tomatoes	2 / 0.63	37
35%	Tea (dried leaves of	50 / 23	35
35%	Apricots	2 / 1	35
23%	Brussels sprouts	4 / 2.7	23
22%	Sweet peppers/bell peppers	0.7 / 0.37	22
15%	Quinces	0.9 / 0.59	15
14%	Melons	0.2 / 0.09	14
12%	Cherries (sweet)	2 / 1	12
11%	Watermelons	0.2 / 0.09	11

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
42%	Celeries	6 / 2.62	42
27%	Table grapes	2 / 0.81	27
19%	Wine grapes	2 / 0.81	19
19%	Peaches	2 / 1	19
18%	Pears	0.9 / 0.59	18
18%	Plums	2 / 1	18
17%	Apples	0.9 / 0.59	17
16%	Brussels sprouts	4 / 2.7	16
12%	Tea (dried leaves of	50 / 23	12
11%	Apricots	2 / 1	11
10%	Cherries (sweet)	2 / 1	10.0
10%	Tomatoes	2 / 0.63	10.0
9%	Quinces	0.9 / 0.59	9.0
7%	Beans (with pods)	2 / 0.9	6.9
6%	Sweet peppers/bell peppers	0.7 / 0.37	6.0

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
27%	Brussels sprouts / boiled	4 / 2.7	27
26%	Peaches / canned	2 / 1	26
11%	Beans (with pods) / boiled	2 / 0.9	11
10%	Peaches / juice	2 / 0.59	9.8
8%	Pears / juice	0.9 / 0.25	8.1
8%	Tea (dried leaves of Camelli	50 / 0.23	8.1
8%	Pumpkins / boiled	0.2 / 0.09	8.0
6%	Plums / juice	2 / 0.59	5.6
5%	Lentils / boiled	1 / 0.59	4.8
4%	Peas / canned	1 / 0.24	4.2
3%	Peas (without pods) / canne	2 / 0.43	3.4
3%	Tomatoes / sauce/puree	2 / 0.35	3.3
3%	Courgettes / boiled	0.2 / 0.09	3.2
3%	Tomatoes / juice	2 / 0.15	2.8
2%	Gherkins / pickled	0.2 / 0.09	2.1

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)
88%	Celeries / boiled	6 / 2.62	88
8%	Peaches / canned	2 / 1	8.2
8%	Wine grapes / wine	2 / 0.81	7.7
5%	Pumpkins / boiled	0.2 / 0.09	5.0
5%	Tea (dried leaves of	50 / 0.23	4.7
5%	Beans (without pods) /	2 / 0.9	4.6
4%	Beans / canned	1 / 0.59	4.2
3%	Peas (with pods) / boiled	2 / 0.9	3.1
3%	Tomatoes / sauce/puree	2 / 0.35	2.9
3%	Peas (without pods) / boiled	2 / 0.9	2.8
2%	Courgettes / boiled	0.2 / 0.09	2.1
2%	Peas / canned	1 / 0.24	1.6
0.7%	Wine grapes / juice	2 / 0.03	0.70
0.5%	Apples / juice	0.9 / 0.02	0.50
0.3%	Quinces / jam	0.9 / 0.25	0.31

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

EFSA PRIMo revision 3.1; 2021/01/06

Fluopyram

LOQs (mg/kg) range from: 0.01 to: 40.0

Toxicological reference values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 7

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)
329%	NL toddler	39.45	239%	Milk: Cattle	12%	Apples	9%	Bananas		329%
186%	UK infant	22.36	155%	Milk: Cattle	5%	Bovine: Muscle/meat	5%	Eggs: Chicken		186%
158%	NL child	18.95	98%	Milk: Cattle	7%	Wheat	7%	Apples		158%
157%	FR toddler 2 3 yr	18.89	117%	Milk: Cattle	5%	Bovine: Muscle/meat	5%	Swine: Muscle/meat		157%
146%	DE child	17.50	79%	Milk: Cattle	14%	Apples	7%	Table grapes		146%
141%	FR child 3 15 yr	16.91	91%	Milk: Cattle	7%	Wheat	6%	Bovine: Muscle/meat		141%
116%	UK toddler	13.96	83%	Milk: Cattle	6%	Wheat	5%	Bovine: Muscle/meat		116%
98%	SE general	11.73	50%	Milk: Cattle	19%	Bovine: Muscle/meat	5%	Wheat		98%
96%	DK child	11.56	51%	Milk: Cattle	9%	Swine: Muscle/meat	7%	Wheat		96%
95%	ES child	11.38	50%	Milk: Cattle	7%	Wheat	6%	Bovine: Muscle/meat		95%
85%	GEMS/Food G07	10.17	26%	Milk: Cattle	7%	Wheat	6%	Wine grapes		85%
84%	FR infant	10.09	67%	Milk: Cattle	2%	Apples	2%	Beans (with pods)		84%
84%	RO general	10.08	46%	Milk: Cattle	8%	Wheat	6%	Wine grapes		84%
82%	DE women 14-50 yr	9.86	50%	Milk: Cattle	4%	Swine: Muscle/meat	3%	Wheat		82%
81%	DE general	9.78	49%	Milk: Cattle	5%	Swine: Muscle/meat	3%	Wine grapes		81%
81%	GEMS/Food G11	9.76	31%	Milk: Cattle	7%	Celeries	6%	Wheat		81%
79%	GEMS/Food G15	9.43	28%	Milk: Cattle	7%	Wheat	6%	Swine: Muscle/meat		79%
72%	GEMS/Food G08	8.64	22%	Milk: Cattle	8%	Swine: Muscle/meat	6%	Wheat		72%
70%	IE adult	8.42	17%	Milk: Cattle	7%	Sheep: Liver	5%	Basil and edible flowers		70%
69%	GEMS/Food G10	8.30	22%	Milk: Cattle	6%	Wheat	4%	Lettuces		69%
64%	NL general	7.73	34%	Milk: Cattle	4%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		64%
56%	GEMS/Food G06	6.75	11%	Wheat	10%	Milk: Cattle	5%	Table grapes		56%
52%	ES adult	6.28	20%	Milk: Cattle	7%	Lettuces	4%	Wheat		52%
48%	FR adult	5.81	18%	Milk: Cattle	9%	Wine grapes	4%	Wheat		48%
46%	DK adult	5.53	21%	Milk: Cattle	4%	Swine: Muscle/meat	4%	Wine grapes		46%
33%	LT adult	3.98	16%	Milk: Cattle	4%	Swine: Muscle/meat	2%	Apples		33%
32%	UK adult	3.80	12%	Milk: Cattle	4%	Wine grapes	3%	Bovine: Muscle/meat		32%
31%	UK vegetarian	3.72	13%	Milk: Cattle	3%	Wheat	3%	Wine grapes		31%
27%	PT general	3.29	10%	Wine grapes	6%	Wheat	1%	Table grapes		27%
25%	IT toddler	3.04	11%	Wheat	4%	Lettuces	2%	Tomatoes		25%
22%	IE child	2.60	14%	Milk: Cattle	2%	Wheat	1%	Swine: Fat tissue		22%
21%	IT adult	2.57	7%	Wheat	5%	Lettuces	1%	Tomatoes		21%
18%	FI 3 yr	2.13	2%	Bananas	2%	Wheat	2%	Raspberries (red and yellow)		18%
14%	FI 6 yr	1.65	2%	Wheat	1%	Raspberries (red and yellow)	1%	Bananas		14%
10%	PL general	1.16	2%	Apples	2%	Table grapes	1%	Tomatoes		10%
9%	FI adult	1.14	2%	Lettuces	1%	Wine grapes	0.7%	Tomatoes		9%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 328.7 % of the ADI.
For 7 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Uni

The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
76%	Lettuces	15 / 10	381
73%	Celeries	20 / 9.74	364
42%	Rhubarbs	15 / 5.6	208
18%	Florence fennels	15 / 5.6	91
18%	Peaches	1.5 / 0.95	90
15%	Sweet peppers/bell peppers	2 / 1.23	73
15%	Table grapes	2 / 1	73
14%	Pears	0.6 / 0.5	69
12%	Bovine: Liver	8 / 7.4	60
12%	Milk: Cattle	0.8 / 0.48	60
11%	Apples	0.6 / 0.5	53
10%	Bananas	0.8 / 0.52	50
8%	Oranges	0.5 / 0.32	42
8%	Escaroles/broad-leaved	2 / 0.98	39
7%	Apricots	1.5 / 0.95	33

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
31%	Celeries	20 / 9.74	156
24%	Lettuces	15 / 10	121
21%	Florence fennels	15 / 5.6	104
12%	Cardoons	15 / 5.6	58
10%	Rhubarbs	15 / 5.6	52
8%	Blueberries	7 / 4.33	39
7%	Table grapes	2 / 1	34
6%	Bovine: Liver	8 / 7.4	30
5%	Wine grapes	1.5 / 0.95	23
4%	Chinese cabbages/pe-tsai	2 / 0.84	21
4%	Sheep: Liver	8 / 7.4	21
4%	Sweet peppers/bell peppers	2 / 1.23	20
4%	Escaroles/broad-leaved	2 / 0.98	20
4%	Blackberries	5 / 2.39	20
4%	Purslanes	20 / 10	19

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
51%	Florence fennels / boiled	15 / 5.6	254
42%	Rhubarbs / sauce/puree	15 / 5.6	209
13%	Escaroles/broad-leaved endi	2 / 0.98	65
6%	Chards/beet leaves / boiled	2 / 0.98	30
5%	Peaches / canned	1.5 / 0.95	25
4%	Currants (red, black and whi	4 / 0.78	22
4%	Beans (with pods) / boiled	3 / 1.65	21
4%	Leeks / boiled	0.8 / 0.32	18
4%	Broccoli / boiled	0.5 / 0.23	18
3%	Spinaches / frozen; boiled	2 / 0.98	14
3%	Raspberries / juice	5 / 1.12	13
2%	Elderberries / juice	4 / 0.78	12
2%	Witloofs / boiled	0.3 / 0.14	12
2%	Courgettes / boiled	0.6 / 0.3	11
2%	Cauliflowers / boiled	0.3 / 0.14	9.7

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)
66%	Celeries / boiled	20 / 9.74	329
22%	Florence fennels / boiled	15 / 5.6	109
16%	Rhubarbs / sauce/puree	15 / 5.6	82
14%	Cardoons / boiled	15 / 5.6	68
8%	Purslanes / boiled	20 / 10	41
4%	Escaroles/broad-leaved	2 / 0.98	20
2%	Chards/beet leaves / boiled	2 / 0.98	12
2%	Currants (red, black and	4 / 0.78	9.9
2%	Spinaches / frozen; boiled	2 / 0.98	8.1
2%	Peaches / canned	1.5 / 0.95	7.8
1%	Elderberries / juice	4 / 0.78	7.2
1%	Courgettes / boiled	0.6 / 0.3	6.9
1%	Wine grapes / wine	1.5 / 0.67	6.3
1%	Cauliflowers / boiled	0.3 / 0.14	5.8
1%	Peas (with pods) / boiled	3 / 1.65	5.6

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

EFSA PRIMo revision 3.1; 2021/01/06

Thiamethoxam

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

Toxicological reference values

ADI (mg/kg bw/day):	0.026	ARfD (mg/kg bw):	0.5
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2006	Year of evaluation:	2006

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)
12%	NL toddler	3.20	9%	Milk: Cattle	0.4%	Apples	0.3%	Maize/corn	3%	10%
7%	UK infant	1.90	6%	Milk: Cattle	0.2%	Bovine: Edible offals (other than liver and	0.1%	Potatoes	0.9%	6%
6%	FR toddler 2 3 yr	1.53	5%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	1%	5%
6%	NL child	1.48	4%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Apples	2%	4%
5%	FR child 3 15 yr	1.32	4%	Milk: Cattle	0.2%	Wheat	0.1%	Sugar beet roots	1%	4%
5%	DE child	1.26	3%	Milk: Cattle	0.5%	Apples	0.2%	Wheat	2%	3%
4%	UK toddler	1.12	3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1.0%	3%
3%	DK child	0.87	2%	Milk: Cattle	0.2%	Rye	0.2%	Swine: Muscle/meat	1%	2%
3%	FR infant	0.83	3%	Milk: Cattle	0.1%	Potatoes	0.1%	Apples	0.5%	3%
3%	ES child	0.82	2%	Milk: Cattle	0.2%	Wheat	0.1%	Bovine: Muscle/meat	1%	2%
3%	SE general	0.80	2%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%	Potatoes	1%	2%
3%	DE women 14-50 yr	0.78	2%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	1.0%	2%
3%	DE general	0.77	2%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	1.0%	2%
3%	RO general	0.76	2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	2%
3%	GEMS/Food G11	0.71	1%	Milk: Cattle	0.2%	Potatoes	0.1%	Soyabeans	1%	1%
3%	GEMS/Food G15	0.68	1%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	1%
3%	GEMS/Food G07	0.68	1%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	1%
2%	GEMS/Food G08	0.61	0.9%	Milk: Cattle	0.2%	Wheat	0.2%	Swine: Muscle/meat	1%	1.0%
2%	GEMS/Food G10	0.60	0.9%	Milk: Cattle	0.2%	Wheat	0.1%	Soyabeans	1%	1.0%
2%	NL general	0.59	1%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Potatoes	0.9%	1%
2%	IE adult	0.57	0.7%	Milk: Cattle	0.2%	Sheep: Liver	0.1%	Sweet potatoes	1%	1%
2%	GEMS/Food G06	0.50	0.4%	Milk: Cattle	0.3%	Wheat	0.1%	Tomatoes	1%	0.5%
2%	FR adult	0.40	0.7%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat	0.7%	0.8%
2%	ES adult	0.39	0.8%	Milk: Cattle	0.1%	Wheat	0.1%	Bovine: Muscle/meat	0.7%	0.8%
1%	DK adult	0.36	0.8%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Potatoes	0.5%	0.9%
1%	FI adult	0.35	1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	1%	
1%	LT adult	0.31	0.6%	Milk: Cattle	0.1%	Potatoes	0.1%	Swine: Muscle/meat	0.5%	0.7%
1.0%	UK vegetarian	0.25	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.4%	0.5%
0.9%	UK adult	0.25	0.5%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.5%	0.5%
0.8%	PT general	0.21	0.2%	Potatoes	0.2%	Wheat	0.1%	Wine grapes	0.8%	
0.8%	IE child	0.20	0.6%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.6%
0.7%	FI 3 yr	0.17	0.2%	Potatoes	0.1%	Bananas	0.0%	Wheat	0.7%	
0.6%	IT toddler	0.16	0.3%	Wheat	0.1%	Other cereals	0.1%	Tomatoes	0.6%	
0.5%	FI 6 yr	0.14	0.1%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.5%	
0.5%	IT adult	0.12	0.2%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.5%	
0.4%	PL general	0.10	0.1%	Potatoes	0.1%	Apples	0.0%	Tomatoes	0.4%	

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Thiamethoxam is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European U

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Milk: Cattle	0.05 / 0.04	5.1
0.6%	Bovine: Liver	0.4 / 0.37	3.0
0.5%	Bovine: Edible offals (other	0.4 / 0.37	2.7
0.3%	Potatoes	0.01 / 0.01	1.5
0.3%	Melons	0.01 / 0.01	1.5
0.3%	Bovine: Kidney	0.4 / 0.37	1.4
0.3%	Pears	0.01 / 0.01	1.4
0.3%	Oranges	0.01 / 0.01	1.3
0.2%	Watermelons	0.01 / 0.01	1.2
0.2%	Swine: Edible offals (other	0.4 / 0.37	1.1
0.2%	Apples	0.01 / 0.01	1.1
0.2%	Pineapples	0.01 / 0.01	1.0
0.2%	Milk: Goat	0.05 / 0.04	0.99
0.2%	Bananas	0.01 / 0.01	0.97
0.2%	Peaches	0.01 / 0.01	0.95

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Poultry: Liver	0.4 / 0.37	1.7
0.3%	Milk: Cattle	0.05 / 0.04	1.6
0.3%	Bovine: Liver	0.4 / 0.37	1.5
0.2%	Bovine: Edible offals (other	0.4 / 0.37	1.2
0.2%	Sheep: Liver	0.4 / 0.37	1.0
0.2%	Swine: Edible offals (other	0.4 / 0.37	0.97
0.2%	Swine: Kidney	0.4 / 0.37	0.81
0.2%	Bovine: Kidney	0.4 / 0.37	0.78
0.2%	Milk: Goat	0.05 / 0.04	0.75
0.1%	Milk: Sheep	0.05 / 0.04	0.62
0.1%	Swine: Liver	0.4 / 0.37	0.52
0.10%	Poultry: Kidney	0.4 / 0.37	0.48
0.08%	Head cabbages	0.01 / 0.01	0.42
0.08%	Watermelons	0.01 / 0.01	0.41
0.08%	Melons	0.01 / 0.01	0.39

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.2%	Potatoes / fried	0.01 / 0.01	0.93
0.2%	Pumpkins / boiled	0.01 / 0.01	0.89
0.2%	Witloofs / boiled	0.01 / 0.01	0.89
0.2%	Broccoli / boiled	0.01 / 0.01	0.79
0.1%	Cauliflowers / boiled	0.01 / 0.01	0.70
0.1%	Escaroles/broad-leaved end	0.01 / 0.01	0.66
0.1%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
0.1%	Leeks / boiled	0.01 / 0.01	0.57
0.1%	Apples / juice	0.01 / 0.01	0.54
0.1%	Oranges / juice	0.01 / 0.01	0.53
0.1%	Turnips / boiled	0.01 / 0.01	0.51
0.1%	Parsnips / boiled	0.01 / 0.01	0.51
0.1%	Sweet potatoes / boiled	0.01 / 0.01	0.50
0.1%	Florence fennels / boiled	0.01 / 0.01	0.45

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%	Pumpkins / boiled	0.01 / 0.01	0.55
0.09%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.08%	Cauliflowers / boiled	0.01 / 0.01	0.42
0.08%	Beetroots / boiled	0.01 / 0.01	0.39
0.07%	Celeries / boiled	0.01 / 0.01	0.34
0.07%	Apples / juice	0.01 / 0.01	0.33
0.05%	Broccoli / boiled	0.01 / 0.01	0.24
0.05%	Coffee beans / extraction	0.05 / 0.01	0.24
0.05%	Courgettes / boiled	0.01 / 0.01	0.23
0.04%	Parsnips / boiled	0.01 / 0.01	0.21
0.04%	Kohlrabies / boiled	0.01 / 0.01	0.21
0.04%	Wine grapes / juice	0.01 / 0.01	0.21
0.04%	Escaroles/broad-leaved	0.01 / 0.01	0.20
0.04%	Florence fennels / boiled	0.01 / 0.01	0.19
0.04%	Turnips / boiled	0.01 / 0.01	0.19

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

EFSA PRIMo revision 3.1; 2021/01/06

Dinotefuran

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

Toxicological reference values

ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	1
Source of ADI:	JMPR	Source of ARfD:	JMPR
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 : ---

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)
7%	GEMS/Food G06	14.36	6%	Rice	0.5%	Table grapes	0.1%	Milk: Cattle	0.0%	0.0%
6%	NL toddler	12.95	3%	Milk: Cattle	3%	Rice	0.7%	Table grapes		0.0%
6%	GEMS/Food G10	11.75	5%	Rice	0.3%	Milk: Cattle	0.2%	Wine grapes	0.0%	0.0%
5%	UK infant	9.22	3%	Rice	2%	Milk: Cattle	0.1%	Bovine: Muscle/meat		0.0%
5%	PT general	9.09	3%	Rice	1%	Wine grapes	0.1%	Peaches		
4%	FR toddler 2 3 yr	8.28	2%	Rice	1%	Milk: Cattle	0.1%	Wine grapes	0.0%	0.0%
4%	UK toddler	7.19	2%	Rice	1%	Milk: Cattle	0.1%	Table grapes		0.0%
4%	FR child 3 15 yr	7.01	2%	Rice	1%	Milk: Cattle	0.2%	Wine grapes	0.0%	0.0%
3%	DE child	5.95	1%	Rice	1.0%	Milk: Cattle	0.6%	Table grapes		0.0%
3%	GEMS/Food G07	5.67	1%	Rice	0.7%	Wine grapes	0.3%	Milk: Cattle	0.0%	0.0%
3%	ES child	5.67	2%	Rice	0.6%	Milk: Cattle	0.1%	Peaches		0.0%
3%	SE general	5.20	2%	Rice	0.6%	Milk: Cattle	0.2%	Bovine: Muscle/meat		0.0%
3%	NL child	5.19	1%	Milk: Cattle	0.7%	Rice	0.5%	Table grapes		0.0%
3%	RO general	5.17	1.0%	Rice	0.8%	Wine grapes	0.6%	Milk: Cattle		0.0%
2%	GEMS/Food G15	4.89	1%	Rice	0.5%	Wine grapes	0.4%	Milk: Cattle	0.0%	0.0%
2%	GEMS/Food G08	4.85	1%	Rice	0.5%	Wine grapes	0.3%	Milk: Cattle	0.0%	0.0%
2%	FI 3 yr	4.83	2%	Rice	0.1%	Table grapes	0.0%	Peaches		
2%	GEMS/Food G11	4.82	1%	Rice	0.5%	Wine grapes	0.4%	Milk: Cattle	0.0%	0.0%
2%	IE adult	4.46	0.9%	Rice	0.6%	Wine grapes	0.2%	Milk: Cattle		0.0%
2%	UK adult	4.42	1%	Rice	0.5%	Wine grapes	0.1%	Milk: Cattle		0.0%
2%	UK vegetarian	4.38	2%	Rice	0.4%	Wine grapes	0.2%	Milk: Cattle		0.0%
2%	DK child	4.29	1%	Rice	0.6%	Milk: Cattle	0.1%	Swine: Muscle/meat		0.0%
2%	FR adult	4.20	1%	Wine grapes	0.6%	Rice	0.2%	Milk: Cattle	0.0%	0.0%
2%	FI 6 yr	3.66	2%	Rice	0.1%	Table grapes	0.0%	Peaches		
2%	ES adult	3.23	1.0%	Rice	0.2%	Milk: Cattle	0.2%	Wine grapes		0.0%
1%	NL general	2.96	0.5%	Rice	0.4%	Milk: Cattle	0.3%	Wine grapes		0.0%
1%	IE child	2.85	1%	Rice	0.2%	Milk: Cattle	0.0%	Table grapes	0.0%	0.0%
1%	DE women 14-50 yr	2.57	0.6%	Milk: Cattle	0.4%	Wine grapes	0.1%	Table grapes	0.0%	0.0%
1%	DE general	2.52	0.6%	Milk: Cattle	0.4%	Wine grapes	0.1%	Table grapes	0.0%	0.0%
1%	DK adult	2.46	0.4%	Wine grapes	0.3%	Rice	0.3%	Milk: Cattle		0.0%
1%	FR infant	2.39	0.8%	Milk: Cattle	0.3%	Rice	0.0%	Swine: Muscle/meat	0.0%	0.0%
1%	LT adult	2.26	0.9%	Rice	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.0%
1.0%	IT toddler	1.96	0.8%	Rice	0.1%	Peaches	0.0%	Table grapes		
0.9%	IT adult	1.88	0.7%	Rice	0.2%	Peaches	0.1%	Table grapes		
0.7%	FI adult	1.41	0.5%	Rice	0.1%	Wine grapes	0.0%	Table grapes		
0.2%	PL general	0.37	0.1%	Table grapes	0.0%	Peaches	0.0%	Onions		

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Dinotefuran is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Rice	8 / 8	101
8%	Peaches	0.8 / 0.8	76
7%	Table grapes	0.9 / 0.9	66
6%	Spring onions/green onions and Welsh onions	4 / 4	63
2%	Mangoes	0.6 / 0.3	24
2%	Celeries	0.6 / 0.6	22
1%	Milk: Cattle	0.1 / 0.1	12
0.8%	Wine grapes	0.9 / 0.9	8.4
0.3%	Watercress	7 / 7	3.2
0.2%	Milk: Goat	0.1 / 0.1	2.4
0.2%	Onions	0.1 / 0.1	2.3
0.1%	Swine: Muscle/meat	0.1 / 0.1	1.2
0.08%	Bovine: Liver	0.1 / 0.1	0.81
0.07%	Bovine: Edible offals (other than liver and kidney)	0.1 / 0.1	0.73
0.07%	Bovine: Muscle/meat	0.1 / 0.1	0.72

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Rice	8 / 8	68
3%	Table grapes	0.9 / 0.9	31
2%	Wine grapes	0.9 / 0.9	21
2%	Spring onions/green onions and Welsh onions	4 / 4	18
1%	Peaches	0.8 / 0.8	15
1.0%	Celeries	0.6 / 0.6	9.6
0.8%	Watercress	7 / 7	8.3
0.8%	Mangoes	0.6 / 0.3	7.8
0.4%	Milk: Cattle	0.1 / 0.1	3.9
0.2%	Milk: Goat	0.1 / 0.1	1.8
0.2%	Milk: Sheep	0.1 / 0.1	1.5
0.1%	Onions	0.1 / 0.1	1.5
0.06%	Bovine: Muscle	0.1 / 0.1	0.57
0.06%	Other farmed animals: Muscle/meat	0.1 / 0.1	0.56
0.05%	Swine: Muscle/meat	0.1 / 0.1	0.48

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Rice / milling (polishing)	8 / 3.2	49
4%	Wine grapes / juice	0.9 / 0.9	39
2%	Peaches / canned	0.8 / 0.8	21
1%	Peaches / juice	0.8 / 0.8	13
0.1%	Cranberries / juice	0.15 / 0.15	0.87

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%	Rice / milling (polishing)	8 / 3.2	31
2%	Celeries / boiled	0.6 / 0.6	20
2%	Wine grapes / juice	0.9 / 0.9	19
0.9%	Wine grapes / wine	0.9 / 0.9	8.5
0.7%	Peaches / canned	0.8 / 0.8	6.5
0.5%	Table grapes / raisins	0.9 / 4.23	5.2
0.09%	Onions / boiled	0.1 / 0.1	0.94
0.01%	Cranberries / dried	0.15 / 0.15	0.11

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Dinotefuran is unlikely to present a public health risk.

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

EFSA PRIMo revision 3.1; 2021/01/06

Cyantraniliprole

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 2

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
191%	NL toddler	19.11	125%	Milk: Cattle	17%	Apples	8%	Escaroles/broad-leaved endives		191%
110%	DE child	10.99	41%	Milk: Cattle	20%	Apples	4%	Table grapes		110%
98%	UK infant	9.77	81%	Milk: Cattle	3%	Apples	2%	Tea (dried leaves of Camellia sinens		98%
90%	NL child	8.95	51%	Milk: Cattle	9%	Apples	3%	Escaroles/broad-leaved endives		90%
83%	FR toddler 2 3 yr	8.28	62%	Milk: Cattle	5%	Apples	2%	Beans (with pods)		83%
74%	FR child 3 15 yr	7.36	48%	Milk: Cattle	4%	Other lettuce and other salad plants	3%	Apples		74%
71%	SE general	7.06	26%	Milk: Cattle	13%	Lettuces	12%	Chinese cabbages/pe-tsai		71%
63%	GEMS/Food G10	6.29	12%	Milk: Cattle	11%	Lettuces	9%	Chinese cabbages/pe-tsai		63%
60%	UK toddler	5.95	43%	Milk: Cattle	3%	Apples	1%	Tea (dried leaves of Camellia sinens		60%
59%	ES child	5.95	26%	Milk: Cattle	14%	Lettuces	4%	Olives for oil production		59%
59%	IE adult	5.89	11%	Other leafy brassica	9%	Milk: Cattle	5%	Tea (dried leaves of Camellia sinens		59%
54%	GEMS/Food G07	5.44	14%	Milk: Cattle	8%	Lettuces	5%	Wine grapes		54%
54%	GEMS/Food G08	5.43	12%	Milk: Cattle	6%	Lettuces	5%	Parsley		54%
53%	GEMS/Food G11	5.28	16%	Milk: Cattle	6%	Celeries	3%	Wine grapes		53%
52%	DE women 14-50 yr	5.20	26%	Milk: Cattle	4%	Apples	4%	Lettuces		52%
52%	GEMS/Food G15	5.17	15%	Milk: Cattle	5%	Head cabbages	4%	Parsley		52%
51%	DE general	5.08	26%	Milk: Cattle	4%	Apples	3%	Lettuces		51%
51%	RO general	5.06	24%	Milk: Cattle	8%	Head cabbages	5%	Wine grapes		51%
48%	FR infant	4.85	35%	Milk: Cattle	3%	Apples	1%	Cauliflowers		48%
45%	DK child	4.51	27%	Milk: Cattle	5%	Lettuces	4%	Apples		45%
44%	ES adult	4.44	17%	Lettuces	10%	Milk: Cattle	4%	Chards/beet leaves		44%
44%	GEMS/Food G06	4.42	6%	Tomatoes	5%	Milk: Cattle	3%	Lettuces		44%
42%	NL general	4.16	18%	Milk: Cattle	3%	Escaroles/broad-leaved endives	3%	Lettuces		42%
39%	FR adult	3.90	9%	Milk: Cattle	7%	Wine grapes	6%	Tea (dried leaves of Camellia sinens		39%
36%	IT adult	3.61	12%	Lettuces	5%	Other lettuce and other salad plants	3%	Other spinach and similar	0.0%	36%
31%	IT toddler	3.09	9%	Lettuces	4%	Other lettuce and other salad plants	3%	Chards/beet leaves	0.0%	31%
25%	DK adult	2.50	11%	Milk: Cattle	3%	Wine grapes	3%	Lettuces		25%
25%	UK vegetarian	2.46	7%	Milk: Cattle	5%	Lettuces	3%	Wine grapes		25%
23%	UK adult	2.25	6%	Milk: Cattle	4%	Lettuces	3%	Wine grapes		23%
22%	PT general	2.23	8%	Wine grapes	3%	Lettuces	2%	Apples		22%
20%	LT adult	1.97	8%	Milk: Cattle	3%	Apples	2%	Head cabbages		20%
15%	FI 3 yr	1.47	2%	Raspberries (red and yellow)	2%	Strawberries	2%	Apples		15%
15%	PL general	1.46	3%	Apples	2%	Head cabbages	2%	Tomatoes		15%
13%	FI 6 yr	1.34	3%	Lettuces	2%	Chinese cabbages/pe-tsai	1%	Raspberries (red and yellow)		13%
13%	FI adult	1.29	5%	Lettuces	1%	Chinese cabbages/pe-tsai	1.0%	Wine grapes		13%
11%	IE child	1.08	8%	Milk: Cattle	0.5%	Apples	0.3%	Broccoli		11%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 191.1 % of the ADI.
For 2 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Proquinazid

EFSA PRIMo revision 3.1; 2021/01/06

Pyriofenone

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

Toxicological reference values

ADI (mg/kg bw/day):	0.07	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

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

Comments:

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)
4%	NL toddler	2.73	0.9%	Milk: Cattle	0.7%	Currants (red, black and white)	0.4%	Rose hips	2%	0.4%
3%	PT general	2.35	3%	Wine grapes	0.1%	Sweet peppers/bell peppers	0.1%	Potatoes	0.2%	0.2%
3%	FR adult	2.24	3%	Wine grapes	0.1%	Strawberries	0.1%	Milk: Cattle	0.3%	0.2%
3%	RO general	2.21	2%	Wine grapes	0.2%	Sweet peppers/bell peppers	0.2%	Milk: Cattle	0.5%	0.5%
3%	IE adult	1.93	1%	Wine grapes	0.2%	Melons	0.2%	Strawberries	0.4%	0.4%
3%	GEMS/Food G07	1.86	2%	Wine grapes	0.1%	Milk: Cattle	0.1%	Tomatoes	0.5%	0.2%
3%	GEMS/Food G15	1.86	1%	Wine grapes	0.3%	Sweet peppers/bell peppers	0.2%	Rose hips	0.5%	0.5%
2%	GEMS/Food G08	1.74	1%	Wine grapes	0.2%	Currants (red, black and white)	0.1%	Sweet peppers/bell peppers	0.5%	0.3%
2%	NL child	1.71	0.5%	Currants (red, black and white)	0.3%	Milk: Cattle	0.3%	Strawberries	0.9%	0.4%
2%	DE child	1.64	0.4%	Strawberries	0.3%	Milk: Cattle	0.2%	Table grapes	0.8%	0.7%
2%	GEMS/Food G06	1.56	0.3%	Watermelons	0.3%	Tomatoes	0.2%	Sweet peppers/bell peppers	0.4%	0.8%
2%	GEMS/Food G11	1.51	1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Sweet peppers/bell peppers	0.5%	0.3%
2%	DE women 14-50 yr	1.44	1.0%	Wine grapes	0.2%	Milk: Cattle	0.1%	Strawberries	0.5%	0.2%
2%	DE general	1.37	0.9%	Wine grapes	0.2%	Milk: Cattle	0.1%	Strawberries	0.5%	0.2%
2%	FR child 3 15 yr	1.22	0.4%	Wine grapes	0.3%	Milk: Cattle	0.2%	Strawberries	0.8%	0.3%
2%	GEMS/Food G10	1.19	0.5%	Wine grapes	0.1%	Tomatoes	0.1%	Sweet peppers/bell peppers	0.5%	0.3%
2%	DK adult	1.13	1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Cucumbers	0.2%	0.2%
2%	UK adult	1.12	1%	Wine grapes	0.0%	Milk: Cattle	0.0%	Strawberries	0.2%	0.1%
2%	FI 3 yr	1.08	0.3%	Strawberries	0.3%	Cucumbers	0.2%	Raspberries (red and yellow)	0.2%	0.4%
1%	NL general	1.03	0.7%	Wine grapes	0.1%	Milk: Cattle	0.1%	Strawberries	0.4%	0.1%
1%	UK vegetarian	1.00	0.9%	Wine grapes	0.1%	Strawberries	0.0%	Tomatoes	0.2%	0.2%
1%	DK child	1.00	0.5%	Cucumbers	0.2%	Milk: Cattle	0.1%	Strawberries	0.5%	0.3%
1%	UK toddler	0.99	0.3%	Milk: Cattle	0.3%	Currants (red, black and white)	0.2%	Strawberries	0.6%	0.2%
1%	FR toddler 2 3 yr	0.94	0.4%	Milk: Cattle	0.3%	Wine grapes	0.1%	Strawberries	0.8%	0.2%
1%	UK infant	0.92	0.6%	Milk: Cattle	0.2%	Strawberries	0.1%	Currants (red, black and white)	0.9%	0.2%
1%	FI adult	0.90	0.4%	Coffee beans	0.4%	Wine grapes	0.1%	Strawberries	0.5%	0.2%
1%	SE general	0.87	0.2%	Milk: Cattle	0.1%	Strawberries	0.1%	Sweet peppers/bell peppers	0.5%	0.3%
1%	FI 6 yr	0.77	0.2%	Strawberries	0.2%	Cucumbers	0.2%	Raspberries (red and yellow)	0.2%	0.3%
1%	ES adult	0.75	0.5%	Wine grapes	0.1%	Sweet peppers/bell peppers	0.1%	Milk: Cattle	0.3%	0.2%
0.9%	ES child	0.60	0.2%	Milk: Cattle	0.1%	Tomatoes	0.1%	Wheat	0.5%	0.2%
0.8%	FR infant	0.57	0.2%	Milk: Cattle	0.2%	Strawberries	0.1%	Courgettes	0.4%	0.2%
0.6%	IT toddler	0.44	0.1%	Tomatoes	0.1%	Strawberries	0.1%	Wheat	0.2%	0.3%
0.5%	IT adult	0.37	0.1%	Tomatoes	0.1%	Wheat	0.1%	Aubergines/egg plants	0.1%	0.2%
0.5%	LT adult	0.35	0.1%	Cucumbers	0.1%	Milk: Cattle	0.0%	Tomatoes	0.2%	0.1%
0.4%	PL general	0.31	0.1%	Gooseberries (green, red and yellow)	0.1%	Tomatoes	0.0%	Potatoes	0.1%	0.1%
0.2%	IE child	0.16	0.1%	Currants (red, black and white)	0.1%	Milk: Cattle	0.0%	Strawberries	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 Pyriofenone is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2021/01/06

Metconazole (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2006	Year of evaluation:	2006

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)
50%	NL toddler	5.00	24%	Milk: Cattle	7%	Maize/corn	5%	Bananas	34%	34%
24%	UK infant	2.39	15%	Milk: Cattle	1%	Bananas	1%	Potatoes	20%	20%
23%	NL child	2.31	10%	Milk: Cattle	2%	Bananas	2%	Sugar beet roots	17%	17%
20%	DE child	2.04	8%	Milk: Cattle	2%	Apples	2%	Wheat	16%	13%
20%	FR toddler 2 3 yr	1.96	12%	Milk: Cattle	1%	Wheat	0.7%	Potatoes	17%	16%
19%	FR child 3 15 yr	1.93	9%	Milk: Cattle	2%	Wheat	0.7%	Sugar beet roots	15%	15%
16%	UK toddler	1.62	8%	Milk: Cattle	2%	Wheat	1%	Potatoes	13%	13%
14%	DK child	1.41	5%	Milk: Cattle	2%	Wheat	1%	Bananas	10%	11%
14%	GEMS/Food G11	1.40	3%	Milk: Cattle	2%	Soyabeans	2%	Potatoes	12%	7%
14%	SE general	1.40	5%	Milk: Cattle	2%	Bananas	2%	Bovine: Muscle/meat	11%	10%
14%	ES child	1.38	5%	Milk: Cattle	2%	Wheat	1%	Bananas	10%	10%
14%	RO general	1.38	5%	Milk: Cattle	2%	Wheat	1%	Potatoes	9%	9%
13%	GEMS/Food G15	1.35	3%	Milk: Cattle	2%	Wheat	1%	Potatoes	10%	8%
13%	GEMS/Food G08	1.32	2%	Milk: Cattle	2%	Wheat	2%	Potatoes	10%	7%
13%	GEMS/Food G07	1.32	3%	Milk: Cattle	2%	Wheat	2%	Potatoes	10%	7%
13%	GEMS/Food G10	1.30	2%	Milk: Cattle	2%	Soyabeans	2%	Wheat	10%	6%
13%	GEMS/Food G06	1.27	3%	Wheat	1%	Maize/corn	1.0%	Milk: Cattle	7%	6%
12%	DE women 14-50 yr	1.15	5%	Milk: Cattle	0.9%	Sugar beet roots	0.9%	Wheat	9%	8%
11%	DE general	1.13	5%	Milk: Cattle	0.8%	Sugar beet roots	0.8%	Wheat	9%	8%
11%	IE adult	1.11	2%	Milk: Cattle	1%	Sweet potatoes	0.9%	Wheat	8%	5%
10%	FR infant	1.02	7%	Milk: Cattle	0.8%	Potatoes	0.3%	Apples	9%	8%
10%	NL general	1.00	3%	Milk: Cattle	1.0%	Potatoes	0.8%	Wheat	8%	7%
8%	FI adult	0.76	6%	Coffee beans	0.5%	Potatoes	0.3%	Bananas	7%	0.7%
7%	PT general	0.72	2%	Potatoes	2%	Wheat	0.5%	Wine grapes	4%	2%
7%	ES adult	0.71	2%	Milk: Cattle	0.9%	Wheat	0.4%	Potatoes	5%	5%
7%	FR adult	0.68	2%	Milk: Cattle	0.9%	Wheat	0.5%	Wine grapes	5%	4%
6%	FI 3 yr	0.60	2%	Potatoes	1%	Bananas	0.5%	Wheat	4%	2%
6%	DK adult	0.57	2%	Milk: Cattle	0.5%	Potatoes	0.5%	Bananas	5%	4%
5%	IT toddler	0.54	3%	Wheat	0.5%	Bananas	0.4%	Potatoes	2%	3%
5%	LT adult	0.54	2%	Milk: Cattle	1%	Potatoes	0.4%	Wheat	5%	3%
5%	UK vegetarian	0.48	1%	Milk: Cattle	0.8%	Wheat	0.5%	Potatoes	3%	3%
5%	UK adult	0.46	1%	Milk: Cattle	0.7%	Wheat	0.6%	Potatoes	3%	3%
5%	FI 6 yr	0.46	2%	Potatoes	0.8%	Bananas	0.4%	Wheat	3%	2%
4%	IT adult	0.37	2%	Wheat	0.2%	Potatoes	0.2%	Tomatoes	2%	2%
3%	IE child	0.30	1%	Milk: Cattle	0.5%	Wheat	0.2%	Potatoes	2%	2%
3%	PL general	0.29	1%	Potatoes	0.4%	Apples	0.2%	Bananas	3%	0.3%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Metconazole (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European U

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
97%	Bananas	0.1 / 0.1	9.7
95%	Peaches	0.1 / 0.1	9.5
76%	Melons	0.05 / 0.05	7.6
62%	Potatoes	0.04 / 0.04	6.2
50%	Milk: Cattle	0.04 / 0.04	5.0
35%	Apricots	0.1 / 0.1	3.5
28%	Pears	0.02 / 0.02	2.8
27%	Oranges	0.02 / 0.02	2.7
24%	Cherries (sweet)	0.2 / 0.2	2.4
24%	Watermelons	0.02 / 0.02	2.4
22%	Apples	0.02 / 0.02	2.2
20%	Pineapples	0.02 / 0.02	2.0
18%	Blueberries	0.4 / 0.3	1.8
16%	Mangoes	0.02 / 0.02	1.6
16%	Grapefruits	0.02 / 0.02	1.6

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
27%	Blueberries	0.4 / 0.3	2.7
21%	Bananas	0.1 / 0.1	2.1
20%	Cherries (sweet)	0.2 / 0.2	2.0
20%	Melons	0.05 / 0.05	2.0
19%	Peaches	0.1 / 0.1	1.9
15%	Milk: Cattle	0.04 / 0.04	1.5
12%	Potatoes	0.04 / 0.04	1.2
11%	Yams	0.04 / 0.04	1.1
11%	Apricots	0.1 / 0.1	1.1
8%	Head cabbages	0.02 / 0.02	0.84
8%	Sweet potatoes	0.04 / 0.04	0.83
8%	Watermelons	0.02 / 0.02	0.81
7%	Milk: Goat	0.04 / 0.04	0.74
7%	Swedes/rutabagas	0.02 / 0.02	0.68
7%	Table grapes	0.02 / 0.02	0.68

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
37%	Potatoes / fried	0.04 / 0.04	3.7
26%	Peaches / canned	0.1 / 0.1	2.6
24%	Potatoes / dried (flakes)	0.04 / 0.18	2.4
23%	Maize / oil	0.1 / 2.5	2.3
22%	Sugar beets (root) / sugar	0.06 / 0.24	2.2
20%	Sweet potatoes / boiled	0.04 / 0.04	2.0
18%	Pumpkins / boiled	0.02 / 0.02	1.8
18%	Witloofs / boiled	0.02 / 0.02	1.8
16%	Broccoli / boiled	0.02 / 0.02	1.6
14%	Cauliflowers / boiled	0.02 / 0.02	1.4
13%	Escaroles/broad-leaved end	0.02 / 0.02	1.3
11%	Leeks / boiled	0.02 / 0.02	1.1
11%	Apples / juice	0.02 / 0.02	1.1
11%	Oranges / juice	0.02 / 0.02	1.1
10%	Turnips / boiled	0.02 / 0.02	1.0

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)
13%	Maize / oil	0.1 / 2.5	1.3
11%	Pumpkins / boiled	0.02 / 0.02	1.1
9%	Sugar beets (root) / sugar	0.06 / 0.24	0.88
8%	Cauliflowers / boiled	0.02 / 0.02	0.83
8%	Peaches / canned	0.1 / 0.1	0.82
8%	Beetroots / boiled	0.02 / 0.02	0.78
8%	Cassava roots / boiled	0.04 / 0.04	0.76
7%	Celeries / boiled	0.02 / 0.02	0.68
7%	Apples / juice	0.02 / 0.02	0.67
6%	Sweet potatoes / boiled	0.04 / 0.04	0.62
5%	Broccoli / boiled	0.02 / 0.02	0.48
5%	Coffee beans / extraction	0.1 / 0.02	0.48
5%	Courgettes / boiled	0.02 / 0.02	0.46
4%	Parsnips / boiled	0.02 / 0.02	0.43
4%	Kohlrabies / boiled	0.02 / 0.02	0.43

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

EFSA PRIMo revision 3.1; 2021/01/06

Mefentrifluconazole (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.035	ARfD (mg/kg bw):	0.15
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
34%	NL toddler	11.76	12%	Milk: Cattle	5%	Spinaches	2%	Apples		34%
21%	DE child	7.30	4%	Milk: Cattle	3%	Apples	2%	Oranges		21%
18%	NL child	6.38	5%	Milk: Cattle	2%	Spinaches	2%	Sugar beet roots		18%
16%	GEMS/Food G06	5.44	3%	Tomatoes	2%	Wheat	2%	Sugar canes		16%
14%	FR child 3 15 yr	4.97	5%	Milk: Cattle	2%	Oranges	1%	Wheat		14%
14%	GEMS/Food G08	4.84	2%	Sugar canes	1%	Milk: Cattle	1%	Barley		14%
14%	GEMS/Food G07	4.77	2%	Sugar canes	1%	Milk: Cattle	1%	Wine grapes		14%
14%	GEMS/Food G11	4.76	2%	Sugar canes	2%	Milk: Cattle	0.9%	Barley		14%
14%	UK infant	4.74	8%	Milk: Cattle	0.8%	Oranges	0.7%	Wheat		14%
13%	FR toddler 2 3 yr	4.69	6%	Milk: Cattle	1%	Spinaches	0.9%	Oranges		13%
13%	GEMS/Food G15	4.52	1%	Milk: Cattle	1%	Sugar canes	1%	Wheat		13%
13%	GEMS/Food G10	4.50	1%	Sugar canes	1%	Tomatoes	1%	Milk: Cattle		13%
12%	IE adult	4.04	0.9%	Wine grapes	0.9%	Spinaches	0.9%	Milk: Cattle		12%
11%	ES child	4.02	2%	Milk: Cattle	1%	Oranges	1%	Lettuces		11%
11%	UK toddler	3.87	4%	Milk: Cattle	1%	Oranges	1%	Wheat		11%
11%	DE women 14-50 yr	3.85	2%	Milk: Cattle	1%	Oranges	0.8%	Sugar beet roots		11%
11%	DE general	3.74	2%	Milk: Cattle	1.0%	Oranges	0.8%	Sugar beet roots		11%
10%	SE general	3.59	2%	Milk: Cattle	1%	Lettuces	0.8%	Wheat		10%
10%	DK child	3.52	3%	Milk: Cattle	1%	Rye	1%	Wheat		10%
10%	RO general	3.51	2%	Milk: Cattle	2%	Tomatoes	1%	Wheat		10%
9%	ES adult	3.10	2%	Lettuces	1.0%	Milk: Cattle	0.8%	Oranges		9%
8%	NL general	2.87	2%	Milk: Cattle	1%	Spinaches	0.6%	Oranges		8%
8%	FR infant	2.76	3%	Milk: Cattle	2%	Spinaches	0.4%	Apples		8%
7%	IT toddler	2.51	2%	Wheat	1%	Tomatoes	0.9%	Lettuces		7%
7%	PT general	2.51	2%	Wine grapes	1%	Wheat	0.8%	Tomatoes		7%
7%	IT adult	2.33	1%	Lettuces	1%	Wheat	1.0%	Tomatoes		7%
6%	FR adult	2.27	2%	Wine grapes	0.9%	Milk: Cattle	0.6%	Wheat		6%
6%	FI 3 yr	2.06	0.7%	Oat	0.5%	Raspberries (red and yellow)	0.5%	Tomatoes		6%
5%	DK adult	1.77	1%	Milk: Cattle	0.7%	Wine grapes	0.4%	Tomatoes		5%
5%	UK vegetarian	1.76	0.7%	Milk: Cattle	0.6%	Wine grapes	0.5%	Oranges		5%
5%	FI 6 yr	1.59	0.4%	Spinaches	0.4%	Oat	0.4%	Tomatoes		5%
4%	UK adult	1.53	0.8%	Wine grapes	0.6%	Milk: Cattle	0.4%	Wheat		4%
4%	LT adult	1.31	0.8%	Milk: Cattle	0.5%	Tomatoes	0.4%	Apples		4%
3%	FI adult	1.13	0.5%	Tomatoes	0.4%	Lettuces	0.2%	Oranges		3%
3%	PL general	1.01	0.7%	Tomatoes	0.5%	Apples	0.3%	Cherries (sweet)		3%
2%	IE child	0.68	0.7%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Fat tissue		2%

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
83%	Table grapes	3 / 1.7	124
66%	Peaches	2 / 1.04	99
62%	Oranges	1 / 0.7	93
56%	Lettuces	5 / 2.2	84
54%	Spinaches	7 / 3.6	81
39%	Mandarins	1.5 / 0.98	58
38%	Celeries	3 / 1.51	56
38%	Tomatoes	1.5 / 0.97	56
37%	Rhubarbs	3 / 1.51	56
37%	Bananas	1.5 / 0.57	55
33%	Sweet peppers/bell peppers	1.5 / 0.84	50
28%	Plums	1.5 / 1	42
25%	Pears	0.4 / 0.27	37
24%	Apricots	2 / 1.04	36
23%	Melons	0.5 / 0.23	35

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
38%	Table grapes	3 / 1.7	58
27%	Wine grapes	3 / 1.7	40
19%	Blueberries	5 / 3.2	29
19%	Florence fennels	3 / 1.51	28
18%	Lettuces	5 / 2.2	27
16%	Celeries	3 / 1.51	24
16%	Cherries (sweet)	5 / 2.4	24
15%	Aubergines/egg plants	1.5 / 0.84	23
14%	Oranges	1 / 0.7	21
14%	Currants (red, black and	5 / 3.2	21
13%	Peaches	2 / 1.04	19
12%	Plums	1.5 / 1	18
12%	Mandarins	1.5 / 0.98	18
10%	Cardoons	3 / 1.51	16
10%	Tomatoes	1.5 / 0.97	15

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
46%	Florence fennels / boiled	3 / 1.51	68
38%	Rhubarbs / sauce/puree	3 / 1.51	56
33%	Spinaches / frozen; boiled	7 / 3.6	50
24%	Broccoli / boiled	0.7 / 0.46	36
21%	Cauliflowers / boiled	0.7 / 0.46	32
18%	Peaches / canned	2 / 1.04	27
14%	Pumpkins / boiled	0.5 / 0.23	20
13%	Turnips / boiled	0.5 / 0.38	19
13%	Parsnips / boiled	0.5 / 0.38	19
11%	Beetroots / boiled	0.5 / 0.38	17
11%	Currants (red, black and whi	5 / 0.58	17
8%	Wine grapes / juice	3 / 0.26	11
8%	Oranges / juice	1 / 0.22	11
7%	Raspberries / juice	3 / 0.96	11
7%	Oat / boiled	3 / 3	11

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)
34%	Celeries / boiled	3 / 1.51	51
20%	Spinaches / frozen; boiled	7 / 3.6	30
20%	Florence fennels / boiled	3 / 1.51	29
15%	Rhubarbs / sauce/puree	3 / 1.51	22
14%	Barley / beer	3 / 0.6	22
13%	Cauliflowers / boiled	0.7 / 0.46	19
12%	Cardoons / boiled	3 / 1.51	18
11%	Wine grapes / wine	3 / 1.7	16
10%	Beetroots / boiled	0.5 / 0.38	15
8%	Pumpkins / boiled	0.5 / 0.23	13
7%	Broccoli / boiled	0.7 / 0.46	11
7%	Table grapes / raisins	3 / 7.99	9.8
6%	Peaches / canned	2 / 1.04	8.5
5%	Parsnips / boiled	0.5 / 0.38	8.1
5%	Currants (red, black and	5 / 0.58	7.4

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

EFSA PRIMo revision 3.1; 2021/01/06

Broflanilide (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	not necessary
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2022	Year of evaluation:	2022

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)
4%	NL toddler	0.90	2%	Spinaches	1%	Milk: Cattle	0.2%	Broccoli		
2%	SE general	0.46	0.6%	Lettuces	0.4%	Bovine: Muscle/meat	0.4%	Chinese cabbages/pe-tsai		
2%	NL child	0.41	0.8%	Spinaches	0.6%	Milk: Cattle	0.1%	Kales		
2%	GEMS/Food G10	0.37	0.5%	Lettuces	0.3%	Chinese cabbages/pe-tsai	0.2%	Spinaches		
2%	ES child	0.35	0.7%	Lettuces	0.3%	Milk: Cattle	0.3%	Spinaches		
2%	DE child	0.34	0.6%	Spinaches	0.5%	Milk: Cattle	0.1%	Lettuces		
2%	FR toddler 2 3 yr	0.33	0.7%	Milk: Cattle	0.5%	Spinaches	0.1%	Bovine: Muscle/meat		
2%	ES adult	0.31	0.9%	Lettuces	0.2%	Spinaches	0.1%	Milk: Cattle		
2%	GEMS/Food G11	0.30	0.3%	Spinaches	0.2%	Celeries	0.2%	Milk: Cattle		
1%	FR infant	0.30	0.8%	Spinaches	0.4%	Milk: Cattle	0.1%	Broccoli		
1%	FR child 3 15 yr	0.29	0.6%	Milk: Cattle	0.3%	Spinaches	0.1%	Bovine: Muscle/meat		
1%	IE adult	0.27	0.4%	Spinaches	0.2%	Rhubarbs	0.1%	Lettuces		
1%	GEMS/Food G07	0.26	0.4%	Lettuces	0.2%	Milk: Cattle	0.1%	Spinaches		
1%	NL general	0.25	0.5%	Spinaches	0.2%	Milk: Cattle	0.1%	Lettuces		
1%	GEMS/Food G08	0.25	0.3%	Lettuces	0.2%	Swine: Muscle/meat	0.1%	Milk: Cattle		
1%	UK infant	0.24	1.0%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Spinaches		
1%	GEMS/Food G06	0.24	0.3%	Tomatoes	0.2%	Lettuces	0.2%	Spinaches		
1%	GEMS/Food G15	0.23	0.2%	Lettuces	0.2%	Milk: Cattle	0.2%	Sweet peppers/bell peppers		
1%	DK child	0.23	0.3%	Milk: Cattle	0.2%	Lettuces	0.2%	Swine: Muscle/meat		
1%	IT adult	0.23	0.6%	Lettuces	0.3%	Spinaches	0.1%	Tomatoes		
1.0%	DE women 14-50 yr	0.20	0.3%	Milk: Cattle	0.2%	Lettuces	0.2%	Spinaches		
1.0%	DE general	0.19	0.3%	Milk: Cattle	0.2%	Lettuces	0.1%	Spinaches		
0.9%	UK toddler	0.19	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Spinaches		
0.9%	IT toddler	0.17	0.5%	Lettuces	0.2%	Spinaches	0.1%	Tomatoes		
0.8%	RO general	0.15	0.3%	Milk: Cattle	0.2%	Tomatoes	0.1%	Swine: Muscle/meat		
0.7%	DK adult	0.14	0.1%	Lettuces	0.1%	Milk: Cattle	0.1%	Swine: Fat tissue		
0.7%	PT general	0.13	0.4%	Kales	0.2%	Lettuces	0.1%	Tomatoes		
0.6%	UK vegetarian	0.12	0.2%	Lettuces	0.1%	Spinaches	0.1%	Milk: Cattle		
0.6%	FR adult	0.11	0.2%	Spinaches	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat		
0.5%	UK adult	0.10	0.2%	Lettuces	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat		
0.5%	FI 6 yr	0.10	0.2%	Spinaches	0.1%	Lettuces	0.1%	Chinese cabbages/pe-tsai		
0.5%	FI 3 yr	0.09	0.2%	Spinaches	0.1%	Lettuces	0.1%	Cucumbers		
0.5%	LT adult	0.09	0.1%	Lettuces	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat		
0.4%	FI adult	0.08	0.2%	Lettuces	0.0%	Tomatoes	0.0%	Spinaches		
0.3%	IE child	0.05	0.1%	Milk: Cattle	0.1%	Swine: Fat tissue	0.0%	Broccoli		
0.2%	PL general	0.03	0.1%	Tomatoes	0.0%	Chinese cabbages/pe-tsai	0.0%	Sweet peppers/bell peppers		

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Broflanilide (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2021/01/06

Acynonapyr

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	not necessary
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2024	Year of evaluation:	2024

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	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)	12%	DE child	11.59	11%	Apples	0.2%	Pears	0.1%	Mandarins		
	11%	NL toddler	10.99	10%	Apples	1%	Pears	0.1%	Mandarins		
	6%	NL child	5.74	5%	Apples	0.3%	Pears	0.2%	Mandarins		
	3%	FR toddler 2 3 yr	3.19	3%	Apples	0.2%	Mandarins	0.1%	Pears		
	2%	DE women 14-50 yr	2.40	2%	Apples	0.0%	Pears	0.0%	Mandarins		
	2%	DK child	2.30	2%	Apples	0.2%	Pears	0.0%	Mandarins		
	2%	DE general	2.25	2%	Apples	0.0%	Pears	0.0%	Mandarins		
	2%	PL general	1.93	2%	Apples	0.1%	Pears	0.0%	Mandarins		
	2%	LT adult	1.74	2%	Apples	0.0%	Pears	0.0%	Mandarins		
	2%	UK toddler	1.68	2%	Apples	0.1%	Mandarins	0.0%	Pears		
	2%	FR child 3 15 yr	1.64	2%	Apples	0.1%	Pears	0.0%	Mandarins		
	2%	FR infant	1.61	2%	Apples	0.0%	Pears	0.0%	Mandarins		
	2%	GEMS/Food G11	1.50	1%	Apples	0.1%	Mandarins	0.0%	Pears		
	1%	UK infant	1.48	1%	Apples	0.1%	Pears				
	1%	NL general	1.42	1%	Apples	0.1%	Mandarins	0.0%	Pears		
	1%	RO general	1.36	1%	Apples	0.0%	Pears	0.0%	Aubergines/egg plants		
	1%	GEMS/Food G08	1.21	1%	Apples	0.1%	Mandarins	0.0%	Pears		
	1%	ES child	1.20	1%	Apples	0.1%	Pears	0.1%	Mandarins		
	1%	SE general	1.18	1.0%	Apples	0.1%	Mandarins	0.1%	Pears		
	1%	GEMS/Food G15	1.08	1.0%	Apples	0.0%	Mandarins	0.0%	Pears		
	1%	PT general	1.06	1.0%	Apples	0.1%	Pears	0.0%	Mandarins		
	1%	GEMS/Food G07	1.03	0.9%	Apples	0.1%	Mandarins	0.0%	Pears		
	1%	FI 3 yr	1.02	0.9%	Apples	0.1%	Mandarins	0.0%	Pears		
	1.0%	GEMS/Food G06	1.00	0.8%	Apples	0.1%	Mandarins	0.0%	Aubergines/egg plants		
	1.0%	DK adult	0.98	0.9%	Apples	0.1%	Pears	0.0%	Mandarins		
	1.0%	IT toddler	0.97	0.8%	Apples	0.1%	Pears	0.1%	Mandarins		
	0.9%	IE adult	0.95	0.6%	Apples	0.2%	Mandarins	0.1%	Pears		
	0.8%	IT adult	0.84	0.7%	Apples	0.1%	Pears	0.0%	Mandarins		
	0.8%	ES adult	0.83	0.7%	Apples	0.1%	Pears	0.0%	Mandarins		
	0.8%	GEMS/Food G10	0.78	0.7%	Apples	0.1%	Mandarins	0.0%	Pears		
	0.8%	FR adult	0.75	0.7%	Apples	0.0%	Pears	0.0%	Mandarins		
	0.7%	FI 6 yr	0.67	0.5%	Apples	0.1%	Mandarins	0.0%	Pears		
	0.6%	FI adult	0.58	0.5%	Apples	0.0%	Mandarins	0.0%	Pears		
	0.6%	UK vegetarian	0.57	0.5%	Apples	0.0%	Pears	0.0%	Mandarins		
	0.4%	UK adult	0.40	0.4%	Apples	0.0%	Mandarins	0.0%	Pears		
	0.3%	IE child	0.30	0.3%	Apples	0.0%	Pears	0.0%	Mandarins		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Acynonapyr is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2021/01/06

Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.065	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2024	Year of evaluation:	2024

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)
23%	GEMS/Food G07	15.15	8%	Sunflower seeds	4%	Wheat	4%	Cotton seeds		23%
23%	NL toddler	15.03	6%	Sunflower seeds	5%	Rapeseeds/canola seeds	5%	Milk: Cattle		23%
22%	GEMS/Food G08	14.55	9%	Sunflower seeds	4%	Wheat	2%	Rapeseeds/canola seeds		22%
22%	RO general	14.34	13%	Sunflower seeds	5%	Wheat	2%	Wine grapes		22%
22%	GEMS/Food G15	14.04	10%	Sunflower seeds	4%	Wheat	1%	Wine grapes		22%
20%	GEMS/Food G06	12.79	7%	Wheat	6%	Cotton seeds	4%	Sunflower seeds		20%
18%	NL child	11.83	7%	Sunflower seeds	4%	Wheat	3%	Rapeseeds/canola seeds		18%
16%	GEMS/Food G10	10.08	4%	Sunflower seeds	4%	Wheat	3%	Cotton seeds		16%
13%	FR child 3 15 yr	8.74	5%	Sunflower seeds	4%	Wheat	2%	Milk: Cattle		13%
13%	PT general	8.64	6%	Sunflower seeds	4%	Wheat	4%	Wine grapes		13%
13%	DK child	8.32	5%	Rye	4%	Wheat	2%	Swine: Muscle/meat		13%
12%	GEMS/Food G11	8.01	3%	Wheat	2%	Sunflower seeds	2%	Cotton seeds		12%
12%	IE adult	7.85	4%	Sunflower seeds	3%	Linseeds	2%	Wheat		12%
11%	DE child	7.34	4%	Wheat	2%	Table grapes	2%	Sunflower seeds		11%
10%	NL general	6.79	4%	Sunflower seeds	2%	Wheat	1%	Rapeseeds/canola seeds		10%
9%	FR toddler 2 3 yr	6.13	3%	Wheat	3%	Sunflower seeds	2%	Milk: Cattle		9%
9%	FR adult	5.73	3%	Wine grapes	2%	Sunflower seeds	2%	Wheat		9%
9%	ES child	5.63	4%	Wheat	2%	Sunflower seeds	1.0%	Milk: Cattle		9%
8%	DE general	5.01	2%	Wheat	1%	Wine grapes	1%	Sunflower seeds		8%
8%	DE women 14-50 yr	4.90	2%	Wheat	1%	Sunflower seeds	1%	Wine grapes		8%
7%	IT toddler	4.30	6%	Wheat	0.3%	Sunflower seeds	0.1%	Table grapes		7%
6%	ES adult	4.18	2%	Wheat	2%	Sunflower seeds	0.6%	Wine grapes		6%
6%	UK infant	3.92	3%	Milk: Cattle	2%	Wheat	0.3%	Oat		6%
6%	UK toddler	3.84	4%	Wheat	2%	Milk: Cattle	0.4%	Table grapes		6%
5%	SE general	3.00	3%	Wheat	1.0%	Milk: Cattle	0.3%	Bovine: Muscle/meat		5%
4%	DK adult	2.83	1%	Wine grapes	1%	Wheat	0.7%	Swine: Muscle/meat		4%
4%	IT adult	2.73	4%	Wheat	0.2%	Table grapes	0.2%	Sunflower seeds		4%
4%	LT adult	2.67	1.0%	Rye	1.0%	Wheat	0.8%	Sunflower seeds		4%
4%	UK adult	2.32	2%	Wheat	2%	Wine grapes	0.2%	Milk: Cattle		4%
4%	UK vegetarian	2.31	2%	Wheat	1%	Wine grapes	0.3%	Milk: Cattle		4%
3%	FI 3 yr	2.20	1%	Wheat	0.6%	Oat	0.6%	Rye		3%
3%	FR infant	1.88	1%	Milk: Cattle	0.7%	Wheat	0.4%	Sunflower seeds		3%
3%	FI 6 yr	1.68	0.9%	Wheat	0.6%	Rye	0.4%	Oat		3%
2%	FI adult	1.27	0.6%	Rye	0.4%	Wine grapes	0.3%	Wheat		2%
2%	IE child	1.06	1%	Wheat	0.3%	Milk: Cattle	0.1%	Swine: Muscle/meat		2%
0.6%	PL general	0.41	0.5%	Table grapes	0.2%	Sunflower seeds	0.0%	Cultivated fungi		0.6%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health concern.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
83%	Table grapes	4 / 3.41	248
17%	Cultivated fungi	0.09 / 2.95	50
13%	Sunflower seeds	40 / 12.5	40
11%	Wine grapes	4 / 3.41	32
4%	Linseeds	40 / 11.5	12
4%	Mustard seeds	40 / 11.5	12
3%	Wheat	3 / 0.6	8.7
2%	Milk: Cattle	0.07 / 0.05	6.2
2%	Rapeseeds/canola seeds	15 / 3.65	5.0
1%	Barley	4 / 0.73	4.1
1%	Bovine: Liver	0.5 / 0.49	4.0
1%	Rye	3 / 0.6	3.8
0.6%	Milk: Goat	0.15 / 0.07	1.7
0.5%	Bovine: Kidney	0.8 / 0.4	1.5
0.3%	Eggs: Chicken	0.07 / 0.07	0.87

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
39%	Table grapes	4 / 3.41	116
27%	Wine grapes	4 / 3.41	81
5%	Cultivated fungi	0.09 / 2.95	15
4%	Sunflower seeds	40 / 12.5	13
3%	Poppy seeds	40 / 11.5	8.1
3%	Mustard seeds	40 / 11.5	8.1
2%	Linseeds	40 / 11.5	5.5
2%	Wheat	3 / 0.6	5.0
1%	Barley	4 / 0.73	3.5
1.0%	Rye	3 / 0.6	2.9
0.9%	Sheep: Liver	0.6 / 0.94	2.6
0.7%	Bovine: Liver	0.5 / 0.49	2.0
0.6%	Milk: Cattle	0.07 / 0.05	1.9
0.6%	Rapeseeds/canola seeds	15 / 3.65	1.9
0.4%	Milk: Goat	0.15 / 0.07	1.3

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
13%	Wine grapes / juice	4 / 0.92	40
10%	Sunflower seeds / oils	40 / 25	29
5%	Cultivated fungi / fried	0.09 / 2.95	15
2%	Wheat / milling (flour)	3 / 0.6	7.3
1%	Wheat / milling (wholemeal)-baking	3 / 0.6	3.3
0.9%	Oat / boiled	3 / 0.73	2.6
0.9%	Barley / cooked	4 / 0.73	2.6
0.7%	Oat / milling (flakes)	3 / 0.73	2.2
0.7%	Rye / boiled	3 / 0.6	2.2
0.7%	Rapeseeds / oils	15 / 7.3	2.1
0.7%	Rye / milling (wholemeal)-baking	3 / 0.6	2.1

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)
11%	Wine grapes / wine	4 / 3.41	32
7%	Table grapes / raisins	4 / 16.01	20
6%	Wine grapes / juice	4 / 0.92	19
2%	Barley / beer	4 / 0.15	5.3
0.9%	Wheat / bread/pizza	3 / 0.6	2.6

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

EFSA PRIMo revision 3.1; 2021/01/06

Metarylpicoxamid

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

Toxicological reference values

ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	not nececessary
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2025	Year of evaluation:	2025

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0.3%	NL toddler	0.63	0.3%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.3%
0.2%	UK infant	0.42	0.2%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Bovine: Muscle/meat		0.2%
0.2%	FR toddler 2 3 yr	0.33	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.2%
0.1%	FR child 3 15 yr	0.28	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.1%
0.1%	NL child	0.28	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.1%	UK toddler	0.23	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		0.1%
0.1%	DE child	0.23	0.1%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		0.1%
0.1%	GEMS/Food G11	0.19	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Swine: Muscle/meat		0.1%
0.1%	FR infant	0.18	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.1%	DK child	0.18	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.1%	SE general	0.18	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		0.1%
0.1%	ES child	0.18	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Poultry: Muscle/meat		0.1%
0.1%	GEMS/Food G10	0.16	0.0%	Soyabeans	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		0.0%
0.1%	DE general	0.15	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.1%	DE women 14-50 yr	0.15	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.1%	RO general	0.15	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Poultry: Muscle/meat		0.1%
0.1%	GEMS/Food G15	0.14	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Swine: Muscle/meat		0.1%
0.1%	GEMS/Food G07	0.14	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Poultry: Muscle/meat		0.1%
0.1%	GEMS/Food G08	0.13	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Swine: Muscle/meat		0.0%
0.1%	NL general	0.11	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.0%	ES adult	0.08	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.0%
0.0%	DK adult	0.08	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.0%
0.0%	FR adult	0.07	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.0%
0.0%	IE adult	0.07	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.0%
0.0%	GEMS/Food G06	0.06	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Poultry: Muscle/meat		0.0%
0.0%	LT adult	0.06	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		0.0%
0.0%	UK adult	0.04	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Poultry: Muscle/meat		0.0%
0.0%	IE child	0.04	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		0.0%
0.0%	UK vegetarian	0.04	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		0.0%
0.0%	PT general	0.01								
0.0%	FI adult	0.00								
0.0%	IT toddler	0.00								
0.0%	FI 3 yr	0.00								
0.0%	FI 6 yr	0.00								
0.0%	IT adult	0.00								
0.0%	PL general	0.00								

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Metarylpicoxamid is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2021/01/06

Proquinazid (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.2
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2009	Year of evaluation:	2009

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)	26%	NL toddler	2.64	14%	Milk: Cattle	9%	Apples	3%	Pears		26%
	15%	DE child	1.54	10%	Apples	5%	Milk: Cattle	0.5%	Pears		15%
	12%	NL child	1.18	6%	Milk: Cattle	5%	Apples	1.0%	Pears		12%
	12%	UK infant	1.16	9%	Milk: Cattle	1%	Apples	0.6%	Bovine: Edible offals (other than liver		12%
	10%	FR toddler 2 3 yr	1.03	7%	Milk: Cattle	3%	Apples	0.2%	Pears		10%
	8%	FR child 3 15 yr	0.79	5%	Milk: Cattle	1%	Apples	0.3%	Bovine: Muscle/meat		8%
	7%	UK toddler	0.69	5%	Milk: Cattle	1%	Apples	0.3%	Bovine: Muscle/meat		7%
	6%	DK child	0.63	3%	Milk: Cattle	2%	Apples	0.5%	Pears		6%
	6%	FR infant	0.56	4%	Milk: Cattle	1%	Apples	0.1%	Pears		6%
	5%	DE women 14-50 yr	0.54	3%	Milk: Cattle	2%	Apples	0.2%	Swine: Muscle/meat		5%
	5%	DE general	0.53	3%	Milk: Cattle	2%	Apples	0.2%	Swine: Muscle/meat		5%
	5%	SE general	0.50	3%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.8%	Apples		5%
	5%	ES child	0.50	3%	Milk: Cattle	0.9%	Apples	0.4%	Pears		5%
	4%	RO general	0.43	3%	Milk: Cattle	1%	Apples	0.2%	Swine: Muscle/meat		4%
	4%	NL general	0.37	2%	Milk: Cattle	1%	Apples	0.2%	Swine: Muscle/meat		4%
	4%	GEMS/Food G11	0.37	2%	Milk: Cattle	1%	Apples	0.2%	Swine: Muscle/meat		4%
	3%	GEMS/Food G15	0.32	2%	Milk: Cattle	0.9%	Apples	0.3%	Swine: Muscle/meat		3%
	3%	GEMS/Food G07	0.30	1%	Milk: Cattle	0.8%	Apples	0.2%	Swine: Muscle/meat		3%
	3%	GEMS/Food G08	0.30	1%	Milk: Cattle	1.0%	Apples	0.4%	Swine: Muscle/meat		3%
	3%	LT adult	0.29	1%	Apples	0.9%	Milk: Cattle	0.2%	Swine: Muscle/meat		3%
	3%	IE adult	0.28	1%	Milk: Cattle	0.6%	Apples	0.4%	Sheep: Edible offals (other than liver		3%
	3%	DK adult	0.27	1%	Milk: Cattle	0.8%	Apples	0.3%	Pears		3%
	3%	ES adult	0.25	1%	Milk: Cattle	0.6%	Apples	0.3%	Pears		3%
	2%	GEMS/Food G10	0.25	1%	Milk: Cattle	0.6%	Apples	0.2%	Bovine: Muscle/meat		2%
	2%	FR adult	0.24	1%	Milk: Cattle	0.6%	Apples	0.1%	Swine: Muscle/meat		2%
	2%	PL general	0.18	2%	Apples	0.2%	Pears				2%
	2%	GEMS/Food G06	0.16	0.7%	Apples	0.6%	Milk: Cattle	0.1%	Pears		2%
	1%	UK vegetarian	0.14	0.7%	Milk: Cattle	0.5%	Apples	0.1%	Eggs: Chicken		1%
	1%	UK adult	0.13	0.7%	Milk: Cattle	0.3%	Apples	0.1%	Bovine: Muscle/meat		1%
	1%	IE child	0.12	0.8%	Milk: Cattle	0.3%	Apples	0.0%	Swine: Muscle/meat		1%
	1%	PT general	0.11	0.8%	Apples	0.3%	Pears				1%
	1.0%	IT toddler	0.10	0.7%	Apples	0.3%	Pears				1.0%
	0.9%	FI 3 yr	0.09	0.7%	Apples	0.1%	Pears				0.9%
	0.8%	IT adult	0.08	0.6%	Apples	0.2%	Pears				0.8%
	0.6%	FI 6 yr	0.06	0.5%	Apples	0.1%	Pears				0.6%
	0.5%	FI adult	0.05	0.5%	Apples	0.0%	Pears				0.5%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Proquinazid (F) is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results 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)
12%	Pears	0.3 / 0.17	24
9%	Apples	0.3 / 0.17	18
1%	Bovine: Edible offals (other than liver and kidney)	0.4 / 0.4	2.9
1%	Milk: Cattle	0.03 / 0.02	2.9
0.6%	Swine: Edible offals (other than liver and kidney)	0.4 / 0.4	1.2
0.6%	Bovine: Kidney	0.4 / 0.31	1.2
0.4%	Bovine: Liver	0.4 / 0.1	0.84
0.3%	Milk: Goat	0.03 / 0.02	0.56
0.2%	Swine: Kidney	0.4 / 0.31	0.40
0.1%	Swine: Muscle/meat	0.03 / 0.02	0.28
0.1%	Eggs: Chicken	0.02 / 0.02	0.25
0.08%	Bovine: Muscle/meat	0.03 / 0.02	0.17
0.08%	Other farmed animals: Muscle/meat	0.03 / 0.02	0.16
0.07%	Equine: Muscle/meat	0.03 / 0.02	0.14
0.07%	Bovine: Fat tissue	0.07 / 0.07	0.14
0.06%	Swine: Liver	0.4 / 0.1	0.13
0.06%	Sheep: Muscle/meat	0.03 / 0.02	0.13
0.06%	Swine: Fat tissue	0.07 / 0.07	0.11
0.04%	Milk: Sheep	0.03 / 0.02	0.08

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)
3%	Pears	0.3 / 0.17	5.2
2%	Apples	0.3 / 0.17	4.8
0.7%	Bovine: Edible offals (other than liver and kidney)	0.4 / 0.4	1.3
0.5%	Swine: Edible offals (other than liver and kidney)	0.4 / 0.4	1.0
0.4%	Milk: Cattle	0.03 / 0.02	0.89
0.3%	Swine: Kidney	0.4 / 0.31	0.69
0.3%	Bovine: Kidney	0.4 / 0.31	0.66
0.2%	Milk: Goat	0.03 / 0.02	0.42
0.2%	Bovine: Liver	0.4 / 0.1	0.42
0.2%	Milk: Sheep	0.03 / 0.02	0.35
0.1%	Sheep: Liver	0.4 / 0.1	0.29
0.1%	Sheep: Edible offals (other than liver and kidney)	0.4 / 0.4	0.27
0.07%	Swine: Liver	0.4 / 0.1	0.15
0.07%	Swine: Fat tissue	0.07 / 0.07	0.13
0.07%	Bovine: Muscle	0.03 / 0.02	0.13
0.06%	Other farmed animals: Muscle/meat	0.03 / 0.02	0.13
0.06%	Swine: Muscle/meat	0.03 / 0.02	0.11
0.06%	Equine: Muscle/meat	0.03 / 0.02	0.11
0.05%	Sheep: Muscle/meat	0.03 / 0.02	0.11
0.04%	Eggs: Chicken	0.02 / 0.02	0.09
0.03%	Bovine: Fat tissue	0.07 / 0.07	0.06
0.02%	Goat: Muscle	0.03 / 0.02	0.04
0.02%	Sheep: Kidney	0.4 / 0.31	0.03

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Pears / juice	0.3 / 0.08	2.6
0.4%	Apples / juice	0.3 / 0.01	0.73

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)
0.2%	Apples / juice	0.3 / 0.01	0.45

Expand/collapse list

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

Tiafenacil

EFSA PRIMo revision 3.1; 2021/01/06

Tiafenacil (F)

LOQs (mg/kg) range from: 0.01 to: 0.03

Toxicological reference values

ADI (mg/kg bw/day):	0.004	ARfD (mg/kg bw):	not necessary
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2025	Year of evaluation:	2025

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	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)	7%	NL toddler	0.27	4%	Maize/corn	2%	Wheat	0.4%	Milk: Cattle	0.6%	
	5%	GEMS/Food G06	0.21	4%	Wheat	0.6%	Maize/corn	0.6%	Soyabeans	0.4%	
	5%	GEMS/Food G10	0.21	2%	Wheat	2%	Soyabeans	1%	Poultry: Muscle/meat	1%	
	5%	GEMS/Food G11	0.19	2%	Soyabeans	2%	Wheat	0.7%	Poultry: Muscle/meat	0.7%	
	4%	GEMS/Food G15	0.17	2%	Wheat	0.9%	Soyabeans	0.7%	Poultry: Muscle/meat	0.7%	
	4%	GEMS/Food G07	0.17	2%	Wheat	0.9%	Poultry: Muscle/meat	0.9%	Soyabeans	0.9%	
	4%	FR child 3 15 yr	0.17	2%	Wheat	0.9%	Eggs: Chicken	0.5%	Poultry: Muscle/meat	1%	
	4%	RO general	0.17	3%	Wheat	0.6%	Poultry: Muscle/meat	0.5%	Maize/corn	1%	
	4%	GEMS/Food G08	0.16	2%	Wheat	1.0%	Soyabeans	0.7%	Poultry: Muscle/meat	0.7%	
	4%	ES child	0.16	2%	Wheat	1.0%	Poultry: Muscle/meat	0.5%	Eggs: Chicken	2%	
	4%	DE child	0.15	2%	Wheat	0.9%	Eggs: Chicken	0.5%	Poultry: Muscle/meat	1%	
	4%	UK infant	0.14	1%	Wheat	1%	Eggs: Chicken	0.5%	Maize/corn	1%	
	3%	DK child	0.14	2%	Wheat	0.6%	Eggs: Chicken	0.4%	Poultry: Muscle/meat	1%	
	3%	IT toddler	0.13	3%	Wheat	0.0%	Maize/corn	0.0%	Soyabeans		
	3%	NL child	0.13	2%	Wheat	0.4%	Poultry: Muscle/meat	0.4%	Eggs: Chicken	0.8%	
	3%	UK toddler	0.13	2%	Wheat	0.7%	Eggs: Chicken	0.4%	Poultry: Muscle/meat	1%	
	3%	FI adult	0.12	3%	Coffee beans	0.2%	Wheat	0.0%	Soyabeans		
	3%	FR toddler 2 3 yr	0.11	2%	Wheat	0.5%	Eggs: Chicken	0.3%	Poultry: Muscle/meat	0.9%	
	2%	SE general	0.10	2%	Wheat	0.7%	Eggs: Chicken	0.1%	Milk: Cattle	0.7%	
	2%	PT general	0.09	2%	Wheat	0.2%	Maize/corn	0.2%	Soyabeans		
	2%	ES adult	0.08	1%	Wheat	0.5%	Poultry: Muscle/meat	0.3%	Eggs: Chicken	0.8%	
	2%	IT adult	0.08	2%	Wheat	0.0%	Maize/corn	0.0%	Soyabeans		
	2%	FR adult	0.08	1%	Wheat	0.3%	Eggs: Chicken	0.2%	Poultry: Muscle/meat	0.6%	
	2%	DE women 14-50 yr	0.08	1%	Wheat	0.2%	Eggs: Chicken	0.2%	Coffee beans	0.5%	
	2%	IE adult	0.08	1%	Wheat	0.3%	Poultry: Muscle/meat	0.2%	Eggs: Chicken	0.6%	
	2%	NL general	0.07	1.0%	Wheat	0.3%	Poultry: Muscle/meat	0.3%	Eggs: Chicken	0.5%	
	2%	DE general	0.07	0.9%	Wheat	0.2%	Coffee beans	0.2%	Eggs: Chicken	0.4%	
	1%	UK adult	0.06	0.8%	Wheat	0.3%	Poultry: Muscle/meat	0.2%	Eggs: Chicken	0.6%	
	1%	UK vegetarian	0.05	1%	Wheat	0.3%	Eggs: Chicken	0.0%	Poultry: Muscle/meat	0.3%	
	1%	DK adult	0.04	0.6%	Wheat	0.3%	Eggs: Chicken	0.2%	Poultry: Muscle/meat	0.4%	
	1%	LT adult	0.04	0.5%	Wheat	0.2%	Eggs: Chicken	0.2%	Poultry: Muscle/meat	0.5%	
	0.9%	IE child	0.03	0.6%	Wheat	0.1%	Eggs: Chicken	0.1%	Poultry: Muscle/meat	0.3%	
	0.8%	FR infant	0.03	0.4%	Wheat	0.1%	Poultry: Muscle/meat	0.1%	Milk: Cattle	0.3%	
	0.6%	FI 3 yr	0.03	0.6%	Wheat	0.0%	Coffee beans	0.0%	Maize/corn		
	0.5%	FI 6 yr	0.02	0.5%	Wheat	0.0%	Coffee beans	0.0%	Maize/corn		
	0.0%	PL general	0.00	0.0%	Soyabeans	0.0%	Maize/corn				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Tiafenacil (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.